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Which Patients Are Eligible for a 340B Discount?



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Takeaways

- Congress created the 340B program in 1992 to help safety-net providers stretch limited federal resources, but never defined who qualifies for discounted drugs.
- Vague federal guidance opened the door to abuse, allowing hospitals to claim discounts for prescriptions written by outside doctors for patients they had seen only once, years earlier.
- Weak oversight has fueled explosive growth, with the program doubling in four years to $100 billion in 2025.
- Congress needs to define eligible patients and ensure they share in the savings.

Congress left a hole at the heart of the 340B Drug Pricing Program more than 30 years ago—and it has never been filled. The program was created to help safety-net providers "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] But Congress never defined exactly who counts as a 340B patient. That omission has become one of the program's biggest sources of disagreement and controversy.

The 340B program allows safety-net providers to buy outpatient drugs at a discount, bill payers at the standard rate, and keep the difference to preserve and expand access to care for the low-income populations they serve. Safety-net providers may access this

program only for their own patients, but absent statutory or regulatory clarity, 340B providers were left to develop their own patient definitions.

That ambiguity has created a predictable tug-of-war. Providers favor a more expansive patient definition to maximize the drug discounts they can access. Manufacturers favor a narrower definition to minimize the drug discounts they must supply. Without a precise patient definition, the Health Resources and Services Administration (HRSA) is unable to provide consistent oversight or determine whether discounted drugs are being provided to the individuals who Congress intended the program to serve. The Medicare Prescription Drug Price Negotiation Program adds an element of urgency. As negotiated Maximum Fair Prices (MFPs) interact with 340B discount prices, the absence of a clear patient definition increases the complexity of determining which claims qualify for which pricing. The tension around the patient definition has spilled into the courts, producing a narrow ruling rather than a durable resolution—leaving the underlying definitional stalemate for Congress to break.

That ambiguity is no longer just a technical problem—it has real consequences for patients, providers, and manufacturers. Congress and the administration are considering and testing changes to the 340B Program, including a pilot program testing a financing shift from the current upfront discount model to a rebate model, and a claims verification shift to a clearinghouse mechanism. All approaches require a clear patient definition to determine which claims are eligible in the first place. Congress needs to settle the question once and for all by establishing a statutory patient definition that provides clarity and predictability for all parties, protects appropriate access for safety-net providers, and ensures patients benefit from the program's savings, too.

The Out-of-Date Definition of a 340B Patient

The 340B program, created in 1992, allows 340B providers, called "covered entities" in statute, to receive a discount on outpatient drugs their patients use and then charge payers the full price for those drugs. The savings they retain, sometimes called profit or "spread revenue," are meant to extend existing federal support for the vulnerable populations that safety-net providers serve.

While the statute prohibits 340B providers from reselling or transferring a discounted drug to a person who is not their patient (HRSA refers to this as "drug diversion"), it does not clearly define who *is* a patient and for how long or under what circumstances a 340B provider can claim a patient for 340B purposes. HRSA recognized it would be difficult to enforce the drug diversion prohibition without a patient definition and, **in 1996, issued sub-regulatory guidance** establishing a three-prong test:[2]

- The 340B provider has a "relationship with the individual" such that it "maintains records of the individual's care,"
- The individual receives care from a professional who is either employed by the 340B provider or who provides health care under contract or "other arrangements" (including referral for consultation) such that responsibility for the care provided remains with the 340B provider, and
- For clinics, the care the patient receives matches the type of care the clinic is federally funded to provide. Hospitals are exempt from this last part of the patient definition.

This framework proved far too broad to establish a meaningful definition of a 340B patient. Electronic medical records made it easier for providers to satisfy the first prong by expanding their ability to maintain patient records. 340B providers have interpreted the second prong's phrase "other arrangements" to include prescriptions written by non-340B providers to whom they referred patients. HRSA's guidance leaves even this largely to 340B providers' own discretion, stating that how a provider "counts referrals under the 340B program should be addressed in their written policies and procedures."[3] However, a 2014 review by the Department of Health and Human Services Office of the Inspector General found that 340B providers use different methods to determine which prescriptions are eligible for 340B pricing and reach different conclusions about similar types of prescriptions.[4]

In August 2015, HRSA attempted to modernize the 340B program's regulatory structure by issuing proposed guidance clarifying program requirements.[5] The proposal replaced the three-prong test from 1996 with a six-prong test applied on a prescription-by-prescription basis. It drew thousands of comments but **was withdrawn** after President Trump's 2017 inauguration-week executive order froze and required review of all pending federal regulations.[6]

With a vague patient definition and other opportunities for expansion, the 340B program grows each year. In 2025, covered entities purchased $100 billion in discounted outpatient prescription drugs under the program, doubling the program's size in just four years.[7] As described below, 340B discounts have distorting effects on the health care system, including on costs to patients.

[chart]

How do Program Participants Define 340B Patients?

Without a clear statutory definition, 340B providers and manufacturers have developed competing views of who qualifies as a 340B patient. **For example, some 340B providers may treat all prescriptions filled by a patient as 340B-eligible**, even when they were written by non-340B providers. Recent litigation illustrates how far this problem extends. Genesis Health Care, a South Carolina Federally Qualified Health Center (FQHC), was audited by HRSA in 2017 and cited in 2018 for diversion. HRSA found that Genesis treated prescriptions as 340B-eligible even when they were written by non-340B outside providers with no connection to the FQHC. Genesis achieved this by applying a self-adopted two-year lookback.[8] If an individual had any visit with a Genesis provider within the prior two years, **Genesis treated every subsequent prescription from any outside prescriber filled through its pharmacies as 340B-eligible**—even if the Genesis visit was unrelated to the condition for which the prescription was later written.

HRSA also found that Genesis pharmacy technicians had added the note "medication referral" to individuals' visit histories after filling prescriptions, despite having no documented referral from Genesis at all.[9] Genesis sued HRSA, challenging its guidance that a 340B provider must have initiated a patient's care before dispensing a 340B drug to that patient. Genesis argued that this requirement exceeded HRSA's statutory authority. **And Genesis won**; the court held that nothing in the statute requires a 340B prescription to originate from care the 340B provider itself delivered.[10] While this ruling is limited to Genesis, it exposed the larger accountability problem: without a clear statutory patient definition, the government has limited ability to determine which prescriptions legitimately qualify for 340B discounts.

An entire consulting and technology industry has developed around identifying prescriptions written by non-340B providers for 340B pricing purposes. This work, often marketed as "referral capture," involves searching medical records to tie an outside provider's prescription back to an earlier 340B provider encounter. One 340B program operations consulting firm defines referral capture as "looking for a way to tie a visit with a non-qualified referred provider to a qualified provider visit."[11]

And because finding these prescriptions manually is time-consuming, vendors have increasingly automated the process. Another firm markets an AI agent that "scans autonomously using advanced LLMs [Large Language Models], surfaces high-confidence opportunities ranked by drug costs and specialty, and creates the audit trail automatically," explicitly framing its ability to "reconstruct referral intent" and "automate referral documentation" around capturing high-cost medications.[12] In cases where a new patient is already receiving care from another prescriber, one vendor advises covered entities to document any specialist relationships with a referral purely for the purpose of making those prescriptions 340B-eligible.[13]

This defies any common-sense understanding of what a 340B patient should be. Even HRSA itself, defending its own audit finding against Genesis, argued it is hard to reconcile the position that a 340B provider may provide deeply discounted specialty drugs to a person to whom it once gave a flu shot with any ordinary understanding of the term "patient."[14] The problem compounds when a patient sees more than one 340B provider. 340B rules require that only one 340B provider receive a 340B discount on a particular patient transaction.[15] But with each entity independently applying its own expansive lookback and referral capture practices, there is little practical means of enforcing that requirement, creating circumstances in which the same prescription could be claimed by more than one 340B provider and receive more than one discount. Changes to the program's financing, such as moving from an upfront discount to a rebate model, or to a claims verification method, such as a clearinghouse model, could address this problem and help to ensure only one discount is claimed for each prescription.

What This Means for Patients and Payers

The definition of a 340B patient matters because it determines which prescriptions qualify for the discount. HRSA's 1996 guidance resulted in 340B providers claiming the discount on prescriptions written for patients with only a tenuous or long-past connection to the provider. **Each expansion of the definition of a 340B patient increases the number of drug purchases eligible for a discount**—and with it, the program's downstream costs to federal and state programs and the taxpayers who fund them, as well as private payers, employers, and patients, regardless of whether the patient whose prescription generated the discount directly benefits.[16]

The impact is easiest to see in hospital consolidation: when a 340B hospital acquires or establishes an off-site clinic, covered outpatient drugs for every patient of that clinic likely become eligible for 340B pricing, without any independent judgment about whether that patient-provider relationship resembles the safety-net care the 340B program was created to support. **The number of 340B outpatient clinics increased from 6,100 to 27,700 between 2013 and 2021**, and the share of hospitals with at least one off-site clinic increased from 50% to 76%.[17] While a causal effect is impossible to determine, the current patient definition certainly incentivizes these acquisitions and does nothing to rein in this growth.

The same problem extends to Medicaid. When a Medicaid managed care plan pays for a 340B drug, the Medicaid program loses the rebate it would otherwise receive under the Medicaid Drug Rebate Program. This is less of a problem in fee-for-service Medicaid, where reimbursement generally tracks the 340B price. The result is **an estimated $2 billion–$6 billion in annual losses to federal and state governments**.[18] The scale of that loss is directly tied to how many prescriptions the patient definition allows to be claimed as 340B in the first place.

The same dynamic shows up in Medicare. The availability of discounted drugs through the 340B program gives 340B hospitals an incentive to increase their use, which can increase Medicare spending. The Government Accountability Office found that **Medicare Part B drug spending is "substantially higher" at 340B disproportionate share hospitals than at non-340B hospitals**, driven both by higher drug volume and a shift toward higher-cost drugs.[19] A Millman analysis found that this pattern extended to commercial health insurance as well,[20] consistent with hospitals maximizing the pool of prescriptions they can claim as 340B-eligible under a patient definition that does nothing to limit volume.

Finally, the same dynamic reaches private insurance. By expanding the number of prescriptions treated as 340B-eligible, an expansive 340B patient definition can displace manufacturer rebates that private health plans would otherwise receive, at **an estimated annual cost of $14.5 billion to employer-sponsored and non-group health plans**.[21] This dynamic may increase premiums, raising federal spending on Affordable Care Act premium tax credits in the non-group market and reducing federal revenue through larger tax exclusions for employer-sponsored health insurance premiums.[22]

How to Update the Patient Definition

Thirty years after HRSA's original guidance, the patient definition still rests on a single 1996 Federal Register notice that was never subjected to notice-and-comment rulemaking. In *Genesis Health Care v. Becerra*, a federal court rejected HRSA's position that a 340B provider must initiate the care that leads to a 340B-eligible prescription but allowed HRSA to interpret "patient."[23] Because the statute itself is silent on who is a patient, HRSA's interpretations can be challenged case by case. Guidance cannot fix this problem; only Congress can, by writing a definition directly into the statute.

This is true regardless of how the program is financed and how claims are verified. Whether the 340B program continues under the current upfront discount model or moves to a rebate model, and whether claims verification shifts to a clearinghouse model, a claim-by-claim decision about whether a given prescription qualifies as a 340B transaction must be made. Changing the program's financing and claims verification may change when that determination is made and by whom, but it does not answer the underlying question of who counts as a patient. That question needs a statutory answer. In other words, better claims oversight and a clearer patient definition are complementary reforms. One verifies the transaction, while the other establishes the rule the transaction must meet.

Fortunately, Congress is not starting from scratch. Four current proposals each attempt some version of a statutory patient definition: the 340B ACCESS Act (H.R. 5256), Senator Cassidy's discussion draft, the SECURE 340B Act (H.R. 9599), and the SUSTAIN 340B Act (S. 5244).[24] Together, they show where consensus is emerging and where the hardest choices remain.

A clear link between the prescription and the care. At a minimum, a statutory patient definition needs to specify what link a prescription must have to a qualifying visit. All four bills agree on the basic principle: the prescription cannot simply be issued to someone who once walked through the door. A 340B-qualifying prescription must be related to the specific outpatient service the 340B provider delivered to the patient. While the bills differ in the specificity of the patient-provider connection, consensus on the underlying requirement is itself a meaningful starting point for Congress. Congress can provide clarity by requiring eligibility determinations on a prescription-by-prescription basis, ensuring that each prescription written by a 340B provider meets the patient definition.

A time standard. There's also broad agreement that a qualifying patient relationship should not last indefinitely. Three of the four proposals, SUSTAIN, SECURE, and the Cassidy draft, set a 24-month window. The 340B ACCESS Act mostly follows suit but carves out a shorter, 12-month window specifically for DSH hospitals, children's hospitals, free-standing cancer hospitals, and rural referral centers. Outside the 340B program, most states already limit the validity of prescriptions for noncontrolled substances to around 12 months, though a handful of states (Idaho, Illinois, Iowa, Maine, South Carolina, and Wyoming) have extended that window to make it easier to manage chronic conditions.[25] A 24-month 340B standard would exceed the typical 12-month prescribing period in most of the country. Congress should align the time standard with the practice of medicine, and the time standard should apply only to the care delivered and prescription written by the 340B provider, not to every prescription written for a patient during that time.

Closing loopholes. A connection standard and a time standard set the outer boundaries of a patient definition, but at least three additional areas need targeted fixes. The first is referrals, which HHS' Office of Inspector General has identified as a longstanding source of eligibility ambiguity.[26] All three bills that address referrals (SUSTAIN, ACCESS, and SECURE) exclude DSH hospitals from referral eligibility entirely. That convergence reflects a shared concern about referral-based claims at DSH hospitals, which account for a large majority of 340B volume and have drawn the most scrutiny for their patient-definition practices.[27] Congress should carefully consider how to balance legitimate referrals required for care coordination purposes with the impact of referrals on the growth of the 340B program. The second area is the definition of a qualifying outpatient service itself. Current HRSA guidance is vague on this point, offering little

more than the general idea of an outpatient visit that involves more than dispensing or administering a drug. The bills diverge on how to address this gap, but each one offers something more concrete than what exists today, such as a billing-code test, an insurance-payment test, or a scope-of-grant test for grant-funded entities. Whatever test Congress adopts, the patient should be classified as an outpatient when the prescription is written, consistent with the statutory limitation of the 340B program to outpatient drugs. Finally, to ensure the patient definition Congress establishes can be administered and verified, stakeholders should have access to the information required to validate compliance, as described by Third Way in a companion memo.[28]

Passing savings to patients. A statutory fix should also address a basic accountability gap between what 340B is supposed to do for patients and communities served by 340B providers and what it actually requires. There is no requirement anywhere in the statute that any 340B discount reaches the patient who qualified for it. All four bills include some form of patient affordability requirement, a sign that this has become central to the legislative conversation, and Third Way has previously outlined its position.[29] Congress should require 340B hospitals to pass a share of the savings on to low-income and uninsured patients at the pharmacy counter, mirroring requirements for services provided by federal grantees such as community health centers. A portion of the discount should also be applied to insured patients' out-of-pocket costs.[30] A statutory patient definition is an incomplete fix if it answers who qualifies as a patient without also requiring that the qualifying patient actually benefits. Reforming the program's operations in a way that requires claims data submission will create a clear path to direct such benefits to each qualifying patient.

Conclusion

Thirty years on, the 340B program still runs on a patient definition Congress never wrote. As the program has grown, that omission has become increasingly consequential, allowing competing interpretations of who qualifies and making effective oversight more difficult. The *Genesis* case confirms that HRSA cannot fix this through guidance—Congress needs to define "patient" in the statute itself.

The good news is that Congress does not need to start from scratch. Four current proposals already converge on the basic shape of a definition: a prescription must

connect to a patient visit, the patient connection should remain valid for a time-bound period, and the entities most associated with referral-based risk should face tighter limits. There is also agreement that the patients whose prescriptions qualify for the discount should benefit from it.

The pieces of a workable patient definition are already on the table. Congress now needs to put them into law.

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