Senate Committee on Health, Education, Labor,
and Pensions
Washington D.C. 20510

In The Matter of the 340B Drug Pricing Integrity and Affordability for Patients Act

The American Consumer Institute (ACI) is a nonprofit 501(c)(3) education and research organization. Its mission is to promote consumer welfare by enhancing the understanding and impact of public policies and regulations on consumers in a free market.

The current discussion draft of 340B Drug Pricing Integrity and Affordability for Patients Act would go a long way in addressing the abuse of the 340B program and help direct its focus towards patients in need.[1] Proposed changes would address several of the 340B Drug Pricing Program's most serious structural problems such as creating stronger incentives to pass discounts to patients, improving transparency, limiting the expansion of contract pharmacies and hospital child sites, and preventing third-party administrators and pharmacies from collecting excessive shares of 340B savings. Collectively, these actions would help ensure the 340B program is targeted at the low-income and uninsured populations the program is intended to serve.

Reforms are overdue. Covered entities purchased $81.4 billion in discounted drugs through 340B in 2024 with little standardized federal reporting on how they use the savings.[2] With that much at stake, Congress should require evidence that the benefits accrue to the intended communities. The program needs auditable records that show who received the discounts, what intermediaries collected, and how much patients actually saved.

The draft appropriately uses incentives rather than relying exclusively on mandates. Covered entities, hospitals, clinics, and other eligible healthcare organizations authorized to purchase drugs at 340B discounts, and that make outpatient drugs available to patients at no more than the 340B ceiling price, plus a nominal dispensing fee, may select their preferred discount mechanism. Ordinarily, a drug manufacturer could choose the applicable discount mechanism such as an upfront discount, a claims-based discount, or a retrospective rebate. But a covered entity can override that choice and select the mechanism it prefers if the patient is receiving the discount. That links operational flexibility and administrative costs to patient benefit.

[1] *Discussion Draft: 340B Drug Pricing Integrity and Affordability for Patients Act*, U.S. Senate, accessed August 7, 2026, https://www.help.senate.gov/imo/media/doc/340b_drug_pricing_integrity_and_affordability_for_patients_act_discussion_draftpdf.pdf.
[2] "2024 340B Covered Entity Purchases," Health Resources and Services Administration, last reviewed December 2025, https://www.hrsa.gov/opa/updates/2024-340b-covered-entity-purchases.

Transparency is also essential to keeping hospitals accountable. Requiring reporting on claims data, 340B profit margins, acquisition costs and reimbursements, patient categories, and charity-care would make it more difficult for hospital systems to claim that 340B revenue benefits patients without demonstrating how. This is not bookkeeping for its own sake. Transparency changes incentives by allowing patients, regulators, manufacturers, and taxpayers to distinguish safety-net care from revenue maximization and hold hospitals accountable.

The reporting requirements should be strengthened by requiring participating institutions to disclose, in a standardized form, the number of financially vulnerable patients receiving discounts, the average portion of 340B savings passed through to patients, their average savings in dollar value, and the amount retained by the covered entity and each intermediary. Reporting obligations can be scaled to organizational size, but smaller entities should not be exempt from demonstrating that patients receive the program's benefits.

Past experience shows why documentation is necessary. The Government Accountability Office found that only 30 of the 55 covered entities it reviewed reported providing discounts to low-income, uninsured patients at some or all contract pharmacies.[3] Only 23 reported passing through the full 340B discount to patients. Without accountability, the program is a corporate subsidy.

The proposed contract pharmacy restrictions are also important. The draft would generally limit hospital covered entities to five contract pharmacies, require pharmacies to operate within the covered entity's service area, mandate registration and written agreements, and preserve targeted exceptions for mail-order access. These restrictions preserve access where a contract pharmacy serves a legitimate patient need without permitting unlimited national pharmacy networks that expand institutional revenue while providing minimal benefits to patients in need of financial assistance.

Contract pharmacies grew from approximately 1,300 in 2010 to nearly 20,000 in 2017. By 2019, almost one-third of U.S. pharmacies contracted with a 340B institution, with growth concentrated in higher-income neighborhoods while the share of 340B pharmacies in the lowest-income neighborhoods declined.[4] The 340B Drug Pricing Integrity and Affordability for Patients Act should be amended to include a requirement that each contract pharmacy arrangement to demonstrate that the pharmacy is delivering discounts to low-income or uninsured patients.

[3] "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," U.S. Government Accountability Office, June 21, 2018, https://www.gao.gov/products/gao-18-480.
[4] John Lin, Pengxiang Li, Jalpa Doshi, et al., "Assessment of US Pharmacies Contracted With Health Care Institutions Under the 340B Drug Pricing Program by Neighborhood Socioeconomic Characteristics," *JAMA Health Forum*, Vol. 3, No. 6, June 17, 2022, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2793530.

The draft similarly takes the correct approach to hospital child sites. Requiring a site to be wholly owned, meet Medicare provider-based standards, provide services beyond just prescribing drugs, operate in a shortage area, follow financial-assistance policies, and satisfy site-level charity-care and Medicaid thresholds would prevent a hospital's 340B status from automatically following its corporate expansion into affluent outpatient markets. These requirements should be strengthened by annual public reporting, and ongoing review of child site eligibility.

The draft also addresses incentives for third-party administrators (TPAs), which covered entities hired to identify eligible 340B prescriptions, process claims, manage contract-pharmacy arrangements, and administer related payments. Under some arrangements, TPAs are compensated based on the size or value of the 340B transaction, giving them a financial incentive to maximize the number and value of discounted prescriptions rather than identify low-income or uninsured patients.

The Committee's previous investigation found that CVS Health and Walgreens charged covered entities complex pharmacy and TPA fees that generally increased each year and diverted resources from patient care.[5] The draft would limit TPA compensation paid by covered entities to flat, fair-market-value fees unrelated to a drug's price or discount.

Contract pharmacies would likewise receive flat dispensing fees capped at 125 percent of their average dispensing fee from third-party payers. By separating intermediary compensation from the value of the 340B discount, these reforms reduce incentives for TPAs and pharmacies to capture a larger share of funds intended to support patients and safety-net care. Agreements would also be auditable, with violations subject to penalties equal to ten times the improper compensation.

For all the benefits of the draft, there are also criticisms to be made. Its new patient definition is only a limited improvement. It requires a recent outpatient service, an auditable medical record, and a prescription connected to the covered entity to clarify the patient relationship and reduce diversion. However, the definition does not require a patient to be low-income, uninsured, underinsured, or otherwise in need of assistance. Under the current draft, a financially secure, fully insured patient could satisfy the definition and generate a 340B margin for the institution.

The draft also continues the 340B's history of directing subsidies through institutions rather than targeting assistance directly to patients. However, institutional eligibility does not ensure that the person generating the discount is financially vulnerable or receives any of the resulting savings. If Congress retains that structure, covered entities should be required to prove both that the patient needed assistance and that the patient received the benefits of the program. For prescriptions associated with patients who do not meet a financial-need standard, Congress should require the hospital to reimburse the manufacturer for the 340B discount, regardless of if it was passed to the patient.

[5] "Chair Cassidy Releases Report on 340B Reform, Calls for Congressional Action," U.S. Senate Committee on Health, Education, Labor, and Pensions, April 24, 2025, https://www.help.senate.gov/rep/newsroom/press/chair-cassidy-releases-report-on-340b-reform-calls-for-congressional-action/.

Finally, the draft should make Rural Emergency Hospitals eligible for 340B. The discussion draft retains an institution-based eligibility model while excluding a category of institutions specifically designed to preserve emergency and outpatient care in rural communities that have higher rates of low-income and uninsured patients. Separate bipartisan legislation, the Rural 340B Access Act of 2025, would add Rural Emergency Hospitals to the program under governmental, nonprofit, and low-income service requirements.[6] However, the 340B Drug Pricing Integrity and Affordability for Patients Act could make that unnecessary by including this provision as well.

This omission is difficult to justify. The rural poverty rate was 13.6 percent in 2023, compared with 10.7 percent in urban areas.[7] Rural hospitals also face higher uninsured rates and elevated uncompensated-care burdens, and approximately half had negative operating margins from 2017 through 2022.[8] So long as the 340B program remains an institution based system rather than a patient based one, rural Emergency Hospitals should be included subject to the same patient-benefit, transparency, nonprofit, and financial-need requirements applied to other covered entities.

The discussion draft is a substantial improvement over the current system. Its incentive, transparency, contract pharmacy, child-site, and intermediary-compensation provisions would move 340B closer to its safety-net purpose. Congress should strengthen it by requiring proof that patients both need and receive benefits and extend eligibility to Rural Emergency Hospitals.

Respectfully,

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[6] U.S. Congress, House Of Representatives, *Rural 340B Access Act of 2025*, H.R. 44, 119th Congress, Introduced January 3, 2025, https://www.congress.gov/bill/119th-congress/house-bill/44/text.
[7] "Poverty rates highest for rural children under 5 years old in 2023," U.S. Department of Agriculture Economic Research Service, November 13, 2024, https://ers.usda.gov/data-products/charts-of-note/110356.
[8] "Medicaid Coverage Supports Rural Patients, Hospitals, and Communities," American Hospital Association, March 2026, https://www.aha.org/fact-sheets/2026-03-02-medicaid-coverage-supports-rural-patients-hospitals-and-communities.