National Rural Health Association

August 28, 2026

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

Dear Chairman Cassidy,

The National Rural Health Association (NRHA) appreciates the opportunity to submit comments on the discussion draft of the "340B Drug Pricing Integrity and Affordability for Patients Act." NRHA commends the Committee for its continued attention to the 340B Drug Pricing Program, which remains a lifeline for rural safety-net providers operating on thin margins and stretching scarce federal resources to serve their communities. We welcome the Committee's stated interest in program integrity and transparency, and we offer the following comments to help ensure that these goals are achieved without disproportionately harming the rural covered entities the program was designed to support.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

Background

Of the over 4,000 hospitals in the US in 2023, the majority (57%) participated in the 340B program.[1] Of participating hospitals, 41% were rural hospitals, most of which were critical access hospitals (88%), with 8% qualifying under Disproportionate Share Hospital (DSH) and 4% as Sole Community Hospitals (SCH).[2] Note, less than 1% of hospitals located in a rural area qualified under the Rural Referral Center (RRC) status.[3] In the same year, rural 340B hospital Medicare drug claims made up less than 3% of total 340B hospital Medicare drug claims.[4] Rural 340B hospitals were more likely to offer certain long-term services in addition to acute care, such as skilled nursing facility swing beds. Rural hospitals participating in 340B treat a different patient mix and face different financial pressures compared to non-rural hospitals. Rural 340B hospitals are more likely to serve rural, older, and dual-eligible patients located in a rural area than their non-rural 340B hospital counterparts. Specifically, 80% of the patients treated by rural 340B hospitals reside in a rural area whereas non rural 340B hospitals treat only 14% rural residents.

[1] The National Grange; Avalere Health. *Analysis of 340B Program Impact on Rural Hospitals.* February 6, 2026. Accessed August 28, 2026. Analysis-of-340B-Program-Impact-on-Rural-Hospitals-1.pdf

[2] Id.

[3] Id.

[4] In 2023, rural hospitals had 128,043 340B drug claims, compared to over 4.5 million non-rural hospital 340B drug claims.

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Since 2010, 206 rural hospitals have closed or converted to a model that excludes inpatient care, and 41.2 percent of rural hospitals nationally are currently operating at a financial loss, a figure that rises to 52.2 percent in states that have not expanded Medicaid.[5] An additional 417 rural hospitals are presently vulnerable to closure.[6] Rural hospitals face higher facility costs, more uncompensated care and bad debt, and lower operating margins than non-rural hospitals. In 2023, rural 340B hospitals had notably higher non-reimbursed and uncompensated care metrics compared to non-rural 340B hospitals, ($4,981 in rural vs. $2,965 in non-rural).[7] Further, rural 340B hospital non-reimbursed bad debt ($1,656) per discharge was over four times higher than non-rural ($406).[8] For rural hospitals operating with thin financial margins, 340B program savings have become an essential source of financial stability that supports access to such as obstetrics, behavioral health, medication access programs, and other high-need but low-margin programs. As rural hospitals continue to face workforce shortages, service line reductions, and increasing healthcare disparities, concerns have emerged that weakening or eliminating 340B program support could further threaten access to critical services.

NRHA supports the discussion draft's underlying goals of program integrity and transparency, and several provisions align well with NRHA's long-standing 340B principles. However, other provisions, particularly the new limitations on contract pharmacy arrangements and the compliance burdens imposed by the patient definition, transparency, and affordability provisions, would disproportionately harm rural covered entities that are least equipped to absorb new administrative costs. NRHA offers the following section-by-section comments and urges the Committee to consider the amendments below before advancing this discussion draft.

Section 2. Rebate Conditions

NRHA is broadly opposed to a rebate model within the 340B program and would urge Congress to forgo a statutory rebate framework altogether. NRHA is concerned that the approach shifts significant financial risk from manufacturers to safety-net providers, creating cash-flow challenges, new administrative burdens, and uncertainty regarding the timing and accuracy of rebate payments. Providers have warned that rebate models effectively force rural hospitals and health centers to serve as interest-free financiers for pharmaceutical manufacturers while diverting scarce resources away from patient care. In fact, recent analyses have estimated that proposed rebate models would force hospitals to carry significant upfront financial burdens which could lead to reducing staff, halt service expansion, and cut access to discounted medications to vulnerable populations.[9] Rural providers operating on thin margins are particularly vulnerable to delayed or denied rebates, increased compliance costs, and potential service reductions.

In HRSA's response to public comments on the 340B Rebate Model Pilot Program, the agency declined to exempt any category of covered entity from rebate requirements, reasoning that carve-outs would introduce selection bias. Because HRSA has shown it will not grant rural-specific relief administratively, NRHA urges the Committee to build a rural, small-entity exemption directly into statute, allowing small and rural covered entities to retain upfront discount pricing as the default mechanism. Alternatively, accommodations such as delayed effective date or simplified claims

[5] Chartis Center for Rural Health, 2026 Rural Health State of the State (Feb. 10, 2026), https://www.chartis.com/insights/2026-rural-health-state-state.
[6] Id.
[7] Id.
[8] Id.
[9] The National Grange; Avalere Health. *Analysis of 340B Program Impact on Rural Hospitals.* February 6, 2026.

submission pathway for Critical Access Hospitals, Sole Community Hospitals, rural DSH hospitals, Federally Qualified Health Centers, and other low-volume rural covered entities are necessary.

If implemented, NRHA appreciates that the discount, rebate, and claims-repository options in Section 2 are structurally consistent with the rebate model HRSA has already developed and defended through its pilot program, including a comparable manufacturer payment window. NRHA is concerned, however, that Section 2 applies this framework program-wide and permanently, with no comparable pilot period, phase-in, or evaluation checkpoint, unlike HRSA's pilot, which is deliberately scoped to a narrow set of drugs at roughly 5.5% of total 340B sales, with a mandatory first-year evaluation before any expansion. Extending a rebate mechanism to the full program immediately, without a comparable transition period, risks imposing at full scale an administrative and cash-flow burden that HRSA itself judged necessary to test narrowly first.

NRHA also notes that HRSA's pilot explicitly requires manufacturers to bear all IT platform costs associated with rebate administration. Section 2 is silent on cost allocation for the claims repository and standardized data infrastructure it creates. NRHA recommends Section 2 be amended to explicitly place IT and systems costs on manufacturers, consistent with the pilot precedent, and to include a phased implementation timeline for smaller rural covered entities.

NRHA opposes the segregated inventory requirement in clause (i)(I)(aa) for entities receiving a discount at the time of sale. Rural hospitals, particularly those with limited pharmacy staff, cannot feasibly maintain a physically segregated inventory system. Virtual inventory such as the replenishing 340B-purchased drugs based on documented dispensing to eligible patients, is the current, well-functioning standard and has not raised issues in external audits, including HRSA audits. NRHA recommends striking the segregated inventory requirement and explicitly permitting virtual inventory replenishment models to satisfy this requirement.

Separately, NRHA cautions the Committee against treating covered-entity election option under clause (a)(2)(B)(ii) which allows an entity to choose its own pricing mechanism only if it passes along all discounts or rebates to patients. This option removes the margin that many covered entities rely on to fund sliding fee scales and reinvest in rural service lines and should not be characterized as a substitute for the affordability protections rural providers need. NRHA also recommends the Committee to clarify which patients this provision is intended to reach. As drafted, it is unclear whether the requirement to make outpatient drugs available at no more than the ceiling price applies to all patients of the covered entity or only to uninsured patients, and whether insured patients would be subject to some form of adjusted cost-sharing. NRHA recommends adding the word "uninsured" wherever "patients" appears in this clause to resolve the ambiguity. NRHA also has significant concern with the "nominal dispensing fee" permitted under this clause, the amount of which is left entirely to the Secretary's determination. Without a meaningful floor or methodology specified in statute, covered entities risk being left with a fee so low that it fails to cover the actual cost of dispensing, eroding program sustainability over time.

If required, NRHA supports the claims-repository standardized-data option in clause (i)(III) as the most workable of the three rebate mechanisms, and NRHA recommends the Committee consider making a standardized claims repository the preferred or default mechanism rather than one option among three left to manufacturer discretion. Even under a 10-day manufacturer payment window, covered entities are still required to float acquisition-cost cash to manufacturers in the interim, for small and mid-sized rural covered entities, including many FQHCs. This upfront cash requirement could be prohibitive enough that some entities effectively cannot participate for higher-cost drugs, undermining the purpose of the program for exactly the entities it is meant to serve. NRHA is

gathering data to quantify this impact and urges the Committee to consider a bridge-financing mechanism, advance-payment option, or entity-size-based accommodation to address it.

Further, NRHA notes that manufacturer compliance with rebate mechanisms has been a persistent problem. The Medicare Drug Price Negotiation Program's Maximum Fair Price refund process has been marked by significant accuracy issues and difficulty reversing erroneous manufacturer determinations, a cautionary parallel for a 340B rebate structure operating at far greater scale. Several NRHA members have questioned whether Section 2's enforcement mechanism will function in practice: state-level prompt-payment laws for 340B (e.g., in Washington and Colorado) already exist, but manufacturers have not reliably complied, leaving litigation as the only recourse for covered entities. NRHA urges the Committee to strengthen Section 2's enforcement provisions with a faster, non-litigation dispute-resolution pathway rather than relying primarily on after-the-fact audits and civil penalties.

Section 4. Additional Definitions

NRHA supports Congress codifying a statutory patient definition to provide long-needed clarity. We encourage Congress to maintain a patient definition consistent with the way medicine is practiced in rural communities to ensure robust access to the 340B program.

NRHA appreciates that Section 4 permits a covered entity to claim a prescription resulting from a referral, consistent with our members' care models. However, the accompanying "practitioner" definition requires the referring provider to be an employee, independent contractor, or party to an ongoing contractual relationship with the covered entity. This definition is narrower than necessary: many rural covered entities rely on ongoing referral relationships with specialists or other providers where the covered entity retains ultimate clinical responsibility for the patient's care, without a formal contractual arrangement in place. NRHA recommends Section 4 be amended to allow a covered entity to claim a prescription from a referring provider whenever the covered entity retains ultimate responsibility for the patient's care, without requiring a formal ongoing contract.

Section 4 also does not address telehealth. Rural patients increasingly receive care via telehealth, and covered entities should not lose the ability to claim a 340B discount solely because a qualifying visit occurred remotely. NRHA recommends Section 4 explicitly provide that a telehealth encounter with a covered entity's practitioner counts as an "outpatient health care service" for purposes of the patient definition.

Section 5. Contract Pharmacies

This section raises some of NRHA's most significant concerns. NRHA's longstanding position is that Congress should not impose any limitation on the number or location of contract pharmacies a rural covered entity may use. Many rural covered entities are too small to support an in-house pharmacy, and the geographic spread of rural patient populations means access depends on multiple, often distant, contract pharmacy relationships.

As drafted, the 5-pharmacy cap and service-area limitation in clauses (iii)–(iv) apply specifically to covered entities under paragraph (4)(L) (DSH hospitals), the free-standing cancer hospital portion of (4)(M), and rural referral centers under (4)(O) and, notably, do not appear to extend to Critical Access Hospitals (CAHs) under (4)(N). NRHA asks the Committee to confirm in bill text, rather than by omission, that CAHs are excluded from these limitations, given how central CAHs are to rural 340B participation.

NRHA also flags a significant drafting ambiguity: because sole community hospitals and rural referral centers are combined under the same subparagraph (4)(O) in current law, it is unclear whether the cap's reference to "a rural referral center described in paragraph (4)(O)" is intended to reach sole community hospitals as well. NRHA requests the Committee clarify whether sole community hospitals are covered by this limitation, as the current text is ambiguous and subject to mal-interpretation.

For the rural DSH hospitals, rural referral centers, and sole community hospitals, pending clarification, that are covered by this limitation, NRHA continues to oppose both the numeric cap and the service-area restriction. The "service area" definition using Public Use Microdata Area (PUMA) and contiguous PUMAs may not reflect the actual geographic reach of a rural hospital's patient population, which often extends well beyond adjacent areas given the scarcity of rural pharmacy infrastructure. NRHA recommends striking the numeric cap and service-area requirement for these rural hospital types, or at minimum providing a rural-specific exception based on documented patient travel distance or local pharmacy density.

NRHA supports, in principle, the requirement that covered entities implement compliance procedures addressing non-duplication of 340B and Medicare Fair Price discounts, paired with a request that HRSA provide technical assistance, model compliance templates, and an adequate implementation period for entities without dedicated compliance staff.

NRHA raises no objection to annual contract pharmacy compliance certifications but notes the risk that added liability exposure could discourage independent rural pharmacies from entering into 340B agreements, reducing patient access in areas already served by few pharmacy options. NRHA seeks clarification on the annual compliance certification required under clause (ii)(III). As drafted, it appears the covered entity, not the contract pharmacy, must certify annually that the contract pharmacy complies with all requirements under this subparagraph, including the covered entity's own compliance procedures. NRHA is concerned that this places covered entities at risk for compliance matters that may be outside their direct control, since a covered entity cannot fully police a contract pharmacy's day-to-day conduct. NRHA recommends the Committee clarify the scope of the covered entity's certification obligation and consider limiting liability to matters within the covered entity's actual knowledge or control.

NRHA opposes the mail order pharmacy restrictions in clause (v) altogether. These restrictions are unwarranted and would limit a delivery method that rural patients, who often travel significant distances to reach a pharmacy, increasingly rely on. NRHA recommends the mail order restrictions be removed in their entirety, rather than narrowed or extended to additional entity types. If included, NRHA seeks parity between hospital and non-hospital covered entities in the mail order pharmacy provisions. The discussion draft extends a rural, non-Metropolitan Statistical Area exception only to sole community hospitals and rural referral centers, while non-hospital covered entities are held to a stricter service area residency test that does not account for telehealth-enabled and mobile care delivery models. NRHA urges the Committee to extend comparable flexibility to non-hospital covered entities serving similarly dispersed rural populations.

NRHA supports the existing service area standard for non-hospital covered entity pharmacies, which preserves the ability to operate a single pharmacy across multiple clinic sites. However, NRHA raises concern on behalf of hospital members that the four walls standard applied to hospital covered entities could push multi-site rural hospital systems into the newly capped contract pharmacy limits, and urges the Committee to consider an equivalent multi-site accommodation for hospital covered entities. NRHA strongly opposes, however, restricting hospital covered entity pharmacies to the four

walls of the hospital. This standard would hold hospital covered entities to a stricter location requirement than contract pharmacies, which would effectively eliminate entity pharmacy arrangements for multi-site rural hospital systems, pushing them into the newly capped contract pharmacy limits. NRHA recommends the entity pharmacy standard for hospital covered entities instead be defined by the covered entity's service area, consistent with the standard applied elsewhere in Section 5, rather than a physical four-walls requirement.

Section 6. Transparency

NRHA recognizes that a lack of transparency in the 340B Program is a bipartisan concern, and that some form of reporting reform is likely to advance regardless of NRHA's concerns regarding administrative burden on rural providers. NRHA's approach is therefore to identify where new reporting requirements can align with existing data collection, rather than to oppose overall transparency reforms outright.

NRHA appreciates that Section 6's reporting requirements are tiered by net patient revenue and rely substantially on data elements already captured in existing Medicare cost report worksheets, which is consistent with NRHA's principle that new reporting obligations should build on data entities already collect rather than create new unfunded mandates. Because the thresholds are set at $200 million and $1 billion in net patient revenue, most small rural hospitals should fall into the lightest reporting tier or below Section 6's scope entirely. NRHA asks the Committee to confirm this reading and to ensure the implementing regulations do not inadvertently sweep in small rural DSH hospitals through revenue-calculation methodology.

Further, NRHA notes two points from NRHA members that support an alternative, more targeted approach to Section 6. First, HRSA's existing 340B audit process already captures data on how program savings are used, which raises the question of whether a new, separate annual transparency reporting requirement duplicates information the agency can already obtain through auditing. Second, federally qualified health centers already report detailed data on program usage and spending through HRSA's Uniform Data System (UDS), and NRHA is not aware of confusion about how FQHC 340B savings are used as a result. For grant-funded covered entities already subject to UDS or comparable federal reporting, NRHA recommends Section 6 explicitly allow that existing reporting to satisfy the transparency requirement rather than creating a new, duplicative structure.

Section 7. Ensuring Affordability

NRHA supports the underlying goal of ensuring low-income and uninsured patients are not priced out of accessing 340B drugs, and many rural safety-net providers already operate sliding fee scales. However, the sliding-fee-scale certification, posting, and billing-communication requirements in Section 7 apply uniformly to all hospital covered entities under (4)(L)–(O) with no rural or small-entity accommodation, adding new compliance obligations layered on top of Section 6's reporting requirements. As previously stated, the 340B program has become a foundational financing mechanism that enables rural hospitals to sustain critical services despite ongoing financial pressures. Rural hospitals reinvest 340B program savings to support obstetric care, oncology and infusion services, behavioral health, medication assistance programs, telepharmacy, care coordination, workforce recruitment and retention, uncompensated care, and other services that would otherwise be financially unsustainable. NRHA recommends a simplified certification pathway for small rural hospitals already demonstrating compliance through existing charity care policies, for example those satisfying IRS Section 501(r) requirements.

Section 8. Hospital Child Sites

NRHA has long supported codifying HRSA's existing child site guidance in statute, and we are glad to see Section 8 do so. The grandfather provision for shortage area designations made before the specified date is a helpful accommodation for existing rural provider-based sites. However, the new charity-care and Medicaid/CHIP outpatient revenue-share thresholds in subclauses (IX) and (X) are new financial tests not found in current HRSA guidance and could be difficult for a small rural provider-based clinic to track or satisfy, particularly relative to a statewide hospital benchmark that may not reflect local conditions. NRHA recommends either removing these two new thresholds or providing a simplified compliance pathway for child sites of CAHs, rural hospitals and rural health centers.

Section 9. Contracting Reforms

NRHA supports the flat-fee requirement on third-party administrators and contract pharmacies. Excessive dispensing fees have eroded 340B savings for rural providers, and this section is intended to addresses that concern. However, NRHA requests that rural pharmacies be exempted from the 125-percent dispensing fee-cap. Rural independent pharmacies have already absorbed significant dispensing-fee erosion from other payers and are closing at a rate that is deepening rural pharmacy deserts. Applying the cap uniformly risks driving rural contract pharmacies out of 340B participation altogether, eroding covered entities' savings and their ability to pass those savings on to patients.

Section 10. Prime Vendor Program

NRHA supports requiring at least two prime vendor options, prohibiting fees for educational services, and requiring vendors to be free of conflicts of interest. This section should benefit rural covered entities without introducing new burdens.

Section 11. Transfer of Civil Penalty Amounts Collected

NRHA supports directing collected civil penalties to HRSA's Office of Pharmacy Affairs to fund program administration, consistent with our position that HRSA needs additional regulatory authority and resources to effectively oversee the program.

Finally, NRHA urges the Committee to use this legislative vehicle to address three additional rural priorities not currently reflected in the discussion draft:

Rural Emergency Hospital (REH) 340B eligibility. NRHA urges Congress to add REHs as an eligible 340B covered entity type as proposed in H.R. 44 Rural 340B Access Act (S. 4587/H.R. 8144 in the 118th Congress). This bill would allow facilities designated as REHs to participate in the 340B drug discount program without losing status during the conversion process. The REH program was created in 2020 to help provide rural and critical access hospitals with financial support and increased Medicare reimbursements if they maintain 24-hour emergency rooms, observation beds, and other key health services. However, REHs are not currently eligible for the 340B drug discount program. Without REH participation in 340B far fewer hospitals will consider converting as 340B payments are vital to financial viability of rural hospitals.

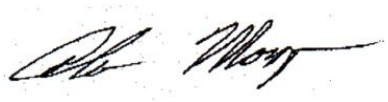
Orphan drug exclusion relief. Critical access hospitals, and sole community hospitals remain subject to the orphan drug exclusion, limiting access to critical treatments such as oncology care. NRHA urges relief from this exclusion for these rural hospital types. While exact data is not publicly available, a substantial portion of orphan designated drugs used in 340B are oncology related. Between 2014-2024, more than 450 rural hospitals have eliminated chemotherapy services, demonstrating the

challenges accessing these drugs in rural settings.[10] This ask carries added urgency: as Medicaid-related cuts from the recently enacted reconciliation law reduce hospitals' disproportionate share percentages, some DSH hospitals, which are not subject to the orphan drug exclusion, may be reclassified as sole community hospitals, which are. Absent relief, more rural hospitals are likely to newly face this exclusion in the near term.

PBM and payer discrimination protections. Pharmacy benefit managers and payers have increasingly treated 340B covered entities and contract pharmacies differently, restricting patient choice of pharmacy, reducing reimbursement, or excluding 340B providers from preferred networks. NRHA urges the Committee to include statutory protections against this discrimination, consistent with the bipartisan PROTECT 340B Act (H.R. 2534, 118th Congress).

NRHA appreciates the Committee's genuine effort to address program integrity while preserving 340B's core purpose. We would welcome the opportunity to discuss these comments further with you and your staff and stand ready to provide additional data or member examples to support any of the amendments requested above. If you have any questions or wish to discuss further, please contact NRHA's Chief Policy Officer, Carrie Cochran-McClain (ccochran@ruralhealth.us).

Sincerely,



Alan Morgan
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[10] The Chartis Center for Rural Health. *2026 Rural Health State of the State.* February 10, 2026. Accessed August 21, 2026. https://www.chartis.com/insights/2026-rural-health-state-state