Issue No. 2 | May 2026

A Decisionmaker's Guide to Competing Health Evidence

The 340B Drug Pricing Program

The 340B drug pricing program requires drug companies to sell discounted drugs to safety-net hospitals and clinics — and now moves more money than any federal drug program except Medicare Part D. Here's what the evidence shows about whether those discounts reach the patients Congress designed the program to help, where the research runs out, and what to watch as reform debates heat up.

AT A GLANCE

What the program does: Requires drug companies that participate in Medicaid to sell certain outpatient drugs at steep discounts to safety-net hospitals and clinics, called "covered entities."

How big it is: **$81.4 billion in discounted drug purchases in 2024**, representing roughly $66 billion in discounts off list prices. That makes 340B the second-largest federal drug program after Medicare Part D. Hospitals account for 87% of the purchases.

What's at stake: Whether tens of billions of dollars in drug discounts reach the low-income patients Congress designed the program to help, and whether the program's structure is distorting drug markets and federal spending.

What the evidence shows: Strong evidence that community health centers use 340B revenue to expand care for safety-net populations. Weaker and more mixed evidence for the hospitals that receive most of the money.

Who's Saying What

This section describes public positions of major stakeholders. It does not endorse or evaluate them.

Defenders of the current structure are mostly hospital and safety-net provider associations, including **340B Health**, the **American Hospital Association**, the **Association of American Medical Colleges**, the **National Association of Community Health Centers, Ryan White Clinics for 340B Access**, the **Children's Hospital Association**, and **America's Essential Hospitals**. They argue 340B revenue supports safety-net care and oppose converting the discount to rebates or restricting outside pharmacy use.

The reform camp is led by drug manufacturers and biotech groups, primarily **PhRMA** and **BIO**, who favor converting the discount into rebates, tightening the patient definition, limiting outside pharmacies, and increasing transparency. They're joined by **ASAP 340B**, the **Community Oncology Alliance**, the **National Pharmaceutical Council**, and the **USC Schaeffer Center**, which generally support limiting hospital participation while preserving the program for grantees.

Government voices are split. **HRSA** administers the program and has asked Congress for more authority. **GAO** and **CBO** have criticized oversight and warned the program encourages behaviors that increase federal spending. **Senator Bill Cassidy** and a bipartisan **"Gang of Six" working group** are crafting reform legislation, and the House Energy and Commerce Committee is reportedly considering reforms that could include payment cuts.

1. Why This Matters Right Now

If you work on health policy in Washington, 340B has become hard to avoid. The program now moves more drug spending than the Medicaid Drug Rebate Program. Hospital lobbyists call it essential to the safety net; drug companies call it a loophole. States are passing laws to protect it, but federal courts are striking down agency attempts to change it. And the basic empirical question, whether the program's billions in discounts actually reach the low-income patients Congress designed it to help, still doesn't have a clean answer.

Recently, activity has been intense. In February 2026, **a federal court vacated HRSA's pilot program** to convert 340B's upfront discounts into after-the-fact rebates. The Senate's bipartisan **"Gang of Six" working group** has been negotiating reform for over two years without introducing a bill. The Senate HELP Committee released a **195-page reform report** in April 2025. The Congressional Budget Office's **September 2025 analysis** found 340B "encourages behaviors that tend to increase federal spending." And **eight states now have laws** protecting covered entities' use of outside pharmacies, with drug companies challenging each one.

2. Why Do Smart People Disagree?

Almost everyone agrees on the original purpose of 340B. Congress's **report language from 1992** said the program would "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Unfortunately, almost no one agrees on whether the current program does that.

Part of this is empirical: a lot of money flows through 340B, but hospitals aren't required to disclose how they use the revenue, so researchers rely on indirect indicators. But more of the disagreement is about which questions to ask. The program serves multiple stakeholders with different objectives, and each asks the question most useful to them.

THE QUESTIONS BEHIND THE DEBATE

The question being asked	What It Measures	Who Tends to Ask It
Are 340B savings reaching low-income patients directly?	Sliding-scale fees, point-of-sale discounts, charity care	Drug companies, conservative reform groups, the Cassidy investigation
Is the program reaching the right covered entities in the first place?	Eligibility criteria, location of growth, share of true safety-net providers among participants	Reform-focused researchers, eligibility critics
Are 340B revenues funding safety-net activities at the institution level?	Uncompensated care, financial assistance, community benefit spending	Hospitals, hospital trade groups, safety-net advocates
Is the program distorting the drug market?	Hospital acquisition of physician practices, slow uptake of cheaper drugs, growth of outside pharmacy contracts	CBO, academic researchers, drug companies
Is the program raising costs in commercial insurance and federal programs?	Commercial drug spending, Medicare Part B, Medicaid rebates	CBO, employer and insurer groups, drug companies
Does the program serve as an indirect check on drug list prices?	Counterfactual prices and manufacturer behavior without 340B	Some hospital advocates and health economists

The honest answer is that the program does some of all of these things, in different proportions for different covered entities. **The disagreement is mostly about which effects deserve the most weight, and whether the program's costs are justified by its benefits.**

3. What Does the Evidence Show?

The most important finding from a decade of 340B research is that the answer to "is the program working" depends on which covered entity you're asking about. The evidence on hospitals tells one story. The evidence on community health centers tells a different one. Reform proposals that ignore this difference are likely to misfire.

How the program creates revenue

A covered entity buys an outpatient drug at the discounted 340B price, often 20% to 50% below what other buyers pay, then bills the patient's insurance at the standard rate. The difference is the entity's net 340B revenue. There's no requirement that the spread be passed to patients, that it fund safety-net activities, or, for hospitals, that it even be tracked or reported.

Covered entities can dispense 340B drugs through their own in-house pharmacies or through contract pharmacies, retail chains that fill 340B prescriptions on a covered entity's behalf. Most of the program's recent growth and most of the controversy around it is on the contract-pharmacy side, where commercial insurers, employers, and the patients those plans cover indirectly subsidize the spread through higher premiums.

The hospital evidence

The strongest evidence comes from a research design that compares hospitals just above the eligibility threshold (a disproportionate share adjustment of 11.75%) to those just below. The two groups look similar in most respects, but only those above the line receive 340B, so differences between them can be attributed to the program.

Studies using this design, led by Sunita Desai (NYU) and J. Michael McWilliams (Harvard), find 340B eligibility is associated with **hospitals acquiring oncology and ophthalmology practices**, more drugs administered in outpatient settings, and no clear evidence of expanded care or reduced mortality among low-income patients. Their **2021 follow-up** found no association with increases in uncompensated care.

Two findings illustrate the incentive structure. A **2023 paper in Health Affairs** found 340B eligibility was associated with a 22.9 percentage point reduction in the use of biosimilars, the cheaper alternatives to expensive biologic drugs, in fee-for-service Medicare hospital outpatient settings. Because brand drugs cost more, they generate a bigger dollar margin under 340B's spread, so the more expensive drug is more profitable to administer. The effect is harder to detect in managed-care settings, where Part D and Medicare Advantage plans can override the prescribing incentive.

Two literature reviews synthesized the broader evidence. The **Knox et al. review** of nearly 300 studies found "mixed evidence" that 340B revenue funded care for low-income populations. The **Levengood et al. review** concluded the highest-quality evidence indicates Disproportionate Share Hospitals (DSH) - those that receive federal payments to offset the high costs of caring for uninsured and low-income patients - hospitals may be using 340B in ways prioritize the generation of financial profit. Both flagged the lack of mandatory reporting as the central obstacle. The **Cassidy HELP Committee report** added institutional detail: Bon Secours Mercy Health and Cleveland Clinic generated hundreds of millions of dollars in 340B revenue without passing discounts to patients, using it instead for "capital improvements" and "community benefit programs" without specific accounting.

The grantee evidence

The picture for federally qualified health centers (FQHCs), also known as community health centers, is different. A **2024 paper in JAMA Health Forum** found that as health centers added 340B locations, they served more uninsured, low-income, unhoused, and non-English-speaking patients, and provided more high-value preventive services such as HIV tests, tobacco cessation counseling, and flu vaccinations.

Community health centers face requirements hospitals don't. They must provide sliding-scale discounts to low-income patients and report patient and service data through HRSA's Uniform Data System. The combination of better incentives and better reporting suggests they're using 340B largely as Congress intended. Reforms aimed at hospitals should be designed to avoid harming FQHCs.

The growth question

The Congressional Budget Office addressed program growth in **September 2025**. 340B drug purchases grew from \$6.6 billion in 2010 to \$43.9 billion in 2021 to \$81.4 billion in 2024, far exceeding the brand drug market. About a third reflects the kinds of drugs the program covers, especially cancer drugs and anti-infectives. The rest reflects

things specific to 340B: hospitals acquiring or building eligible outpatient clinics, and the rapid expansion of contracts with outside pharmacies.

CBO concluded 340B "encourages behaviors that tend to increase federal spending" through three mechanisms: (1) hospitals have incentives to prescribe more drugs and higher-priced drugs; (2) drug companies negotiate smaller rebates with commercial insurers, because the largest commercial rebates would lower Medicaid best price and, with it, the 340B ceiling, increasing the manufacturers' 340B exposure; and (3) hospitals have incentives to acquire physician practices and turn them into 340B sites. Higher commercial drug costs flow back to the federal budget through Medicare and Medicaid managed care payments and through the tax exclusion for employer-sponsored health insurance.

4. Risks and Unknowns

Reform options aren't free. Below are effects worth tracking if particular reforms are enacted.

If Congress tightens hospital eligibility...
Watch for collateral damage to true safety-net providers. The DSH percentage measures inpatient mix and doesn't perfectly track which hospitals serve the most vulnerable populations. A higher threshold would catch some hospitals that genuinely serve low-income patients alongside those using the program in margin-motivated ways. Alternative tests based on charity care can help, but those have measurement problems too.

If Congress restructures 340B as a rebate program...
Watch for cash-flow stress at small covered entities. Community health centers and small rural hospitals operate on thin margins. Replacing upfront discounts with after-the-fact rebates could create timing problems and administrative burdens. The intended effect, letting manufacturers verify eligibility through claims data, has program-integrity benefits. The unintended effect is concentrating financial risk on the entities least able to bear it.

If Congress requires direct patient pass-through...
Watch for the unraveling of the cross-subsidy logic. The program's basic mechanism is that revenue from insured patients funds services for uninsured ones. Direct pass-through would change what the program is, from an institutional subsidy supporting the safety net at the system level, to a transactional discount lowering out-of-pocket costs for some patients. Both have value. But services funded by cross-subsidy could be lost.

If Congress mandates transparency without changing structure...
Watch for hospitals reporting program use in technically accurate but uninformative ways. "Capital improvements" and "community benefit" are legitimate categories, but hard to evaluate. The Cassidy investigation illustrated this: the hospitals it examined did report on revenue use, but the categories were broad enough that the reporting didn't allow conclusions about whether the revenue benefited 340B-eligible patients.

If federal courts continue siding with drug companies on outside pharmacies while states protect them...
Watch for growing state-by-state fragmentation. Two federal appeals courts have ruled the federal 340B statute does not prohibit drug companies from imposing conditions on outside pharmacy use. **Eight states have passed laws** prohibiting those conditions, and the Supreme Court **declined in December 2024** to hear the drug industry's challenge to Arkansas's. Without federal clarity, the patchwork will keep growing.

If reform happens through CMS payment cuts rather than program restructuring...
Watch for cost shifting without changing incentives. CMS reduced Part B reimbursement for 340B drugs in 2018, and the Supreme Court reversed that cut in 2022 in **American Hospital Association v. Becerra**. Cuts of this kind reduce the program's effects without reshaping how it works. Hospitals can keep participating while losing margin, which redistributes who bears the cost.

If any reform shrinks the program's overall size...
Watch where the savings actually go. Any reform that reduces 340B contracts the transfer from manufacturers to hospitals. Without explicit pass-through provisions, the dollars flow to drug manufacturers, not to the federal government, insurers, or patients. "Fixing 340B" doesn't automatically generate federal savings.

5. How to Read the Evidence Yourself

Whether reform produces budget effects, lower premiums, or lower out-of-pocket costs depends on what the legislation specifies, not on the contraction itself.

When you encounter a 340B study or claim, five questions are worth asking.

1. **Is the analysis about hospitals or community health centers?** The evidence on whether 340B is used as Congress intended differs sharply by entity type. Studies that lump them together obscure the picture.
2. **What’s the comparison group?** “340B hospitals provide more charity care than non-340B hospitals” is a different claim than “hospitals provide more charity care after they enter 340B than before.” The first can confuse selection (hospitals serving more low-income patients are eligible in the first place) with effect. The strongest designs compare hospitals just above and just below the eligibility threshold, or before and after they enter the program.
3. **Where did the data come from?** The strongest evidence comes from studies using the DSH eligibility threshold. Stakeholder surveys should be read carefully; both critics and defenders have produced reports using selective data.
4. **Does the analysis acknowledge what it can’t see?** The biggest data gap is hospital revenue use. Analyses that draw confident conclusions about how hospitals spend savings should explain how they address that gap. If they don’t, the conclusion is weaker than it sounds.
5. **What’s the counterfactual?** Hospital advocates often point to programs funded by 340B revenue. The

6. The Bottom Line

The program does not have a single answer to the question “is it working.” The evidence indicates it works for community health centers as Congress intended. Whether it works for the hospitals that receive most of the program’s **$81 billion in discounted purchases** is a separate question, and the evidence is much more mixed.

Reformers can tighten eligibility, restructure the discount, require direct patient pass-through, mandate transparency, or some combination. What no reform can eliminate is the underlying tension between 340B’s two roles: a payment mechanism that supports vulnerable patients indirectly through institutional subsidies, and one that generates revenue in ways that don’t always benefit those patients. Reform proposals choose which role to prioritize.

The empirical case for some reform is reasonably strong. The evidence on hospital behavior, biosimilar substitution, and program growth converges on a coherent finding: at scale, the program’s incentive structure produces effects beyond what Congress described in 1992. The case for any specific reform is weaker, because the consequences depend on details that haven’t been studied. Decisionmakers should be more skeptical of confident claims about reform effects than of the underlying evidence about program effects.

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