



July 28, 2023

United States Senate  
Washington, DC 20510  
[bipartisan340brfi@email.senate.gov](mailto:bipartisan340brfi@email.senate.gov)

**RE: Response to Bipartisan Request for Information on the 340B Program**

Dear Bipartisan Senators,

On behalf of the Louisiana Rural Health Association (LRHA), thank you for the opportunity to provide a response to your request for information about the 340B Program sent to stakeholders on June 16, 2023.

LRHA is a membership association that is made up of Louisiana rural health care providers. This includes rural health clinics (RHCs); federally qualified health centers (FQHCs); and rural hospitals across the state. LRHA works to provide a unified voice that promotes and enhances the quality of rural health in Louisiana.

LRHA appreciates the opportunity to provide input on behalf of our members towards strengthening the 340B Drug Discount Program. This Program has become an essential resource for rural providers to support our most vulnerable patients and communities, consistent with Congress' objectives.

You will find our response to your questions below.

**Question 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?**

The Health Resources and Services Administration (HRSA) currently has robust statutory authority to oversee the 340B Program and ensure program integrity. We recommend that HRSA take a full inventory of the regulatory requirements placed on health care providers as compared to drug manufacturers. We believe there to be a lack of enforcement parity between providers and drug manufacturers, with significant oversight and administrative burden on healthcare providers.

HRSA currently audits up to 200 340B covered entities annually to ensure program integrity. In stark contrast, HRSA conducts up to only six audits of drug manufacturers. (See [HRSA Program Integrity Audit Results](#)) HRSA should be provided the resources necessary to conduct sufficient audits of drug manufacturers to ensure greater oversight of manufacturers and audit parity.

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

Contract pharmacies have been recognized by HRSA as an integral part of the 340B Program since 1996. These arrangements with community and specialty pharmacies in rural areas are critical to ensuring patient access to life-sustaining medications. Lack of transportation is a well-known barrier to care in rural areas across the country and many patients are unable to travel outside of their community for medical services.

Dispensing drugs at contract pharmacies allows our rural 340B providers to ensure patients are able to obtain needed prescriptions timely.

We believe that the actions by over twenty of the largest drug companies in the country since 2020 to restrict, condition, or outright deny 340B pricing for drugs dispensed through these arrangements may violate the 340B statute (see [American Hospital Association Amicus Brief](#)) and undermines the purpose of the 340B Program as specified by Congress.

To remedy this situation and make clear Congress' intent, we recommend adding language to the 340B statutes that would explicitly prohibit and prevent drug companies from denying, restricting, prohibiting, or interfering with the acquisition or delivery of a 340B drug at contract pharmacies.

**Question 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?**

As previously mentioned, 340B covered entities are currently subject to significant oversight and audit of their 340B Programs, including review of all policies related to the program and utilization of Program benefits. Our providers also receive general financial oversight through CMS cost reporting. LRHA members are using the savings accrued from this Program in a variety of ways to improve patient care. It is essential that providers have the flexibility to utilize the funding in the way that best meets the unique needs of each facility, patient population, and community.

Our rural providers want to focus their resources on providing the best possible care to the patients in our rural communities. However, unnecessary administrative burden can divert resources away from patient care. As the 340B Program becomes more uncertain and difficult to manage, many providers are diverting staff time or hiring a third party to manage their 340B Program, utilizing funding and resources that could otherwise be allocated to programs that directly benefit patients.

Additionally, many rural pharmacies are struggling to stay open and provide medication access in rural communities. Many of these rural pharmacies are only able to remain viable due to the benefits of the 340B Program. As discussed previously, local availability of affordable pharmaceuticals is essential for the well-being of our rural residents who lack access to transportation.

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

We understand that national stakeholders are supporting the creation of a national claims data clearinghouse to address the alleged duplicate discount issues. For example, Congress has introduced legislation to create a claims clearinghouse for the 340B Program. (See [H.R. 2534](#))

While we do not object to the creation of a national clearinghouse, it is vital that the clearinghouse does not place additional administrative reporting burden on rural health care providers. We recommend that HRSA seek to leverage data and claims already submitted by providers to ensure program integrity.

**Question 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?**

As stated in our response to an earlier question, there is ample authority for HRSA to enforce program integrity on all covered entities and drug companies. We recommend that HRSA assess the requirements and make needed investments into auditing the conduct of a greater number of drug manufacturers.

We believe that there is a misalignment in incentives for the 340B Program. Rural providers are highly incentivized to manage their 340B Programs with integrity to ensure the Program continues to function, as the Program is an essential revenue source to provide care to vulnerable patients in rural areas. However, the pharmaceutical manufacturers have significant interest in the failure of the Program as it requires sale of drugs at a reduced cost. We recommend that Congress explore more mechanisms to shift the incentives inherent in the program to increase pharmaceutical manufacturers' buy-in to the Program's success.

**Question 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?**

Rural 340B hospitals report a variety of information to demonstrate their commitment to providing care to underserved populations. Rural hospitals report uncompensated care, charity care, and other benefits provided to the communities they serve through both the Medicare cost reports and the IRS 990 form required for tax-exempt organizations. In fact, the most recently available IRS 990 data show that 340B hospitals alone provided nearly \$68 billion in community benefits. (See [AHA 990 Data Report](#))

We recommend that HRSA use the information that is available today to evaluate the need for greater transparency in the future.

**Conclusion**

LRHA is thankful for the opportunity to provide input on this request for information. If you would like additional information, please contact Denaé Hebert at [dhebert@lrha.org](mailto:dhebert@lrha.org) or 337.366.5915.

Sincerely,



Denaé M. Hebert  
Executive Director  
Louisiana Rural Health Association