National Rural Health Association

340B Discount Drug Program Reform Policy Principles

Protect Rural Access. NRHA believes 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 Drug Pricing (340B) Program is a lifeline that allows rural safety net providers to keep their doors open and furnish critical services by stretching scarce Federal resources. Rural hospitals and clinics operate on thin margins and 340B savings help them keep needed services local for rural patients. Providers are best situated to determine how 340B savings can be used to benefit their rural communities without broad legislative or regulatory mandates.

Contract Pharmacies. NRHA does not support any limitations on the number and location of contract pharmacies that rural covered entities can work with. Restricting the number of contract pharmacies that a covered entity may use disproportionately constrains access for rural patients. Many rural covered entities are too small to support an in-house pharmacy and must rely upon outside pharmacies. Given the geographic spread of rural areas, patients of rural covered entities travel farther, and thus multiple contract pharmacies should be available to ensure rural access.

Orphan Drugs. NRHA supports relief from the orphan drug exclusion for critical access hospitals, sole community hospitals, and rural referral centers. This exclusion only applies to rural hospitals covered entities and thus comes at an unfair cost for rural patients that require these lifesaving treatments such as oncology treatment, access to which is decreasing in many rural areas.

Discrimination. NRHA supports clear statutory restrictions on Pharmaceutical Benefit Managers (PBM) and payers' ability to treat 340B participants differently. PBMs and insurance companies have increasingly discriminated against 340B patients, covered entities, and contract pharmacies. This is particularly problematic in rural areas where PBMs restrict patient choice of pharmacy or location to receive infusion therapy.

Oversight. NRHA supports granting the Health Resources and Services Administration (HRSA) more oversight and regulatory authority over the 340B Program. HRSA currently has a limited ability to regulate and requires clear statutory authority to oversee and protect the integrity of the 340B Program.

Dispensing Fees. NRHA believes that restrictions should be put in place to prevent abuses from withholding program savings inconsistent with the intent of the law. Collection of large dispensing fees when dispensing 340B drugs puts undue stress and burden on small, rural providers.

Child Site Arrangements. NRHA supports codifying HRSA's current child site guidance in the 340B statute. Maintaining child site access to the 340B program is essential for protecting rural patient access. Many rural hospitals operate offsite locations, such as provider-based rural health clinics, in surrounding areas, thus requiring these locations to serve as access points for rural 340B patients.

Patient Definition. NRHA supports HRSA's 1996 definition of a patient with the addition of allowing telehealth services to count as patient visits for covered entities in rural areas. Current HRSA guidance[i] on defining 340B patients must be codified in the 340B statute to provide clarity. Additionally, the statute should make clear 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.

Reporting Requirements. NRHA encourages limits on program reporting and supports data collection only insofar as it is using data that entities are already reporting in another federal program. Rural hospitals and FQHCs are required to report data demonstrating community benefit for many federal programs. Rural covered entities do not have the capacity to comply with additional unfunded mandates for reporting on 340B savings.

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How the 340B Program Benefits Rural Health Systems and Patients

The 340B Program is an essential source of discounted outpatient drugs for many rural hospitals serving vulnerable populations who may lack insurance or be low income. For many rural safety-net hospitals operating on thin financial margins, the funds distributed through this program are critical to maintain operations and service lines. Rural provider participation, through safety net entities such as Critical Access Hospitals, Sole Community Hospitals, and Rural Referral Centers, comprise five percent of 2022 program purchases; a small component of the overall program that has a significant impact on rural health systems and patients.

"We provide over $100,000 per month in drug discounts to patients through our contract pharmacies. Those discounts used to average closer to $200,000 per month prior to manufacturer restrictions on contract pharmacies in the past few years." *A rural hospital in southwest Missouri.*

“We saw true net savings of approximately $400,000 in calendar year 2022 that directly benefitted the patients in our region. These savings ensure that those who have the least are still able to access the medications they need. While the magnitude of these savings does not compare to higher population-based clinics or hospitals, they are just as impactful for the patients they benefit.” *A rural FQHC in Alaska.*

Impact of Current Abuses on Rural Communities

Since 2010, over 150 rural hospitals have shuttered their doors, including dozens since the onset of COVID-19.[ii] Nearly 45% of rural hospitals are operating with negative margins and therefore vulnerable to closure.[iii] Specific services, such as obstetrics and chemotherapy, continue to vanish at an alarming rate. When a rural hospital or service line closes, the impact can be devastating for a community.

The significant restrictions by manufacturers in recent years are having a disproportionate impact on rural safety net providers. For example, one rural Missouri hospital experienced over $400,000 per month in lost revenue. Coupled with Medicare payment updates at rates lower than actual inflation, rural hospitals are suffering significant operating deficits, with many evaluating ways to curtail operations to maintain core services.

“In the past six years our gross 340B revenue topped out in 2021 at $1,400,000. In 2022 it was $872,000, a 38% decrease. For 2023 I predict our gross revenue will be around $500,000 which is a 65% decrease as compared to our high in 2021. This has a direct impact on our bottom line, which in turns impacts our ability to keep needed services local. This also reduces the likelihood of investing in new services for the community and limits the ability to secure leases/loans to update aging equipment. ” *A rural hospital in Michigan.*

“We have incurred an approximate 60% erosion in 340B savings resulting in a loss of $531,720 per year. Savings that were invested in access to prescription medications, patient navigational services, and integrated dental and oral health services. The most severe impact of this loss is the closure of one of our five operatory dental and oral health centers. In addition, restricting contract pharmacy to one versus multiple forces our poorest patients to drive great distance to obtain mediation.” *A rural FQHC in New Hampshire.*

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[i] 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.
[ii] https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.
[iii] https://www.chartis.com/insights/rural-health-safety-net-under-renewed-pressure-pandemic-fades.