



AMERICA'S ESSENTIAL HOSPITALS

Sept. 30, 2026

The Honorable Tammy Baldwin
United States Senate
141 Hart Senate Office Building
Washington, DC 20510

The Honorable John Boozman
United States Senate
555 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
170 Russell Senate Office Building
Washington, DC 20510

The Honorable John Hickenlooper
United States Senate
316 Hart Senate Office Building
Washington, DC 20510

The Honorable Tim Kaine
United States Senate
231 Russell Senate Office Building
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
521 Dirksen Senate Office Building
Washington, DC 20510

Dear Sens. Baldwin, Boozman, Capito, Hickenlooper, Kaine, and Moran:

America's Essential Hospitals appreciates the Senate 340B Working Group's continued bipartisan leadership to protect and strengthen the 340B Drug Pricing Program and its intentional engagement with stakeholders before reintroduction of the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B (SUSTAIN 340B) Act. We are grateful for this opportunity to provide additional feedback on the bill, following our initial [response to the discussion draft in the 118th Congress](#).

America's Essential Hospitals represents hospitals committed to providing high-quality care to all patients, including those who face significant financial and social barriers to health care access. Essential hospitals are the backbone of the nation's health care safety net, providing disproportionate amounts of un- and under-compensated care while operating on substantially narrower margins than other hospitals.¹ Although essential hospitals account for just 6% of U.S. hospitals, they provide 29% of all charity care and include 16% of neonatal intensive care unit beds, 21% of psychiatric beds, 31% of level I trauma centers, and 43% of burn care beds.² 340B savings are critical to essential hospitals' ability to provide a robust infrastructure of care for the communities they serve.

America's Essential Hospitals appreciates several updates to the SUSTAIN 340B Act that reflect concerns the association raised via the formal request for information (RFI) response last

¹ Miu R, Kelly K, Nelb R. *Essential Data 2025: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2023 Annual Member Characteristics Survey*. America's Essential Hospitals. November 2025. essentialdata.info. Accessed September 15, 2026.

² Ibid.

Congress and in ongoing conversations. To that end, **one of the most impactful updates is the reiteration of Congress’ original intent and an associated requirement that 340B discounts be provided at the point of purchase** to providers serving disproportionate numbers of low-income, underserved, and medically vulnerable patients. This provision codifying point-of-purchase discounts comes at a critical time, as the Health Resources and Services Administration (HRSA) announced a revised 340B Rebate Model Pilot Program to begin on Jan. 1, 2027. This announcement came despite the [association’s response to HRSA’s RFI outlining how such models would harm patients](#) and incur more than \$1.5 billion in annual additional direct administrative costs for 340B hospitals.³

We also appreciate the bill’s protections against manufacturer restrictions on contract pharmacy arrangements, including explicit prohibitions on manufacturers refusing to offer or deliver discounted drugs and conditioning access to 340B pricing on the submission of claims data. Given manufacturers’ recent activity and pharmaceutical manufacturer Eli Lilly’s suspension of lawful 340B discounts from some covered entities, including at least one association member, this provision is clearly a necessary protection for the program and its beneficiaries.⁴ Further, **preserving use of contract pharmacies without numeric or geographic limitations will protect access to care**, particularly in underserved communities, and we appreciate the working group’s refusal to arbitrarily limit contract pharmacy access.

We likewise appreciate the thoughtfulness of the proposed independent, third-party clearinghouse as a means of preventing statutory duplicate discounts. Some critical issues remain, including requiring the submission of claims data directly to manufacturers and not permitting hospitals to submit retrospectively. However, the overall approach is one that clearly demonstrates the senators’ careful consideration of comments from a broad coalition of stakeholders, including America’s Essential Hospitals.

Despite positive adjustments to the SUSTAIN 340B Act, some of which are highlighted above, we remain extremely concerned that certain provisions in the discussion draft will inadvertently restrict the scope of the program for the patients who need it most. We are particularly worried about provisions that would create patient definition restrictions and related restrictions incorporated into child site eligibility, delay child site eligibility, and make HRSA the arbiter of private nonprofit hospital contracts with state or local government. As the working group continues deliberating, we urge lawmakers to ensure that new transparency and integrity requirements strengthen program oversight without limiting patient access or imposing burdens that disproportionately affect providers serving the nation’s most vulnerable communities.

Below, we offer specific feedback on key sections:

Sec. 3 Contract Pharmacy

America’s Essential Hospitals appreciates the working group’s decision to preserve and strengthen protections against unlawful manufacturer restrictions on contract pharmacy arrangements. We are particularly grateful that the working group did not adopt arbitrary caps

³ DeCubellis J. Letter to Thomas Engels on April 20, 2026. https://essentialhospitals.org/wp-content/uploads/2026/04/Americas-Essential-Hospitals_340B-RFI.pdf. Accessed Aug. 10, 2026.

⁴ DeCubellis J. Letter to Thomas Engels on June 18, 2026. https://essentialhospitals.org/wp-content/uploads/2026/06/Americas-Essential-Hospitals_June-18-Eli-Lilly-Claims-Response.pdf. Accessed Sept. 15, 2026.

on the geographic location or number of contract pharmacy relationships. Essential hospitals operate in unique geographic and clinical environments, and patient access needs vary significantly across settings. The revised approach, which rightfully moves away from previously contemplated broad restrictions, better recognizes these realities.

We strongly support the provisions prohibiting manufacturers from:

- Refusing to provide the 340B ceiling price on covered outpatient drugs
- Refusing to deliver discounted drugs to covered entities and associated contract pharmacies
- Imposing discriminatory distribution conditions
- Requiring covered entities to submit claims data directly to manufacturers

We also appreciate the reduction of the proposed record-retention period from the prior working draft to three years. Essential hospitals serve large volumes of complex patients, and lengthy record retention policies will increase operational complexity and burden. **We also appreciate that manufacturers would have to demonstrate credible allegations of noncompliance and engage in good faith outreach to the covered entity prior to proceeding with an audit.**

However, we remain concerned that several requirements could discourage or disproportionately burden covered entities that are more invested in patient access. One example is the provision allowing more frequent audits on covered entities that use a “high number” of contract pharmacies. While this provision explicitly requires the frequency of audits not to be “overly burdensome to the covered entities,” we remain concerned that it could become so despite good intentions. As a point of clarification, would it be the Secretary conducting the increased audits on covered entities with a high number of contract pharmacies, or would the Secretary’s role simply be to develop the process? Essential hospitals maintain a larger number of contract and specialty pharmacy arrangements for good reasons, including to facilitate patient access to medication. Moreover, existing pharmacy deserts often require essential hospitals to maintain a larger number of contract relationships than other covered entities to improve patient outcomes.

We encourage the working group to ensure that any audit thresholds are clear—but not arbitrary—and flexible enough to account for differences in covered entity patient population. We also recommend greater flexibility for covered entities to maintain contract pharmacy relationships when they can demonstrate that the arrangement is necessary for improved patient access, defined more broadly than simply for emergency or contingency use, even if not active over the prior 12 months. Finally, since prescriptions provided through contract pharmacies are already subject to covered entity audits, lawmakers should ensure that any provisions dealing with contract pharmacies in the SUSTAIN Act are neither duplicative nor overly burdensome.

Sec. 4 Patient Definition

While we appreciate the working group’s continued interest in promoting accountability and program integrity, **we continue to have serious concerns with codifying a prescriptive definition of “patient” that could unintentionally disrupt access to care.**

The updated draft defines a patient by receipt of an outpatient health care service within the preceding two years, among other requirements. It also excludes individuals whose only service consists of drug administration or an infusion, services that occur in the outpatient hospital setting and require professional intervention and monitoring.

America's Essential Hospitals recognizes the effort to provide greater statutory clarity, but the proposed definition would still recreate many of the problems associated with HRSA's withdrawn 2015 "mega-guidance." The proposed definition risks creating distinctions between individuals who are clearly patients of an essential hospital in other contexts, but who would not be considered a patient for purposes of 340B.

Patients of essential hospitals may receive care across hospitals, specialty clinics, ambulatory sites, emergency departments, and other settings as part of a coordinated system of care. The complexity of essential hospital systems makes a rigid statutory definition particularly problematic. The definition of patient should not penalize hospitals for structuring care around clinical need and patient access, and the working group should not promote policy which may encourage suboptimal care directives.

We are also concerned about the proposed audit and enforcement regime associated with the definition, including mandatory recurring audits for all covered entities and more frequent audits for "high risk and high-volume" covered entities. Additionally, the penalties for unintentional noncompliance with patient definition are harsh and disproportionate, as covered entities could face exclusion from the 340B program for up to three years and civil monetary penalties.

Moreover, some manufacturers are now proposing their own restrictive definitions of patient, with a clear goal of reducing the drugs for which they are mandated to provide discounts. Such actions call for greater protection for covered entities.

We urge the working group to retain flexibility for covered entities to determine patient relationships consistent with their existing clinical, legal, and medical-record requirements rather than establishing a prescriptive standard.

Sec. 5 Rebate Model Pilot Program Sunset

We support the proposal to sunset the rebate model pilot. We have shared our extensive concern about the impact of denying up-front discounts and the harm to patients resulting from limiting access to the full range of services that essential hospitals provide. The financial burden associated with a rebate model would disproportionately harm essential hospitals, which account for 9% of 340B covered entities but would bear approximately 15% of the added cost.⁵ Thus, we agree that HRSA should not be permitted to operate a rebate model program.

We urge you, however, to drop the allowance of a rebate model for *any* period and to instead require that the discount continue to be provided at the point of purchase, as was eloquently stated in the Sec. 2 Sense of Congress. Additionally, implementation of the Medicare drug inflation rebate program has not been prevented without a rebate model.

⁵ DeCubellis J. Letter to Thomas Engels on July 13, 2026. <https://essentialhospitals.org/wp-content/uploads/2026/07/July-2026-Rebate-ICR-Response.pdf>. Accessed Sept. 20, 2026.

We support the working group's proposal to sunset the rebate model pilot, but urge that it not be permitted for any period due to the substantial and disproportionate impacts on essential hospitals.

Sec. 6 Child Sites

America's Essential Hospitals appreciates several improvements in the updated child site provisions, including the explicit use of the Medicare provider-based framework as a basis for certain eligibility determinations. **However, we strongly oppose imposing any child site eligibility requirements, particularly those that overlap with concepts of patient definition that will reduce patient access to care.**

For instance, the discussion draft requirement that “the child site provides a clinically meaningful range of services, as determined by the services that providers employed or contracted by the child site are qualified to deliver” is arbitrary and would eliminate access to discounts in a part of a hospital that, for reasons having to do with patient care, community need, and access, are focused on specialties.

Often 340B discounts make it financially feasible for essential hospitals to open or maintain facilities in specialty areas of shortage and for populations not served by other providers. For example, our members have opened infusion centers in rural, mountainous areas that allow patients to stay closer to home for treatment. Likewise, our members have opened clinics in underserved urban areas where transportation can be just as much of a barrier for low-income patients. We have found that patients seeking oncology care from our member hospitals tend to be both poorer and sicker and, as one illustration, might not otherwise have access to the care they need without the option for specialty care via a child site.⁶

We also urge the working group to reconsider the three-year delay of eligibility for child sites or, at the very least, provide more protection for essential hospitals under the hardship exemption. Essential hospitals acquire or build new child sites to address unmet needs, provide accessible care, and prevent patients from needing to show up at the emergency room with more severe illnesses. Giving full discretion to the Secretary and requiring case-by-case determination of a new child site's eligibility could render it infeasible to operate the facility at all, not merely delay access to discounts.

Finally, while we support building on the Medicare provider-based framework, we urge the working group to reference those rules rather than defining them just for 340B purposes to avoid diverging sets of requirements as Medicare rules evolve.

We urge the working group to avoid requirements that tie eligibility to rigid, narrowly defined specifications that fail to reflect how essential hospitals deliver care in underserved communities.

Sec. 7 Transparency

America's Essential Hospitals supports appropriate transparency that allows Congress and HRSA to understand the 340B program, and that ensures accountability among all program participants. It is important to note, though, that reporting should never be used to restrict permissible uses of 340B savings.

⁶ Siegel B. Letter to Sens. Thune, Baldwin, Stabenow, Moran, Moore Capito, and Cardin on April 1, 2024. <https://essentialhospitals.org/wp-content/uploads/2024/04/SUSTAIN-340B-RFI-Response-2024.pdf>. Accessed Sept. 5, 2026.

We remain concerned about the breadth of the proposed annual reporting requirements and the lack of alignment with hospital operations and reporting for other purposes.

The draft requires covered entities to report extensive information regarding utilization, insurance coverage, charity care, under-reimbursed care, contract pharmacies, third-party administrators, estimated discounts, and other operational information; these requirements go far beyond typical data reporting by requiring narratives and attestations from covered entities.

We also encourage lawmakers to consider the burden associated with certain requests, including separate reporting for each child site and contract pharmacy, as well as reporting by payer. Requiring this level of detail could impose substantial incremental burden on covered entities without a commensurate benefit to policymakers. Perhaps certain information could be reported at the hospital level and still provide sufficient meaningful information about the 340B program.

The association continues to recommend that reporting requirements be limited to information relevant to HRSA's oversight and should not include requests for data that have already been reported to the federal government for other reasons. For example, information otherwise available from the cost report or other 340B-specific data is collected by HRSA and available in the Office of Pharmacy Affairs Information System and need not be duplicated. Requiring hospitals to create new 340B-specific datasets where comparable information already exists creates administrative costs without necessarily improving program integrity.

Of note, the legislation requests information about percentage of patients who reside in a health professional shortage area (HPSA), medically underserved area (MUA), and who reside in or are part of a medically underserved population (MUP); however, these are not the best proxies for the financial demographics or care access challenges of patients essential hospitals serve. Essential hospitals often serve large and diverse patient populations, sometimes in urban areas excluded from the above definitions. In fact, we have found that the presence of an essential hospital and its associated outpatient clinics can be the reason that a particular area is not classified as a HPSA or MUA. This is a benefit to that community and should not be considered a negative metric with respect to any 340B reporting requirements.

We therefore recommend that Congress simply use existing federal reporting sources whenever possible. We also continue to urge parity in transparency requirements. Covered entities should not be subject to such extensive reporting while manufacturers, among other involved parties, participating in the 340B ecosystem face comparatively limited transparency requirements. Congress should exact comparable information from manufacturers where necessary to assess program compliance and integrity.

Sec. 8 Enhancing Program Integrity

The association strongly supports program integrity, as essential hospitals have a significant interest in ensuring that 340B is administered appropriately and that bad actors do not undermine the program.

We support the updated draft's efforts to establish consistent audit standards and publicly available audit protocols. We also support its authorization for HRSA to audit both covered entities *and manufacturers*, specifically the ability to audit manufacturers for inaccurate ceiling prices.

Of note, audit provisions should be implemented in a manner that is proportional to risk and does not impose duplicative or unnecessary audits for covered entities that are already subject to extensive HRSA and manufacturer audits.

We are highly concerned with the consequences of the audit section, as it would limit HRSA's ability to determine appropriate corrective actions. Any corrective action should be flexible, reasonable, and proportionate to the finding, rather than punitive. America's Essential Hospitals supports accountability and oversight, but corrective actions should not be overly impacted by manufacturers who stand to gain from limiting HRSA's authority.

We are also concerned with the proposal that HRSA conduct annual recertification of contracts involving private nonprofit hospitals. Since these contracts are currently reviewed as part of the existing audit process and may be addressed through recertification, requiring annual HRSA review would create a burden for both HRSA and covered entities. Additionally, it would involve assessments of contractual matters that are outside HRSA's traditional expertise. HRSA should not be made to determine the legal validity or binding nature of these contracts between private nonprofit hospitals and state or local governments.

Relatedly, the legislation is written in such a way that technicalities could create noncompliance. For example, if a contracting entity for a hospital has a different legal name or different components of one entity have different legal names, then the seemingly simple requirement that there be a name clearly listed could result in categorical noncompliance. Things like this should not, in themselves, result in noncompliance when the substantive requirements of the 340B program have been satisfied.

Finally, there should be reasonable opportunity to bring contracts into compliance with any new requirements. Also, it is possible that with many contracts, there could be significant delay in review, which should not prevent 340B purchases in the interim.

We recommend that HRSA prioritize audits based on objective risk factors and avoid duplicative requests for information already available to the agency. Additionally, HRSA should not be put in the position of annually recertifying contracts between private nonprofit hospitals and state or local governments.

Sec. 9 Preventing Duplicate Discounts

Essential hospitals long have supported efforts to prevent statutory duplicate discounts. We appreciate the legislation's recognition that preventing such duplicate discounts requires coordination among covered entities, manufacturers, states, payers, and other participants.

We tentatively support a clearinghouse model operated by, as outlined in the bill, an independent, third-party organization. However, we still have serious concerns with the clearinghouse as proposed in the draft legislation. Of particular concern is that the data submitted to the clearinghouse would be disseminated to outside parties, including manufacturers, for them to rectify duplicate discounts. That process defies the precise intent behind a clearinghouse: that the third-party administrator would itself rectify duplicate discount and diversion issues after collecting the data. The approach of restricting permissible uses of the data by manufacturers and pharmacy benefit managers (PBMs) is insufficient to avoid improper use in the first place.

Moreover, claims-level data collection should be narrowly tailored to the statutory duplicate-discount problem. The proposed clearinghouse requires the submission of not only Medicaid claims data and Medicare claims for drugs subject to the Medicare Drug Price Negotiation Program but also broader claims data from Medicare, the Children’s Health Insurance Program, and commercial health plans. Congress should avoid creating a system that requires covered entities to transmit significantly more information than is necessary to prevent duplicate discounts.

Furthermore, the intent of the clearinghouse should not extend to compliance with the prohibition on diversion to nonpatients. Certainly, manufacturers should not be the ones to make such a determination, as seemingly anticipated by the section (f) definition of the proper use of data by manufacturers to include only preventing duplicate discounts and diversion. The federal government is already in litigation with a manufacturer seeking to implement its own patient definition. Moreover, the determination of patient status in health systems with various points of entry across the spectrum of care can require a second level inquiry to which HRSA is better suited through its audit processes.

The draft would also require claims level data to be provided by hospitals, rather than aggregate retrospective data, unless the covered entity meets a hardship exemption as determined by the Secretary. Permission to submit aggregate retrospective data should be granted for all essential hospitals, due to their mission and patient mix, without needing to seek permission via a hardship exemption.

We strongly urge Congress to preserve the ability of all covered entities to use retrospective identification of 340B claims, not just those with the “lowest decile of patient volume.” Essential hospitals operate in diverse environments and maintain large, complex drug inventories, making a prospective claims methodology operationally burdensome to the point of being infeasible.

Sec. 10 Patient Financial Assistance

America’s Essential Hospitals supports efforts to ensure that patients understand the financial assistance available to them and that covered entities communicate financial assistance policies clearly.

In fact, essential hospitals already operate comprehensive financial assistance programs that reflect their communities, patient populations, state requirements, and broader charity-care obligations. These obligations apply to their child sites, which are parts of the hospital covered entity. Drugs administered as part of those hospital services are part of that financial assistance, and many hospitals also run financial assistance programs for retail drugs from their in-house pharmacies. Congress should not also impose a single 340B-specific financial assistance model that could conflict with existing policies or inadvertently limit hospitals’ ability to tailor assistance to patient circumstances. For instance, an existing law, passed as part of the Affordable Care Act, renders pieces of this section duplicative and potentially confusing for patients wherein tax-exempt hospital organizations must establish a written financial assistance policy and post it in a “conspicuous public display”.⁷ Lawmakers should carefully avoid anything that could be duplicative, especially when it could add to confusion for the patients that Sec. 10 intends to support.

⁷ 26 U.S.C. § 501(r)(4); Treas. Reg. § 1.501(r)-4

It remains operationally challenging for hospitals to provide discounts when patients present at contract pharmacies. Our members are interested in working with the agency to develop implementable approaches, but losing access to 340B pricing would ultimately limit, not expand, patient access. We agree that drug affordability is a serious problem and urge Congress to work towards solutions that will arrest the outrageous growth in drug pricing, without hamstringing 340B.

We therefore recommend that the legislation:

- Preserve flexibility for covered entities to design financial assistance policies appropriate to their patient populations
- Avoid imposing a mandatory sliding fee scale for 340B drugs
- Allow existing financial assistance policies that satisfy applicable federal requirements to serve as the basis for compliance
- Avoid duplicative reporting where information is already publicly available (as further discussed in the transparency section above)

We appreciate the inclusion of a GAO study examining the effect of these requirements on patient access, and we urge Congress to require that analysis before imposing prescriptive requirements that could have unintended consequences.

Sec. 12 User Fee Program

The association recognizes the importance of providing HRSA with adequate resources to administer and oversee the 340B program. We support sufficient federal funding for program integrity, technology, oversight, and enforcement; however, we remain concerned about financing those activities through a mandatory user fee assessed on the very covered entities that the program is designed to support.

In addition to some congressionally appropriated funds, the updated draft establishes a \$50 million annual user fee beginning in fiscal year 2031, with the amount thereafter adjusted for inflation, and allocates each covered entity's share based on its proportion of covered outpatient drug prescriptions. Though thoughtful in theory, this will not be workable in reality for essential hospitals.

Imposing any additional mandatory fee on providers that rely on 340B to maintain access to care would divert resources away from patient care to the federal government. In addition, imposing higher fees on entities receiving more 340B drugs could result in diverting more resources from the providers serving the neediest populations. We continue to recommend that Congress directly provide adequate appropriations to HRSA rather than rely on a user fee.

We appreciate the draft's explicit "supplement not supplant" language and the requirement for HHS' Inspector General to oversee the fee program, but we continue to believe that a user fee is a poor replacement for congressional appropriation.

Sec. 13 Studies and Reports

America's Essential Hospitals supports thoughtful study of issues affecting the 340B program.

We recommend that any studies or reports required by Congress be designed to evaluate how proposed policies affect patient access, particularly for safety net providers and their communities.

We also encourage Congress to consider studies examining the impact of manufacturer restrictions, payer and PBM practices, and other third-party policies that may reduce the benefit of 340B to covered entities. Specifically, we would be interested in any study that could investigate manufacturer malfeasance in 340B.

Finally, studies should consider the administrative and financial costs imposed on covered entities when evaluating the effectiveness of new program requirements.

Studies and reports could provide great clarity around 340B for lawmakers and stakeholders; special evaluation of essential hospitals and their communities should be given.

America's Essential Hospitals appreciates the opportunity to provide these comments. If you have questions, please contact Jason Pray, vice president of legislative affairs, at 202-412-2491 or jpray@essentialhospitals.org.

Sincerely,

Jennifer DeCubellis
President and CEO
America's Essential Hospitals