Catholic Health Association of the United States

August 26, 2026

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

Dear Chairman Cassidy,

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization representing more than 2,200 Catholic healthcare systems, hospitals, long-term care facilities, clinics and service providers, I am writing in response to your request for information on the 340B Drug Pricing Integrity and Affordability for Patients Act discussion draft. While we appreciate your attention to this critical program, we are very concerned that some of the policy proposals could undermine the 340B program and harm the communities served by 340B hospitals.

CHA represents the Catholic health ministry, the nation's largest nonprofit provider of healthcare services. In 2025, Catholic hospitals provided care to 1 in 7 patients, employed 750,000 people and recorded more than 5 million admissions, including 1 million Medicaid admissions. In Louisiana alone, our members employ nearly 17,000 people and include 14 acute care hospitals, 7 skilled nursing facilities, 53 clinics and 8 additional Catholic-sponsored services. Grounded in Catholic social teaching, which calls for the responsible use of resources, talents and institutions in service of the common good rather than institutional self-interest, Catholic healthcare prioritizes reaching people who are poor and vulnerable, uses financial and material resources wisely and transparently, treats the whole person rather than just their illness and ensures that our work benefits the broader community beyond hospital walls.

CHA and our members strongly support Section 340B of the Public Health Service Act because it advances our mission to serve people who are poor and vulnerable.

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Purpose of the 340B Program

Congress created the 340B Drug Pricing Program to help safety-net providers stretch limited federal resources and expand access to care for low-income and uninsured patients. Section 340B of the Public Health Service Act requires manufacturers that participate in Medicaid to sell covered outpatient drugs to eligible covered entities at or below a statutory ceiling price. For rural and safety-net hospitals, purchasing pharmaceuticals through the program is central to meeting patient and community needs, allowing them, in the statute's words, to "reach more eligible patients and provide more comprehensive services." The resulting discounts help these hospitals sustain and expand services that vulnerable populations might otherwise go without.

It is also worth noting that Section 340B places no burden on federal taxpayers: drug manufacturers finance these discounts as a condition of participating in Medicaid and Medicare Part B, and the program adds nothing to federal health spending. This structure is precisely what allows our ministry to redirect resources toward the patients who need them most.

Section 2 of Discussion Draft. Rebate Conditions

CHA shares your goal of ensuring that 340B savings benefit the patients and communities the program was created to serve, and we recognize the significant work reflected in this discussion draft. We are concerned, however, that Section 2 as currently drafted could create significant financial and operational challenges for Catholic hospitals and health systems serving rural and vulnerable populations.

Section 2 would permit manufacturers to elect a rebate mechanism under which covered entities would pay a non-ceiling acquisition price and seek reimbursement of the 340B discount after the drug is dispensed. Although the draft requires manufacturers to pay undisputed rebate claims within 10 days of receiving a valid request, the model would still increase hospitals' working-capital needs by requiring them to finance the higher acquisition cost before receiving the rebate. This is particularly concerning for nonprofit hospitals operating on narrow margins. Furthermore, while the draft imposes strict, penalty-backed compliance guidelines on hospitals, it provides no comparable deadline enforcement or consequence structure for drug companies.

The proposed mechanisms would also add administrative complexity to already burdened hospital systems. Implementation could require new systems and processes for standardized claims submissions, patient identification, inventory controls, attestations, reconciliation, and resolution of disputed claims, as well as additional compliance and legal costs. Many rural and safety-net members would have difficulty absorbing these costs without diverting resources from patient care.

CHA is also concerned about the administrative consequences of allowing each drug manufacturer to choose among an upfront discount, a claims-data repository or a rebate. Because a single Catholic health system may purchase from dozens of manufacturers, our members could be forced to operate many different compliance workflows at once, each with its own claims, attestation and reconciliation requirements.

Section 2 would allow a covered entity to choose its own discount mechanism but only if it commits to passing along the full value of every discount to the individual patient, leaving only a nominal dispensing fee for the covered entity to retain. This proposal contradicts the purpose and structure of the statute and implies individual patients do not currently benefit from the 340B savings. In fact, patients are directly served because the savings enable hospitals to fund clinics, serve rural communities through mobile health units, support counseling programs and provide myriad other services that exist only because 340B savings made it financially possible. Tying a covered entity's choice of discount mechanism to full pass-through would strip away the very flexibility that allows our ministry to meet the whole range of needs in the communities we serve, and we ask the Committee to decouple this election from any pass-through mandate.

Again, CHA asks the Committee to look closely at how enforcement authority is distributed under Section 2. As drafted, manufacturers retain significant discretion over whether and how quickly a covered entity actually receives the discount it is owed, while covered entities have comparatively few tools to compel a manufacturer's compliance or seek a remedy when a manufacturer falls short. Effective stewardship requires accountability running in both directions: manufacturers who fail to honor their statutory obligations should face consequences at least as meaningful as those covered entities face, audits should be scoped narrowly to the specific concern raised rather than serving as an open-ended inquiry, and covered entities should have a genuine, federally

supervised process for resolving disputes rather than relying on a manufacturer's own good faith.

CHA urges the Committee to revise Section 2 in line with the concerns outlined above.

Section 4 of Discussion Draft. Additional Definitions

CHA is concerned about Section 4's new statutory definition of "patient," which would require, among other things, that an individual have received an outpatient healthcare service from the covered entity within the preceding two years, maintain a documented patient relationship with the entity and receive the prescription or order from a practitioner as a result of that service or a referral.

While CHA supports clear, verifiable standards that address genuine program abuse, the proposed definition would impose a rigid two-year lookback period and additional documentation requirements that may not reflect how many patients access care. Patients referred to affiliated specialists, individuals receiving care through multi-site or telehealth arrangements, and low-income or transient patients whose interactions with a health system are episodic could be affected. As drafted, Section 4 could exclude patients with legitimate ongoing relationships with covered entities while imposing significant new patient-level compliance burdens.

CHA asks the Committee to preserve HRSA's existing patient definition rather than replace it with a new statutory standard. HRSA's guidance, in place and unchanged since 1996, gives the agency a clear and enforceable standard for program integrity while remaining flexible enough to keep pace with how care delivery evolves. Many of our systems now coordinate care across a hospital, its affiliated specialists, and telehealth or remote monitoring platforms that barely existed in their current form a few years ago, and patients managing chronic conditions may touch several parts of that network over time rather than through one discrete visit. HRSA's current definition has absorbed changes of exactly this kind before, most notably the rise of telehealth, without needing Congress to intervene. A narrower, encounter-specific definition written into statute would not offer that same durability. Doing so risks excluding legitimate patients whose care does not map neatly onto a single visit, and codifying a rigid standard now could force Congress to revisit and rewrite it repeatedly as care delivery continues to change.

CHA urges that the current HRSA standard remains in place.

Section 5 of Discussion Draft. Contract Pharmacies

As shared with this Committee in October 2025, arrangements between 340B covered entities and community and specialty pharmacies, recognized by HRSA since 1996, have long helped patients, particularly those in rural areas, access medications without traveling long distances. These arrangements remain critical to ensuring that patients can get the medications they need close to home, and we appreciate the opportunity to work with Congress to strengthen protections for them in federal law, particularly in light of ongoing challenges involving manufacturer restrictions on contract pharmacy access. The proposed five-pharmacy limit for certain hospital covered entities, together with the proposed service-area requirement, could leave patients in large or multi-county rural areas without a nearby pharmacy able to serve them. Additionally, in large, multi-county rural territories, where a single hospital may be the only inpatient provider for a wide radius, patients often have no nearby pharmacy able to stock the specialty medication they need, and the closest one that can is frequently well outside a narrowly drawn service area. CHA is concerned that Section 5's pharmacy cap and service-area rules would compound this problem.

CHA is also concerned about patients losing access to a pharmacy under the draft's approach to ending a pharmacy relationship after a fixed number of violations, regardless of severity. Paperwork errors should not carry the same consequence as an actual diversion violation, and covered entities and their pharmacy partners should have a genuine chance to correct a compliance issue before patients lose access to a pharmacy they may have relied on for years.

CHA requests the elimination of a statutory numerical cap or service-area limitation as well as clarification of protections for contract pharmacy arrangements in the federal 340B statute.

Section 6 of Discussion Draft. Transparency

CHA appreciates the Chairman’s interest in ensuring that the 340B program operates with strong accountability, and we share the goal of demonstrating that program savings benefit the patients and communities the program was designed to serve. We are

concerned, however, that Section 6 would impose new reporting requirements that could be duplicative and costly without providing commensurate value to patients or policymakers. Covered entities already operate under substantial oversight, including annual recertification and HRSA audits.

CHA also has specific concerns about the new financial metric Section 6 would require covered entities to publish, commonly described as a 340B margin. Comparing what a hospital collects for a 340B drug against only its acquisition cost, without accounting for the substantial infrastructure, staffing and compliance costs of actually operating a 340B program, would produce a figure that looks far more favorable than the hospital's true financial picture. Because covered entities already file detailed cost and community benefit information annually through Medicare cost reports and IRS Form 990, CHA urges Congress to build any new transparency requirement on that existing foundation rather than introduce a new metric that is misleading.

CHA asks that any new transparency measures be designed to minimize duplication with data hospitals already report elsewhere.

Section 7 of Discussion Draft. Ensuring Affordability

CHA is concerned that Section 7's mandatory sliding fee scale, while well-intentioned, would steer every covered entity toward a single, federally defined method of extending affordability rather than letting each system tailor its approach to their patients' needs. Our members already lower costs in many ways, some through discounted prescriptions at the point of sale, others through charity care policies, free clinics, transportation assistance or programs aimed at conditions especially common in their communities. A uniform sliding fee scale, certified and enforced at the federal level, could force systems to divert staff and resources away from these existing, locally built efforts to stand up a new federally prescribed program alongside them.

CHA asks the Committee to preserve covered entities' discretion to structure affordability assistance in the way that best fits the community each hospital or clinic serves.

Section 8 of Discussion Draft. Hospital Child Sites

CHA is concerned that Section 8, as drafted, would impose additional registration requirements that do not fully reflect the operational realities of many Catholic health systems. Although the proposal incorporates existing Medicare provider-based standards, it would also require a child site to be wholly owned by the covered entity and satisfy additional charity-care, Medicaid/CHIP revenue and health-professional-shortage-area criteria. These requirements could exclude facilities operated through other affiliated governance structures that function as integrated parts of a Catholic health system's charitable mission. They could also disadvantage patients being served at facilities with different state Medicaid policies or patient demographics.

CHA also notes that these eligibility hurdles arrive as more care, by design, moves out of the inpatient setting and into outpatient clinics, including many of the specialty and chronic-disease clinics our systems rely on to reach patients efficiently. A newly opened child site typically will not show up on a covered entity's Medicare cost report right away, simply because of how cost-reporting cycles and hospital fiscal years line up, even when the site is already fully integrated into the sponsoring hospital's operations and actively serving patients. CHA asks that eligibility standards account for this ordinary lag rather than treat a new site's absence from a not-yet-filed cost report as evidence that it does not belong in the program.

CHA urges that Section 8 instead recognize child sites operated through other appropriate affiliated structures, in addition to wholly owned facilities, align compliance requirements with existing Medicare provider-based standards, and reconsider the proposed charity-care and Medicaid/CHIP revenue benchmarks to account for state and community variation. We also ask that good-faith compliance efforts are not subject to automatic audit triggers or compounded-interest liability.

Conclusion

Because stewardship of resources and care for people who are poor and vulnerable are core to our mission, CHA members voluntarily adopted the AHA Good Stewardship Principles, publicly disclosing 340B savings and publishing annual accounts describing how those savings support charity care, expanded services and care for uninsured and

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underinsured patients. CHA urges preserving the flexibility that has enabled Catholic health systems to extend care into underserved communities for decades and encourages Congress to focus new integrity measures on closing genuine gaps without unnecessarily constraining providers demonstrating their commitment to patients and communities. Thank you for considering our recommendations.

Sincerely,

Lucas Swanepoel, JD
Vice President, Public Policy and Advocacy