



July 28, 2023

The Honorable John Thune
Senator
S-208, The Capitol
Washington, DC 20510

The Honorable Tammy Baldwin
Senator
S-221, The Capitol
Washington, DC 20510

The Honorable Debbie Stabenow
Senator
419 Hart Senate Office Building
Washington, DC 20510

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

The Honorable Shelley Moore Capito
Senator
172 Russell Senate Office Building
Washington, DC 20510

The Honorable Benjamin Cardin
Senator
509 Hart Senate Office Building
Washington, DC 20510

Dear Senators Thune, Stabenow, Moore Capito, Baldwin, Moran, and Cardin,

The National Rural Health Association (NRHA) appreciates the opportunity to provide feedback on solutions to ensure the 340B Drug Pricing Program's (340B) stability. We appreciate the Senators' commitment to maintaining the program's integrity and original intent to stretch scarce federal resources. The 340B program plays a crucial role for rural safety net providers that allows them to continue to serve their patient's needs and preserve access to care.

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.

Above all, NRHA stresses that preserving the original intent of the 340B Program – to stretch scarce federal resources – must be the core of any legislative proposal to ensure rural covered entities' continued participation. The 340B program is a lifeline that allows rural safety net providers to keep their doors open and furnish critical services. Rural hospitals and clinics operate on thin margins and 340B savings help them keep needed services local for their patients. We believe that providers are best situated to determine how 340B savings can be used to benefit their rural communities without broad legislative or regulatory mandates. Additional information on NRHA's 340B program reform policy principles can be found [here](#).

1. What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?

NRHA supports granting HRSA more oversight and regulatory authority over the 340B program in order to protect the integrity of the program and take enforcement action against bad actors.



Congress must grant HRSA explicit statutory authority to ensure that the agency has the proper enforcement mechanisms to protect against the abuses that are happening under the program.

One area where HRSA should have greater enforcement authority is around duplicate discounts. Manufacturers have increasingly forced covered entities to report claims data in the 340B ESP portal. NRHA believes that in order to have objective implementation, HRSA should be the entity that collects claims data and monitors duplicate discounts rather than allowing manufacturers to enter the process.

Based on NRHA suggestions below, **Congress should grant HRSA the authority to enforce any provisions that are added to the 340B statute** such as contract pharmacy arrangement, child site arrangements, allowing orphan drug discounts for rural hospitals, and patient definition. In addition, HRSA should be able to impose civil monetary penalties on manufacturers that do not comply or place undue restrictions on covered entities. Please see our answers to the following questions for more detail on these policy suggestions. Crucially, if Congress grants HRSA stronger enforcement and oversight authority, **Congress must also provide further resources to the agencies to ensure these activities are carried out effectively.**

2. What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?

NRHA supports policies that allow rural covered entities to work with contract pharmacies without restrictions on the number and location of such pharmacies. **Specifically, NRHA supports unlimited use of contract pharmacies and restrictions on manufacturers that seek to curb contract pharmacy arrangements.** Restricting the number of contract pharmacies that a covered entity may use disproportionately constrains access for rural patients compared to urban patients. Many rural covered entities are too small to support an in-house pharmacy, or their pharmacies do not have the capability to provide sufficient access to prescription drugs throughout the entire service area. Further, given the geographic spread of rural areas, patients of rural covered entities travel farther, thus multiple contract pharmacies should be available to ensure rural access.

Rural areas are not a monolith, and each has its own unique health care delivery system and access constraints. As such, it is not appropriate to limit contract pharmacy arrangements for rural covered entities. NRHA members have expressed that their covered entity uses anywhere from two to ten contract pharmacies depending upon the needs of their community, the geographic spread of their patient population, and availability of nearby pharmacies.

Codifying contract pharmacy protections in the 340B statute is imperative. After the 3rd Circuit Court of Appeals held that manufacturers may limit contract pharmacy arrangements because the statute is silent,¹ manufacturers subsequently imposed extremely restrictive policies on covered entities.² At least one circuit court has declined to read contract pharmacy protections into the 340B statute where they are not explicitly stated, and the D.C. Circuit and 7th Circuit Courts of Appeals are considering the same contract pharmacy issue. Manufacturers are also increasingly using reporting conditions to allow covered entities to use a limited number of contract pharmacies. Covered entities often have to report claims data through the 340B ESP platform under the guise of program integrity

¹ *Sanofi Aventis U.S. LLC v. Becerra*.

² For example, in the weeks following the 3rd Circuit's decision, Johnson & Johnson [announced](#) that covered entities may only use one contract pharmacy. Please find more restrictive manufacturer policies [here](#).

in order to continue using contract pharmacies. **Congress must clearly provide for unlimited contract pharmacy use with no manufacturer conditions in any upcoming program reform.** NRHA urges Congress to act on this before manufacturers are further emboldened by the courts to continue restraining covered entities access to contract pharmacies.

Additionally, states are beginning to consider and pass legislation protecting contract pharmacy arrangements. However, this is a piecemeal approach to 340B safeguards that only protects participants in those particular states. As 340B is a federal program, we urge Congress to take action at the federal level and amend the 340B statute to protect all rural covered entities' use of contract pharmacies.

3. What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?

NRHA supports providing critical access hospitals, sole community hospitals, and rural referral centers relief from the orphan drug exclusion. This exclusion only applies to these rural hospital designations and thus comes at an unfair cost for rural patients that require these lifesaving treatments. The availability of specialty treatments is limited in rural areas and rural hospitals typically cannot acquire these treatments without a discount. Congress must require that manufacturers provide orphan drugs at a discount for rural hospitals to ensure that patients of covered rural hospitals can access the same treatments as those at other hospitals where appropriate.

NRHA also supports codifying HRSA's current child site guidance in the 340B statute. This is essential for protecting rural patient access as many rural hospitals operate offsite locations, such as provider-based rural health clinics (RHCs), in surrounding areas. For example, one NRHA member hospital serving as a regional access point has a network of RHCs that reach nine surrounding areas. Limiting child site arrangements would unduly restrict rural patient access in this area. Altogether, more than 60% of rural America relies upon RHCs as their primary care provider³ and retaining access to 340B at these provider-based sites is crucial to ensure that the benefits of the 340B program flow to the patients that need it the most.

Further, NRHA strongly opposes all manufacturer attempts to discriminate against 340B covered entities and patients. **We urge Congress to work to pass H.R. 2534, the PROTECT 340B Act, a bipartisan piece of legislation that would ensure payers and manufacturers cannot discriminate against 340B participants.**⁴ Prohibiting discrimination will help to ensure that patients reap the benefits of the program without industry interference.

Last, NRHA urges Congress to codify current HRSA guidance on the patient definition.⁵ Similar to our contract pharmacy concerns, the definition of a "patient" must be explicitly codified in the 340B statute to provide clarity. Congress cannot wait to act on this as a case is pending at the U.S. District Court for the District of South Carolina. NRHA believes that district and circuit court decisions are an inappropriate and ad hoc way to address pressing 340B issues. Congress must legislate and clearly

³ National Association of Rural Health Clinics, *60% of Rural Americans Served by Rural Health Clinics* (Apr. 7, 2023), <https://www.narhc.org/News/29910/Sixty-Percent-of-Rural-Americans-Served-by-Rural-Health-Clinics>.

⁴ <https://www.congress.gov/bill/118th-congress/house-bill/2534>

⁵ Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996) <https://www.govinfo.gov/content/pkg/FR-1996-10-24/pdf/96-27344.pdf>.

lay out terms of the 340B program in the statute to avoid courts indirectly giving manufacturers license to further dilute the benefits of the program for covered entities.

In addition to HRSA's 1996 patient definition, NRHA asks that Congress ensure telehealth services count as patient visits for covered entities in rural areas. Telehealth has been an important tool for connecting rural patients to care prior to the COVID-19 pandemic and will continue to be as the pandemic wanes. Rural patients would be disproportionately left out of the 340B program if telehealth visits are not built into the patient definition.

Another aspect of patient definition that is not specifically referenced in the 340B statute is "referral capture." Congress should make clear in the statute that covered entities are able to claim prescriptions from a referring provider if the covered entity retains the ultimate responsibility for the patient's care. Recently, referrals have satisfied HRSA audits, but NRHA is concerned that this flexibility could be jeopardized by future court decisions and thus it should be explicitly written into the statute. It is of utmost importance that any gray areas that currently expand access for rural 340B patients are codified into the 340B statute.

4. What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?

As discussed above, to ensure appropriate guardrails exist against duplicate discounts, HRSA could be granted the authority to develop a claims reporting database for prescriptions to ensure compliance with the Medicaid duplicate discount prohibition. However, NRHA does not believe that manufacturers are the appropriate enforcement agency for this and should not condition certain program benefits on claims reporting. As referenced above, NRHA members have noted that manufacturers coerce covered entities into uploading claims data into the 340B ESP portal as a condition of maintaining contract pharmacy arrangements. Manufacturers cannot be allowed to hold covered entities hostage on the condition of burdensome claims data reporting.

5. What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?

NRHA reiterates that HRSA should be granted more statutory authority to properly oversee the 340B Program. We firmly believe that the agency implementing the program should also have the ability to take enforcement action against the parties that abuse it. Congress must provide HRSA with not only enforcement authority but resources to carry out enforcement activities. NRHA strongly opposes any action to require covered entities to report on their use of 340B savings in an effort to preserve program integrity. Please see our response below for more detail.

Again, NRHA asks that Congress take action against discriminatory practices by pharmaceutical benefit managers (PBMs) and payers by passing the bipartisan PROTECT 340B Act. Actions by PBMs have weakened the benefits and integrity of the program and must be reined in. This bill would prohibit discrimination against any covered entity or patient and impose civil monetary penalties on PBMs and payers that do not comply.



In the same vein, some pharmacies are collecting large dispensing fees when dispensing 340B drugs as part of the terms of their contracts with covered entities. NRHA asks that Congress put restrictions in place so that pharmacies cannot withhold program savings under the guise of collecting exorbitant dispensing fees. HRSA needs the authority to impose penalties on pharmacies that are collecting fees that do not align with the true cost of dispensing 340B medications. NRHA does not disagree with nominal dispensing fees for pharmacies; however, we believe that fees that go beyond the true administrative cost of dispensing are abusing their role in the program.

6. What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?

NRHA does not support onerous reporting requirements on how 340B savings are used for rural covered entities. Unfunded reporting mandates are a burden on rural providers who have less staff than urban providers. Staff in rural facilities often wear multiple hats and while we agree that integrity measures are important, NRHA stresses that rural covered entities are not the actors that are inappropriately using the program for their financial benefit. Nearly 45% of rural hospitals are operating in the red and the overall median rural hospital operating margin is 1.8%.⁶ Given the financial vulnerability of these providers, it is clear that they are utilizing 340B savings to maintain critical operations, provide care to patients, and keep their doors open. **Rural providers with small or negative profit margins should not be required to report on how 340B savings are being used.**

Further, NRHA believes that rural providers are in the best position to decide how to utilize 340B savings to benefit their patient population. **NRHA opposes any efforts to prescribe how rural covered entities use their 340B savings.** In addition, we also oppose mandating covered entities to report on how 340B savings are used. As already discussed, rural covered entities are not the providers that are abusing the program and misusing 340B savings. Rural covered entities also comply with various other reporting requirements to show community benefit under Medicare, Medicaid, and the Internal Revenue Service programs. **NRHA only supports reporting on the patient benefit of 340B savings insofar as it pulls data and information that is being reported under another federal program.**

NRHA thanks the Senators again for their dedication to protecting the 340B Program. We look forward to working together on this important issue. If you have any questions or would like further information, please contact Alexa McKinley (amckinley@ruralhealth.us).

Sincerely,

A handwritten signature in black ink, appearing to read "Alexa McKinley".

⁶ Michael Topchik, et al., *Rural Health Safety Net Under Renewed Pressure as Pandemic Fades*, THE CHARTIS CENTER FOR RURAL HEALTH (2023), 4
<https://www.chartis.com/sites/default/files/documents/Rural%20Hospital%20Vulnerability-The%20Chartis%20Group.pdf>.



National Rural Health Association

Alan Morgan
Chief Executive Officer
National Rural Health Association