PATIENTS RISING

Putting patients at the center of health policy

August 28, 2026

The Honorable Bill Cassidy, M.D.
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Submitted by email to: 340bforpatients@help.senate.gov

RE: Comments of Patients Rising on the 340B Drug Pricing Integrity and Affordability for Patients Act Discussion Draft

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Dear Chairman Cassidy:

Patients Rising is a national patient advocacy organization representing people living with chronic and life-threatening conditions and the families who care for them. We write to offer comments on your 340B Drug Pricing Integrity and Affordability for Patients Act discussion draft. We recognize that the comment window closed on August 28 and respectfully ask that these comments be received into the record as the Committee continues its work.

We come to this issue from a specific and, we believe, underrepresented vantage point. Patients. Our question is simple: *when a federal program generates substantial savings through medicines dispensed or administered to patients, what does the patient actually receive?*

For patients, this is not an accounting question. It is the cancer patient trying to afford an infusion, the parent wondering why a medicine associated with a substantial federal discount still carries unaffordable cost-sharing, or the rural patient traveling hours to obtain a specialty medicine. Patients rarely know whether 340B was involved in their care, what financial benefit was generated, or whether any portion of that benefit reached them. They simply know what they were asked to pay.

For the past two years we have pressed that question through the appropriations process, urging the Committee on Appropriations to direct the Health Resources and Services Administration to build a public reporting framework showing how 340B savings translate into direct patient benefit, and to pilot mechanisms that tell patients when 340B pricing has been applied to their own medicine. We raised it because the scale of the program has outrun the public's ability to see inside it. HRSA reports that covered entity purchases at 340B prices reached $81.4 billion in 2024. Independent analysis of HRSA data places 2025 purchases at approximately $100 billion, a 22.8

percent increase in a single year and roughly a $19 billion expansion in the twelve months since your Committee released its investigative report. A program of that size, intended to support care for vulnerable patients, should be able to demonstrate what it does for them.

Judged against that standard, this discussion draft is the most consequential 340B proposal Congress has produced. Section 7 would, for the first time in the program's history, require that a 340B discount actually reach certain patients at the counter rather than stopping at the institution's balance sheet. Section 6 would, for the first time, make an individual covered entity's 340B margin and charity care a matter of public record. Section 9 would sever the link between a middleman's compensation and the size of the discount it administers. Each is a meaningful step toward making the program more accountable to patients, and we commend you for including them.

Our comments are offered in support of the draft and focus on places where its patient-facing provisions can be strengthened. In particular, we are concerned that Section 7 appears to exclude Medicare and Medicaid beneficiaries from key affordability protections; Section 6 requires federally funded grantees, but not the largest hospital covered entities, to explain how 340B margin is used; and nothing in the draft tells an individual patient whether 340B was used in connection with their own medicine.

We believe every 340B reform proposal should ultimately answer four questions for patients:

1. Did the patient benefit financially?
2. Can the patient see that benefit?
3. Can the patient access the medicine without unnecessary disruption?
4. Does the patient have recourse when the system fails?

Summary of Recommendations

The recommendations below are numbered to match the section-by-section discussion that follows. Our three central concerns are Recommendations 1, 5, and 10.

1. **Do not exclude low-income Medicare and Medicaid patients from the affordability protections.**
2. Do not make patients ask for a benefit they may not know exists.
3. Give patients a meaningful remedy when they are overcharged.
4. Establish a meaningful affordability floor for nonhospital entities.
5. **Require hospitals to show how 340B savings benefit patients.**
6. Tell Congress and patients how much of the program the reporting thresholds leave invisible.
7. Define “direct patient benefit” in the law.
8. Turn 340B data into transparency patients can actually use.
9. Independently verify what covered entities report.
10. **Give patients the right to know when 340B was used for their medicine.**
11. Protect patient privacy in every 340B claims transaction.

12. Create a meaningful patient-first pathway for entities that pass the full discount through.
13. Protect safety-net patients from unintended service disruptions during the rebate transition.
14. Protect patients before eliminating in-kind subgrantee arrangements.
15. Protect continuity of treatment when 340B eligibility changes.
16. Make 340B patient eligibility understandable to patients.
17. Put patient-access guardrails around contract pharmacy restrictions.
18. Give patients the same financial-assistance protections at every 340B hospital location.
19. Show patients how much of the 340B benefit is going to intermediaries.
20. Make prime vendor costs transparent.
21. Do not make patients wait years for the protections Congress enacts.

Section 7 | Ensuring Affordability

We begin with Section 7 because, from a patient's perspective, it is the most important provision in the draft. For thirty years, 340B has operated on an assumption that savings retained by an institution will ultimately benefit the patients it serves. Section 7 begins to make that benefit explicit by requiring hospital covered entities to establish a sliding fee scale, applying the cap at the point of sale for self-administered medicines, requiring notice of the scale, and extending the requirement to contract pharmacies. We strongly support that direction.

Recommendation 1: Do not exclude low-income Medicare and Medicaid patients from the affordability protections.

Under proposed subparagraph (G)(v)(I), an "applicable patient" appears to be limited to an uninsured patient or certain low-income patients with specified forms of private coverage. Medicare and Medicaid beneficiaries appear to satisfy neither prong. They have minimum essential coverage and their public coverage does not fall within the private coverage categories referenced in the second prong.

If that reading is correct, the practical consequence is severe. A Medicare beneficiary living below the Federal poverty guidelines, receiving an infused therapy for cancer or an autoimmune condition at a disproportionate share hospital, and facing significant coinsurance could receive nothing under Section 7, while an uninsured patient at the same counter could qualify for substantial assistance. The patients may have the same income and the same inability to pay; only the source of coverage differs. A patient affordability provision that omits low-income Medicare and Medicaid beneficiaries is not a patient affordability provision.

We recommend that the Committee revise subparagraph (G)(v)(I) so that any patient with family income below 200 percent of the Federal poverty guidelines qualifies as an applicable patient, regardless of whether that patient is uninsured, commercially insured, enrolled in Medicare, Medicaid, or CHIP. A patient's need for help does not disappear because of the name on their insurance card. We further recommend that the Committee consider a catastrophic affordability backstop for patients above that threshold when the out-of-pocket obligation for a covered

outpatient drug exceeds a defined share of household income. If the exclusion is unintended, it should be corrected. If it is intentional, we urge the Committee to reconsider it.

Recommendation 2: Do not make patients ask for a benefit they may not know exists.

The draft requires the sliding fee scale to be posted and included in billing communications. Those disclosures are useful, but they place the burden of discovery on the patient. Financial assistance programs structured around passive notice tend to favor people with the time, health literacy, and confidence to navigate them. Billing communications may also arrive after the medicine has already been dispensed or administered.

Posting a sliding fee scale is important, but disclosure alone is not access. A patient should not have to know the right question to ask in order to receive a benefit Congress intended them to receive. We recommend that covered entities, and contract pharmacies acting on their behalf, be required to affirmatively offer and document screening for sliding-fee eligibility at or before dispensing or administering the medicine. The process should be simple, standardized, and auditable, and should not impose unnecessary paperwork on patients already navigating illness and treatment.

Recommendation 3: Give patients a meaningful remedy when they are overcharged.

The draft establishes civil monetary penalties and directs OIG to study whether eligible patients actually receive assistance. Those are valuable enforcement tools, but neither returns money to a patient who was improperly charged. The existing 340B administrative dispute resolution process is designed for disputes between manufacturers and covered entities, not for patients.

If Congress creates an enforceable patient affordability protection, the patient must have an enforceable remedy when that protection fails. We recommend a simple, accessible pathway for patients and caregivers to report potential violations directly to the Secretary; automatic refund of any amount improperly charged, with interest; and public reporting of substantiated violations. Civil penalties may deter misconduct, but they do not make an overcharged patient whole. Patient protection requires both.

Recommendation 4: Establish a meaningful affordability floor for nonhospital entities.

Proposed subparagraph (H) requires certain nonhospital covered entities to establish a policy ensuring that a patient is not denied access to a drug because of inability to pay. That principle is sound, but the standard is less concrete than the dollar caps applied to hospital covered entities.

The promise that a patient will not be “denied access” because of inability to pay should have a measurable meaning. A nominal reduction in cost-sharing does little for a patient who still cannot afford the medicine. We recommend that Congress establish a minimum affordability standard under subparagraph (H), or direct the Secretary to do so, that measures whether the patient's remaining out-of-pocket obligation is actually affordable—not simply whether some discount was offered.

Section 6 | Transparency

Section 6 would create the first entity-level public record of 340B economics in the program's history. We strongly support public reporting of margin, charity care, payer mix, and related information. The value of that transparency, however, will depend on whether it captures the institutions generating most program volume, uses comparable definitions, can be trusted, and can be understood by patients.

Recommendation 5: Require hospitals to show how 340B savings benefit patients.

Proposed clause (i)(III) requires certain federally funded grantees—including community health centers, Ryan White clinics, and hemophilia treatment centers—to report how they used their 340B margin. Hospital covered entities would report margin, and the largest would report charity care and payer mix, but they would not be required to report how that margin was used.

By HRSA's 2024 purchase data, hospital covered entities accounted for approximately $70.1 billion of $81.4 billion in 340B purchases—roughly 86 percent of the program—while grantee covered entities accounted for approximately 14 percent. Requiring the 14 percent to explain how margin is used while not asking the same question of the 86 percent creates the wrong accountability structure.

We recommend extending the use-of-margin reporting requirement in clause (i)(III) to hospital covered entities described in subparagraphs (L) through (O). Transparency is not a penalty; it is a reasonable obligation for institutions participating in a federal program intended to support care for vulnerable patients. Hospital reporting should identify, at minimum, 340B resources devoted to charity care, patient financial assistance, cost-sharing reduction, medication assistance, transportation and support services, and expansion of access in underserved communities. Hospitals already assemble comparable information for Schedule H community benefit reporting and Medicare cost reporting, which should help limit unnecessary burden.

Recommendation 6: Tell Congress and patients how much of the program the reporting thresholds leave invisible.

The draft tiers reporting obligations according to net patient revenue. Thresholds can reasonably reduce burden, but their effect cannot be evaluated unless Congress knows how much activity falls below them.

We recommend that the Secretary report annually the percentage of total 340B purchase volume and covered entity sites falling below each reporting threshold. Patients and policymakers should be able to determine whether the public data describes nearly the entire program—or only part of it. If the excluded share is small, the thresholds are validated; if it is substantial, Congress will know to revisit them.

Recommendation 7: Define "direct patient benefit" in the law.

The draft appropriately anchors charity care to an existing Medicare cost report line, creating a comparable measure. But expenditure categories are left largely to rulemaking, and "patient benefit"—the concept the reporting system is ultimately intended to illuminate—is not defined.

If Congress wants to measure whether 340B benefits patients, it should define what patient benefit means. We recommend establishing a statutory floor for "direct patient benefit" that includes reduced patient out-of-pocket costs, charity care, medication and financial assistance, transportation and patient support services, and expanded access to care in designated shortage areas. The Secretary should retain authority to recognize additional categories, but the core definition should not be left entirely to regulation. Without a common definition, institutions may report fundamentally different activities under the same label, making meaningful comparison impossible.

Recommendation 8: Turn 340B data into transparency patients can actually use.

Data disclosure is not the same as patient transparency. Section 6's searchable public data will be valuable to policymakers, researchers, and journalists, but a database of margins, cost-report fields, and payer mix is unlikely to help a patient understand the hospital or health center treating them.

We recommend that the Secretary, in consultation with patients and patient organizations, create a standardized, plain-language Patient Benefit Disclosure for every reporting covered entity. A patient should be able to search for a hospital or health center by name or location and easily understand its participation in 340B, reported margin, charity care, patient financial assistance and cost-sharing reductions, and how 340B resources were used to benefit patients. The underlying data should remain available to researchers and analysts, but patients deserve a translation layer built for them. Patients Rising has developed a detailed concept for such a disclosure and would welcome the opportunity to share it with your staff.

Recommendation 9: Independently verify what covered entities report.

Reported 340B margin will depend partly on self-reported acquisition costs and deductible compliance, legal, educational, administrative, third-party administrator, and contract pharmacy costs. Those may be legitimate expenses, but broad self-reported offsets create a need for verification.

Transparency only works if patients and policymakers can trust the information being disclosed. We recommend that the Secretary audit a statistically valid sample of covered entity submissions each year and publicly report the resulting error rate, material discrepancies, and corrective actions. Public reporting without meaningful verification risks creating the appearance of transparency without its substance.

The Missing Provision | Telling the Patient

Read together, Sections 6 and 7 give patients two important things: affordability protections in defined circumstances and an annual public record of institutional performance. Neither tells an individual patient whether 340B was used in connection with their own medicine. Every disclosure obligation in the draft runs upward—to the Secretary, to manufacturers, or to an aggregate public file. None runs to the person the program is intended to help.

Recommendation 10: Give patients the right to know when 340B was used for their medicine.

We recognize the operational complexity of patient-level notification. Point-of-sale disclosure touches claims systems, pharmacy workflow, timing, and privacy, and the rebate and repository models contemplated in Section 2 may change when 340B status becomes known. Those challenges argue for careful design and piloting, not for leaving the patient permanently outside the information flow.

Patients have a right to know when a federal drug discount program has been used in connection with their medicine. We recommend that Congress direct the Secretary to develop and pilot practical mechanisms—such as point-of-sale notification, receipt disclosure, or another patient-friendly method—to inform patients when a covered outpatient drug dispensed or administered to them was purchased through 340B. The pilot should evaluate operational feasibility, privacy, patient comprehension, and the appropriate timing and content of the disclosure, with findings reported to Congress within two years. If a benefit is generated through a patient's medicine, that patient should not be the only participant in the transaction who cannot see it.

Section 2 | Rebate Conditions

Patients Rising takes no position on whether manufacturers should be permitted to deliver the 340B price through an upfront discount, a retrospective rebate, or a claims repository. That dispute should not obscure the patient questions raised by the mechanics. We offer three recommendations focused on privacy, direct patient benefit, and continuity of safety-net services.

Recommendation 11: Protect patient privacy in every 340B claims transaction.

The standardized claims data contemplated by the draft is detailed. Medical claims include a tokenized patient identifier, while the retail field list includes transaction, prescription, drug, prescriber, pharmacy, date-of-service, and related encounter information. In combination, such data can be meaningfully re-identifiable, particularly for people with rare conditions.

Patients should not have to trade their medical privacy for the government to protect the integrity of the 340B program. We recommend requiring tokenized patient identifiers across both retail and medical claims submissions, establishing a uniform tokenization standard, and expressly prohibiting re-identification, sale, licensing, or secondary use of patient-level data for purposes unrelated to 340B administration. These protections are particularly important for people with rare diseases,

whose diagnosis, provider, geography, and treatment information can make supposedly de-identified records far easier to re-identify.

Recommendation 12: Create a meaningful patient-first pathway for entities that pass the full discount through.

Proposed clause (ii) allows covered entities that make outpatient drugs available to patients at no more than the ceiling price plus a nominal dispensing fee to elect among several participation mechanisms. That provision describes a fundamentally patient-centered version of 340B: an entity passes the full discount through and receives flexibility in return.

We recommend defining the requirements for full pass-through, establishing a reasonable ceiling on dispensing fees, requiring attestation and audit, and providing meaningful advantages for entities that elect this model, potentially including streamlined reporting, flexibility under contract pharmacy rules, or prominent public identification as a full pass-through entity. If an institution chooses to make the patient the direct beneficiary of the 340B discount, federal policy should make that choice easier—not harder.

Recommendation 13: Protect safety-net patients from unintended service disruptions during the rebate transition.

A retrospective rebate cycle can create working-capital pressure for smaller safety-net entities that must front acquisition costs while awaiting reimbursement. The draft's final claim-submission and payment timelines will materially affect that exposure.

Changes intended to improve program integrity should not inadvertently reduce care for the patients the program exists to serve. We recommend resolving the rebate-processing timelines in favor of the shortest operationally workable payment cycle and requiring the Secretary to monitor whether the transition causes community health centers, hemophilia treatment centers, or other safety-net grantees to reduce services, medications, hours, or patient assistance because of increased working-capital demands. Congress should provide authority for corrective action if measurable patient access problems emerge.

Section 3 | Eligibility of Subgrantees

We support requiring subgrantees to document the grant establishing eligibility, their nonprofit or public status, and the consistency of 340B revenue with grant scope. Entities generating 340B revenue on the strength of a federal grant should be able to demonstrate that the revenue is consistent with the grant's purpose.

Recommendation 14: Protect patients before eliminating in-kind subgrantee arrangements.

The draft contemplates excluding entities that receive only in-kind contributions funded through a grant. Some patients, including patients served through Ryan White arrangements, may rely on subgrantees operating through these structures.

Before excluding these entities, Congress should understand who will be affected. We recommend requiring the Secretary to determine how many patients currently receive care through these arrangements and whether alternative sources of care are reasonably available. Any exclusion should include an appropriate transition period and continuity-of-care protections so that patients—particularly those served through specialized safety-net programs—are not displaced while program eligibility rules change.

Section 4 | Additional Definitions

A single national definition of "patient" is overdue. The draft's framework—an outpatient service within the preceding two years, an auditable medical record demonstrating an ongoing relationship, and a prescription from a covered entity practitioner or referral—is a reasonable starting point. We raise two patient-side concerns.

Recommendation 15: Protect continuity of treatment when 340B eligibility changes.

A patient in the middle of treatment should not lose access to an affordable medicine because an administrative status changed. We recommend a continuity-of-care provision protecting patients already receiving a covered outpatient drug when their patient status, practitioner relationship, treatment site, or the entity's 340B eligibility changes. Patients should receive advance written notice, transition assistance, and sufficient time to establish care or obtain their medicine through another appropriate source. Program integrity can be enforced without abruptly interrupting treatment.

Recommendation 16: Make 340B patient eligibility understandable to patients.

A patient cannot exercise a right they cannot understand. We recommend directing the Secretary to publish plain-language guidance explaining who qualifies as a patient of a 340B covered entity, how the determination is made, how long that status lasts, and whom a patient or caregiver can contact with questions. The legal definition can remain technically precise; the patient explanation should not require a lawyer to understand it.

Section 5 | Contract Pharmacies

We support the integrity architecture in Section 5, including written agreements, registration and recertification, compliance obligations, penalties, and the extension of Section 7 affordability protections to contract pharmacies. Our concern is narrower: limits on the number, geography, or use of contract pharmacies can affect patients who rely on specialty, limited-distribution, rural, or mail-order access.

Recommendation 17: Put patient-access guardrails around contract pharmacy restrictions.

For many patients, contract pharmacy limits may have little practical effect. For others, especially patients with rare diseases, oncology diagnoses, limited-distribution products, mobility barriers, or long travel distances, a network change can become a treatment-access problem. Diversion and

duplicate discounting are legitimate integrity concerns, but reforms addressing them should include a patient safety valve.

We recommend three safeguards: a narrow and transparent exception process when the limits would materially impair access to a needed therapy, particularly limited-distribution and specialty medicines; advance notice and transition assistance when a patient's pharmacy relationship will change; and public monitoring of access effects by state, rurality, and relevant patient population during the first two years of implementation. Congress should be able to identify and correct unintended access problems quickly.

Section 8 | Hospital Child Sites

We support the child-site standards in Section 8 because they connect eligibility to measurable service to the populations the program is intended to support, including shortage-area location, charity care, sliding-fee policies, and Medicaid and CHIP patient mix.

Recommendation 18: Give patients the same financial-assistance protections at every 340B hospital location.

A patient's access to financial assistance should not depend on which door of a hospital system they walk through. We recommend extending the child-site requirement for publicly available charity care and sliding-fee policies to every registered 340B location of a hospital covered entity, including on-campus locations and entity pharmacies. Required reports should also be searchable by facility name and location so patients can understand the policies and performance of the specific facility providing their care.

Section 9 | Contracting Reforms

We strongly support delinking third-party administrator and contract pharmacy compensation from the price of or discount on a drug. Percentage-based compensation creates a structural incentive in which intermediary compensation rises with the size of the discount, consuming resources before they can support patient care.

Recommendation 19: Show patients how much of the 340B benefit is going to intermediaries.

Every dollar of a 340B discount consumed by administrative intermediaries is a dollar that cannot directly reduce a patient's cost or support patient care. We recommend requiring every reporting covered entity, regardless of revenue threshold, to separately disclose compensation paid to third-party administrators and contract pharmacies. Patients and policymakers should be able to see how much of the program's financial benefit is retained by the covered entity, directed to patient benefit, and paid to intermediaries.

Sections 10 | Prime Vendor Program

We support the introduction of a second prime vendor, conflict-of-interest requirements, prohibitions on enrollment and participation fees, no-cost educational services, and strong federal rights in data produced under prime vendor contracts.

Recommendation 20: Make prime vendor costs transparent.

Administrative costs throughout the 340B supply chain ultimately affect how much of the program's value remains available for patient care. We recommend requiring annual public disclosure of each prime vendor's fee structure and total fee revenue associated with the program. Congress, covered entities, and patients should be able to understand what it costs to administer 340B and where those dollars go.

Sections 11 and 12 | Penalties and Effective Dates

We support directing collected civil monetary penalties to the Office of Pharmacy Affairs. Effective oversight requires resources commensurate with the scale and complexity of the program.

Recommendation 21. Do not make patients wait years for the protections Congress enacts.

The draft's implementation schedule could cause structural reforms to arrive before patients can see the resulting public data. The first Section 6 reporting year begins substantially after enactment, which could delay meaningful public visibility well beyond the implementation of other provisions.

The bill's patient-facing protections and transparency requirements should not be the last provisions to take effect. We recommend accelerating Section 6 implementation so that the first public data is available no later than 24 months after enactment and ensuring that Section 12 does not delay Section 7's affordability protections beyond the earliest operationally feasible date. Patients should not wait years to see the benefits of reforms Congress has already determined are necessary.

Conclusion

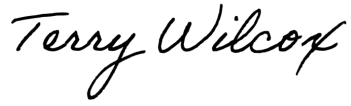
The 340B program has grown from a modest safety-net discount program into one approaching $100 billion in annual discounted purchases, without a corresponding system that allows patients or the public to see clearly what the program delivers to the people it is intended to help. This discussion draft is the most serious congressional effort to change that. Sections 6, 7, and 9 in particular establish important principles: affordability protections should reach patients, institutions benefiting from federal discounts should account publicly for how those resources are used, and intermediaries should not be rewarded simply because a discount is larger.

The measure of 340B reform should not ultimately be how manufacturers, hospitals, pharmacies, or intermediaries fare under a new set of rules. It should be whether a patient can afford the medicine, understand the benefit being generated through 340B, access treatment without unnecessary disruption, and seek meaningful help when the system fails them.

Our recommendations are offered in that spirit. Do not exclude low-income Medicare and Medicaid beneficiaries from the affordability protections. Ask hospitals the same fundamental question the draft asks health centers: how did 340B resources benefit patients? And give individual patients a way to know when 340B was used in connection with their medicine. None of those changes requires reopening the contested questions this draft otherwise seeks to resolve. Each would help make the difference between a program that is better governed and a program that is demonstrably better for patients.

Patients Rising would welcome the opportunity to work with you and your staff as this draft advances. We can provide patient experience data, state-level information on the downstream financial consequences patients face when medicine is unaffordable, and additional detail behind the Patient Benefit Disclosure concept described above. Please contact us at your convenience.

Yours in Advocacy,



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Patients Rising is a national 501(c)(4) patient advocacy organization. Program purchase figures cited above are drawn from HRSA Office of Pharmacy Affairs covered entity purchase data for 2024 (total purchases of $81,437,279,413, of which approximately $70.1 billion was attributable to hospital covered entities) and from independent analysis of HRSA data placing 2025 purchases at approximately $100 billion.