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August 28, 2026

The Honorable Bill Cassidy, MD
Chairman
US Senate Committee on Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, DC, 20510

RE: 340B Drug Pricing Integrity and Affordability for Patients Act (340B for Patients Act) Discussion Draft

Dear Chairman Cassidy,

We are scholars affiliated with the **Program On Regulation, Therapeutics, And Law (PORTAL)** at Brigham and Women's Hospital and Harvard Medical School, as well as the **Pharmaceutical Policy & Outcomes Lab** at the University of California, Los Angeles. Our programs are among the leading academic research centers in the US dedicated to investigating the regulation, use, evidence, and cost of prescription drugs. Our research is independent of the pharmaceutical industry. All views presented here are our own and do not necessarily represent those of our employers.

We appreciate the opportunity to comment on the 340B Drug Pricing Integrity and Affordability for Patients Act. Our comments build directly from testimony given by one of us (Dr. William B. Feldman) to the Senate Committee on Health, Education, Labor, and Pensions on October 23, 2025, and incorporate research that we have conducted in recent years on the 340B program.

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 covering losses associated with uncompensated care.

[1] Knox RP, Wang J, Feldman WB, Kesselheim AS, Sarpatwari A. Outcomes of the 340B Drug Pricing Program: A Scoping Review. *JAMA Health Forum*. 2023;4(11):e233716.
[2] Martin K. The 340B Drug Pricing Program: How It Works and Why It's Controversial. The Commonwealth Fund. Published August 6, 2025.
[3] Centers for Medicare and Medicaid Services (CMS). Medicare Part B Drug Payment Limit Files. Updated August 10, 2026.
[4] Feldman WB, Rome BN, Brown BL, Kesselheim AS. Payer-Specific Negotiated Prices for Prescription Drugs at Top-Performing US Hospitals. *JAMA Intern Med*. 2022;182(1):83-86.
[5] Xiao R, Ross JS, Gross CP, et al. Hospital-Administered Cancer Therapy Prices for Patients With Private Health Insurance. *JAMA Intern Med*. 2022;182(6):603-611.
[6] Community Oncology Alliance. Examining 340B Hospital Price Transparency, Drug Profits, and Incentives. Published September 2022.
[7] Robinson JC, Whaley C, Dhruva SS. Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance. *N Engl J Med*. 2024;390(4):338-345.

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,[9,10] purchasing $100 billion in covered drugs in 2025.[11] More than 40% of all acute care hospitals in the US now qualify.[12] 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 administering 340B drugs increased from 6,100 to 27,700.[13] By 2021, 340B hospitals had an average of 11 child sites (with 75% having at least 1).

Like child sites, contract pharmacies enable 340B-covered entities to distribute 340B-qualifying drugs through pharmaceutical sales at offsite locations. In this case, the arrangement is with third-party pharmacies to treat patients affiliated with the covered entity rather than hospital-affiliated clinics. Before 2010, 340B hospitals could only contract with one outside pharmacy; now, they may contract with an unlimited number. Today, there are more than 33,000 340B contract pharmacy locations in the US (which are predominantly part of large pharmacy chains[14]), up from fewer than 1,300 in 2010.[15]

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 health care 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.[16-18] Many FQHCs also help patients with transportation, food, and social services.[19] Although federal grantees represent around 40% of 340B facilities, they are responsible for just 13% of drug purchases.[20]

Hospitals, by contrast, account for 87% of drug purchases.[21] Many rely on 340B revenue to expand service offerings and cover shortfalls.[22] In 2022, according to the American Hospital Association, 340B

[8] Health Resources & Services Administration (HRSA). 340B Eligibility. Updated July 2024.
[9] Long R, Mulligan K, Frasco MA, Trish E, Chernew M. Cui Bono? Misaligned Incentives in the 340B Program. USC Schaeffer Institute. Published September 29, 2025.
[10] Congressional Budget Office (CBO). Growth in the 340B Drug Pricing Program. Published September 9, 2025.
[11] HRSA. 2025 340B Covered Entity Purchases. Published July 2026.
[12] Knox et al., supra note 1.
[13] CBO, supra note 10.
[14] McGlave C, Bruno JP, Watts E, Nikpay S. 340B Contract pharmacy growth by pharmacy ownership: 2009-2022. *Health Aff Sch*. 2024;2(1):qxad075.
[15] Long et al., supra note 9.
[16] Kao R, Patel AK, Sadigh G. The Role of Federally Qualified Health Centers in Achieving Equitable Cancer Screening. *J Am Coll Radiol*. 2025;22(7):718-721.
[17] Bai P, Burt SS, Woodward MA, et al. Federally Qualified Health Centers as a Model to Improve Vision Health: A Systematic Review. *JAMA Ophthalmol*. 2025;143(3):242-251.
[18] National Institute of Drug Abuse. Medication Treatment for Opioid Use Disorder in the Federally Qualified Health Center Setting. Published November 18, 2024.
[19] National Association of Community Health Centers. What is a Community Health Center? Accessed August 2026.
[20] CBO, supra note 10.
[21] *Ibid.*
[22] Knox et al., supra note 1.

hospitals provided approximately $100 billion in community benefits, including uncompensated care, medical education, financial assistance, and community-building activities.[23,24] 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.[25]

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 biosimilar 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.[26]

(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).[27] 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. We have 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.[28] Several other studies similarly show that 340B hospitals have expanded into more affluent areas over time.[29-31]

(4) Misdirected redistribution: The allocation framework in 340B does not 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 (key characteristic

[23] American Hospital Association. 340B Community Benefit Analysis. Published September 2025.
[24] American Hospital Association. Fact Sheet: The 340B Drug Pricing Program. Published October 2025.
[25] Rana I, von Oehsen W, Nabulsi NA, et al. A comparison of medication access services at 340B and non-340B hospitals. *Res Social Adm Pharm*. 2021;17(11):1887-1892.
[26] Bond AM, Dean EB, Desai SM. The Role of Financial Incentives in Biosimilar Uptake in Medicare: Evidence from the 340B Program. *Health Aff (Millwood)*. 2023;42(5):632-641.
[27] Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. *N Engl J Med*. 2018;378(6):539-548.
[28] Liu BY, Russo M, Kesselheim AS, Knox R, Sarpatwari A, Feldman WB. Expansion of 340B Disproportionate Share Hospitals in the United States From 2010 to 2022. *Health Serv Res*. 2025;60(4):e14446.
[29] Nikpay S, Gracia G, Geressu H, Conti R. Association of 340B contract pharmacy growth with county-level characteristics. *Am J Manag Care*. 2022;28(3):133-136.
[30] Conti RM, Bach PB. The 340B drug discount program: hospitals generate profits by expanding to reach more affluent communities. *Health Aff (Millwood)*. 2014;33(10):1786-92.
[31] Lin JK, Li P, Doshi JA, Desai SM. Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics. *JAMA Health Forum*. 2022;3(6):e221435.

#1) prescribed by the highest-grossing specialties (#2) at locations with the most commercially insured patients (#3).

(5) Higher costs for payers: As greater volumes of medications move 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.[32] For example, discounts on inhalers for chronic obstructive pulmonary disease (COPD) in Medicare can exceed 50%;[33] each time a 340B contract pharmacy dispenses a $500 inhaler to a senior, Medicare could pay the full retail price (assuming no duplicate discounting), thus missing out on $250 that would have otherwise offset prescription drug costs. These high costs for payers may, in turn, 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.[34] 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.[35] 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 meaningful requirements on how 340B revenue is spent or provide guidance on 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 affect 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.[36]

4. The 340B Drug Pricing Integrity and Affordability for Patients Act

The discussion draft contains several components that will reform the 340B program. However, there are some parts that raise concerns; below, we provide comments on three key sections of the legislation.

(1) 340B discounts: Section 2 of the bill would allow drug manufacturers to choose from three options when providing discounts to 340B covered entities: an upfront discount (the current model), a discount provided after covered entities submit standardized claims data to a repository operated by the Department of Health and Human Services (HHS), or a rebate given by manufacturers after the point of sale. Manufacturers have generally expressed a strong preference for rebate models following the third approach. But the problem is that under a rebate model, manufacturers would have profoundly expanded authorities to withhold 340B discounts when adjudicating claims. This could lead to covered entities missing out on revenue owed under the program. In addition, although the bill stipulates that manufacturers must pay rebates on undisputed claims within 10 days of submission, covered entities would require sufficient cash-on-hand to pay for medications at full price while awaiting manufacturer

[32] Feldman WB, Rome BN, Raimond VC, Gagne JJ, Kesselheim AS. Estimating Rebates and Other Discounts Received by Medicare Part D. *JAMA Health Forum*. 2021;2(6):e210626.
[33] Medicare Payment Advisory Commission. July 2024 Data Book: Prescription Drugs. Published July 2024.
[34] Desai SM, McWilliams JM. 340B Drug Pricing Program and hospital provision of uncompensated care. *Am J Manag Care*. 2021;27(10):432-437.
[35] Nikpay SS, Buntin MB, Conti RM. Relationship between initiation of 340B participation and hospital safety-net engagement. *Health Serv Res*. 2020;55(2):157-169.
[36] Martin R, Illich K. Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies? Published October 10, 2022.

rebates. Although some 340B covered entities may be able to afford such payments, many likely would not.

Though the bill would allow covered entities to override the choices of manufacturers in certain instances (and pursue their preferred up-front discounting model), they could exercise this right *only if* they passed on the full value of 340B discounts directly to patients, which is a very burdensome qualification. None of the revenue in such transactions, apart from a nominal dispensing fee, could cover community benefits, uncompensated patient care, or other services offered by covered entities that rely on 340B sales. We worry that this exception would be rarely used and that the end-result of this legislation would be widespread adoption of the manufacturer-preferred 340B rebate models that could disadvantage covered entities.

Separate bipartisan 340B legislation known as SUSTAIN 340B offers a far more effective solution to the question of how discounts ought to be transmitted.[37] Under that bill, manufacturers would provide up-front discounts to covered entities, much as they currently do, but covered entities would then be required to submit claims to a third-party clearinghouse for review. If the third-party clearinghouse deemed a discount to be invalid, the covered entity would then be required to reimburse the manufacturer. This approach would help prevent improper discounts while also protecting 340B covered entities by limiting the potential for improper withholding of discounts and obviating the need for covered entities to shoulder pharmaceutical costs at the point of purchase.

(2) Restrictions on contract pharmacies and child sites: Section 5 of the bill would set new limits on contract pharmacies. Covered entities would generally be permitted to locate contract pharmacies only in statutorily defined "service areas," with some exceptions for mail-order pharmacies. Three types of covered entities (DSHs, freestanding cancer hospitals, and rural referral centers) would have to cap the number of contract pharmacies at five. These provisions aim to curb use of contract pharmacies by hospitals in far-flung (and sometimes wealthier) locations.

We believe that there are better ways to reform the current system. The bill defines the service area based on Public Use Microdata Areas (PUMAs). Only the covered entity's own PUMA and contiguous PUMAs would be permitted to have contract pharmacies. Yet, PUMAs are small, generally containing between 100,000 and 200,000 people. Los Angeles County, for example, has 69 PUMAs (with approximately 145,000 people per PUMA).[38] PUMAs immediately adjacent to a covered entity may not reflect the population served by that entity, nor capture its full catchment area. We encourage Congress to reconsider these restrictions on contract pharmacies and develop an approach that ensures more direct benefit to underserved patient populations.

Some advocates for 340B argue that locating 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 our view, strengthening access to affordable care for underserved populations via contract pharmacies should be a core mission of 340B. But there are better ways of improving access in low-income communities than limiting contract pharmacies to areas immediately adjacent to a given hospital and capping the number of contract pharmacies at five.

[37] S.5244. Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act (SUSTAIN 340B Act). 119th Congress. Introduced August 5, 2026.
[38] United States Census Bureau. 2020 Census Public Use Microdata Area (PUMA) Reference Maps: California. Published January 2020.

(3) Use of 340B revenue by covered entities: Section 7 of the 340B for Patients Act would establish a sliding scale to limit out-of-pocket costs for low-income patients. This is a valuable step forward in improving patient access to prescription drugs. However, the 340B program was not designed merely to subsidize pharmaceutical costs for patients. The program was also designed to help covered entities provide broader support to vulnerable patient populations. In addition to limits on patient cost-sharing, 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). To address this issue, Congress could adopt a set of measures aimed at ensuring hospital offerings that better reflect the mission of 340B.

5. Broader Drug Pricing Reform

Reforms in the 340B Drug Pricing Integrity and Affordability for Patients Act could help strengthen the 340B program, but these measures do not address the broader problem of high 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. 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 undo 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 has estimated that these new provisions will increase health care costs by approximately $8.8 billion over 10 years.[39] Rather than limit the IRA, Congress should find opportunities to protect and expand the law. We 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.[40,41] 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.[42] 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

[39] CBO. Revised Estimate of Changes Under the 2025 Reconciliation Act for Exemptions From Medicare Price Negotiations for Orphan Drugs. Published October 20, 2025.
[40] Wouters OJ, Vogel M, Feldman WB, Beall RF, Kesselheim AS, Tu SS. Differential Legal Protections for Biologics vs Small-Molecule Drugs in the US. *JAMA*. 2024;332(24):2101-2108.
[41] Vogel M, Feldman WB, Cowan Z, et al. Revenue Differences Between Top-Selling Small-Molecule Drugs and Biologics in Medicare. *JAMA Health Forum*. 2025;6(10):e254720.
[42] Syversen ID, Schulman K, Kesselheim AS, Feldman WB. A Comparative Analysis of International Drug Price Negotiation Frameworks: An Interview Study of Key Stakeholders. *Milbank Q*. 2024;102(4):1004-1031.

their products.[43-50] The Federal Trade Commission under both the Biden and Trump administrations has pursued manufacturers for improperly listing patents with the Food and Drug Administration.[51-53] There is strong bipartisan support for reform aimed at removing barriers to generic and biosimilar entry.[54,55] Such competition remains the key way to lower drug prices in the US for all payers and patients,[56,57] and we would encourage Congress to move legislation that addresses pharmaceutical patent abuses.

6. Conclusion

The 340B program needs reform. Some elements of the 340B Drug Pricing Integrity and Affordability for Patients Act would help improve the program, while others may prove detrimental. In addition, 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.

We appreciate your consideration of these comments and would welcome further discussion on ways to improve the 340B program. Please do not hesitate to contact us with any questions at PORTAL@bwh.harvard.edu.

Sincerely,

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Shivaek Venkateswaran
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[43] Feldman WB. Patent Thickets and Product Hops: Challenges and Opportunities for Legislative Reform. *J Law Med Ethics*. 2025:1-6.
[44] Tu SS, Kesselheim AS, Wetherbee K, Feldman WB. Changes in the Number of Continuation Patents on Drugs Approved by the FDA. *JAMA*. 2023;330(5):469-470.
[45] Tu SS, Feldman WB. Use of Track One Prioritized Examination for Pharmaceutical Patents. *JAMA Health Forum*. 2024;5(7):e241886.
[46] Feldman WB, Bloomfield D, Beall RF, Kesselheim AS. Patents And Regulatory Exclusivities On Inhalers For Asthma And COPD, 1986-2020. *Health Aff (Millwood)*. 2022;41(6):787-796.
[47] Alhiary R, Kesselheim AS, Gabriele S, Beall RF, Tu SS, Feldman WB. Patents and Regulatory Exclusivities on GLP-1 Receptor Agonists. *JAMA*. 2023;330(7):650-657.
[48] Horrow C, Gabriele SME, Tu SS, Sarpatwari A, Kesselheim AS. Patent Portfolios Protecting 10 Top-Selling Prescription Drugs. *JAMA Intern Med*. 2024;184(7):810-817.
[49] Sarpatwari A, Kohli S, Tu SS, Kesselheim AS. Patents on Risk Evaluation and Mitigation Strategies for Prescription Drugs and Generic Competition. *JAMA*. 2024;331(11):976-978.
[50] Tu SS, Sarpatwari A. A "Method of Use" to Prevent Generic and Biosimilar Market Entry. *N Engl J Med*. 2023;388(6):483-485.
[51] Federal Trade Commission (FTC). FTC Challenges More Than 100 Patents as Improperly Listed in the FDA's Orange Book. Published November 7, 2023.
[52] FTC. FTC Expands Patent Listing Challenges, Targeting More Than 300 Junk Listings for Diabetes, Weight Loss, Asthma and COPD Drugs. Published April 30, 2024.
[53] FTC. FTC Renews Challenge of More Than 200 Improper Patent Listings. Published May 21, 2025.
[54] Feldman WB, supra note 43.
[55] Welch P. Welch-Sponsored Bipartisan Bills to Lower the Cost of Prescription Drugs Advance Out of Judiciary Committee. Published April 3, 2025.
[56] Dave CV, Kesselheim AS, Fox ER, Qiu P, Hartzema A. High Generic Drug Prices and Market Competition: A Retrospective Cohort Study. *Ann Intern Med*. 2017;167(3):145-151.
[57] Assistant Secretary for Planning and Evaluation (ASPE). Trends in Prescription Drug Spending, 2016-2021. Published September 2022.