NATIONAL HEALTH COUNCIL

August 28, 2026

The Honorable Bill Cassidy
Chairman
Committee on Health, Education, Labor, and Pensions
United State Senate
Washington, DC 20510

Dear Chairman Cassidy

Thank you for the opportunity to provide feedback on the discussion draft of the *340B Drug Pricing Integrity and Affordability for Patients Act*. The National Health Council (NHC) shares your goal of ensuring that the 340B program operates with integrity, transparency, and accountability. From the patient perspective, any changes to the 340B program should ultimately strengthen access to affordable medications and health care services for the people who need them most. At the same time, available evidence raises concerns that the benefits generated through the 340B program are not consistently reaching patients or translating into more affordable care[1]. The NHC supports thoughtful reforms that enhance program integrity and accountability while protecting patients from increased costs, disruptions in care, or reduced access to needed services.

The National Health Council (NHC) unites nearly 200 national organizations—including leading patient groups, research institutions, providers, caregivers, and businesses across the health care sector—to drive patient-centered health policy. Representing 200+ million Americans with chronic diseases and disabilities, the NHC strengthens its members' collective influence to expand access to quality, affordable, and equitable health care. The NHC fosters collaboration to shape policies that reflect the needs of patients. Learn more at: https://www.nationalhealthcouncil.org.

The 340B program is intended to support access to prescription drugs and health care services for vulnerable and low-income populations by providing eligible entities with significant discounts on prescription drugs. Many hospitals, community health centers, and other federal grantees rely on revenue made possible by the 340B program to maintain access to care and provide patients access to discounted medicines. While some 340B covered entities are subject to separate federal requirements to provide affordable care to vulnerable or low-income patients, such program benefit requirements are not applied uniformly across the 340B program. We recognize that Congress is seeking to address concerns regarding oversight, transparency, patient

[1] Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals | U.S. GAO

eligibility, contract pharmacies, and 340B program growth. These are legitimate policy questions. Reforms are needed to promote transparency into how 340B savings are reinvested to ensure that patient access to medications, specialty care, and related patient services are improved. At the same time, Congress should carefully structure reforms so that policy changes, including additional administrative requirements, do not unintentionally reduce access for patients. Reforms should also ensure that rural and underserved communities, individuals with disabilities and chronic conditions, and other marginalized groups benefit from proposed changes.

The NHC appreciates the discussion draft's focus on ensuring that the program benefits those it was intended to serve. Congress should continue to solicit — and address — patient input as Congress evaluates legislative changes that will influence implementation planning, reporting design, and ongoing program evaluation. Those most affected by policy changes who are often the last interest group to be considered should have a seat at the table.

Patient Principles for Evaluating 340B Reform

The patient community believes any 340B reform should be guided by five fundamental principles:

1. 340B savings should be transparent and demonstrably improve patient affordability, access, and/or services.
2. No patient should experience delays accessing prescribed medications because of 340B policy changes.
3. Patient privacy must be protected in reporting and data-sharing systems.
4. The program should be designed to serve the most underserved populations. Rural, specialty-care, rare disease, and medically underserved populations require special consideration.
5. Patients should have a role in providing insight into reforms to ensure that 340B savings go towards benefiting patients.

Patient Engagement

The 340B program is intended to support access to prescription drugs and health care services for vulnerable and low-income populations by providing eligible entities with significant discounts on prescription drugs. Since the inception of the program, patients have never had a role in influencing how the program achieves these objectives and the lack of transparency makes it difficult to determine how 340B savings go toward increasing access and affordability for patients.

The discussion draft provides the Secretary with the authority to promulgate regulations and guidance to implement 340B as needed. The NHC further recommends that an advisory group be established at HHS with significant patient representation to advise the Secretary on priorities and specifics of this regulation and guidance.

Patient Affordability

The NHC strongly supports provisions designed to ensure that 340B benefits reach patients directly. The discussion draft's focus on affordability and sliding-scale assistance will help patients experience measurable financial benefits from the program. Any program changes related to patient out-of-pocket (OOP) costs must consider how those costs are appropriate and scalable to patients based on their household means.

The NHC also encourages additions to the bill that address affordability beyond drug cost-sharing reductions. Patients face transportation costs, caregiving expenses, lost wages, diagnostic testing costs, and other financial burdens associated with illness and/or disability. The NHC encourages oversight and reporting requirements that demonstrate how 340B savings improve the overall affordability of and access to care, rather than focusing solely on prescription expenses.

Patient Definition

The 340B statute prohibits the diversion of 340B priced drugs to individuals who are not "patients" of a covered entity. However, the statute does not define "patient," and HRSA's 1996 guidance—intended to fill this gap—is overly broad. This has led to inconsistent application, program abuse, and disputes over eligibility without and clear benefit to patients while undermining program integrity. The NHC supports establishing a clear statutory definition of a 340B patient. This is a critical aspect of protecting the integrity of the program. The NHC encourages Congress to ensure that definitions of patient and referral guidelines are clear, actionable, and reflective of real, ongoing care relationship between the patient and the covered entity.

Rebate Model

Any method for how manufacturers and covered entities manage the financial exchange of 340B discounts, including a rebate model, must ensure that patients experience no treatment delays due to reimbursement disputes, rebate processing, or other financial issues. Implementation must be monitored by HHS and adjusted if access or affordability issues for patients arise.

Covered Entity Eligibility

The NHC urges Congress to update covered entity eligibility criteria to include new requirements that covered entities deliver at least baseline levels of charity and uncompensated care. Additionally, for 340B hospitals, we encourage Congress to establish a new outpatient payer mix metric layered on to current requirements that rely primarily on an inpatient metric. Together, these reforms will ensure eligibility is tied to both a hospital's level of charity care and the amount of outpatient care a hospital provides to underserved patients, because 340B is fundamentally an outpatient drug discount program.

Transparency and Reporting

The 340B program does not require that hospitals report how much revenue they generate from the program or how that revenue is used. The NHC supports increased and meaningful transparency regarding the use of 340B savings. Transparency on the use of 340B savings is critical for patients and advocates to help assure the appropriate use of program funds and understand the complex mechanisms behind 340B. The patient community needs access to information to understand how 340B savings are benefitting patients. Such transparency must also include data that is meaningful, understandable, and accurate.

Reporting requirements for covered entities to provide meaningful data to HHS must also be appropriate and reasonable and not add levels of bureaucracy that will detract from patient care. This is particularly true for grantees that already produce significant data and other information to grant makers.

Categories of reporting must have input from patients and other neutral parties to balance transparency, affordability, and access. Examples of meaningful, useful patient-centered data fields may include:

- Average and total reductions in patient out-of-pocket costs
- Average and total financial assistance provided
- Medication access programs
- Average and total transportation assistance
- Total funding on expansion of services in underserved communities
- Improvements in access to specialty care
- Health outcomes and adherence measures where appropriate

Data Sharing and Patient Privacy

The NHC supports appropriate data collection that protects program integrity and provides policymakers and stakeholders with reliable information to assess the 340B program. Standardized, reliable data systems can benefit all stakeholders and help support greater transparency and accountability.

The NHC also calls for strong data privacy protections. Any federal repository, clearinghouse, or data-sharing framework should minimize the collection of personally identifiable information and ensure that patient data is used for appropriate program purposes.

At the same time, data collection, transparency, and reporting requirements should be reasonable, appropriate tailored, and designed to avoid unnecessary administrative burden that could divert resources away from patient care or create barriers to patient access.

Audits and Oversight

The NHC supports robust oversight and accountability. Manufacturers' audits are an important tool in preventing duplicate discounts and drug diversion. However, Congress should further strengthen 340B program integrity audits such as those conducted by HRSA to ensure transparency and accountability. Also, privacy protections must be built in, and audits must be fair, transparent, consistent, and standardized.

Medical Debt Protections

Finally, the NHC recommends the addition of patient medical debt protections from patients at covered entities. Patient protection from medical debt when seeking care should be prioritized.

NHC is particularly concerned about the impact of medical debt and financial toxicity on patients and caregivers and believes these concerns should also be considered in any changes to the 340B program. NHC's recent *Managing Financial Toxicity: Patient Experience, Gaps, and Unmet Needs* report[2] found that rising cost sharing can contribute to medical debt, depleted savings, workforce disruption, delayed care, skipped provider visits, and medication rationing. The report also found that poorly coordinated or implemented affordability policies can have unintended consequences for patients, including medication affordability challenges, financial tradeoffs, delayed care, and medical debt.

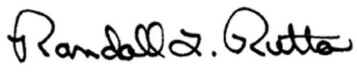
As Congress considers reforms to 340B, the NHC urges policymakers to evaluate how proposed changes may affect patients' total financial burden and ensure that reforms do not inadvertently increase out of pocket costs, contribute to medical debt, or reduce access to medications and other necessary care.

Conclusion

The National Health Council supports policies that lower costs paid by patients, improve transparency and accountability into the 340B program, preserve and improve access to innovative treatments, and ensure that patient perspectives remain central to policymaking.

Thank you for your attention to this critical issue. Please contact Kimberly Beer, Senior Vice President, Policy & External Affairs at kbeer@nhcouncil.org or 202-557-9146 with any questions or requests for additional information.

Sincerely,



Randall L. Rutta

[2] Managing Financial Toxicity Executive Summary

Chief Executive Officer