

July 28, 2023

The Honorable John Thune
United States Senate
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
Washington, DC 20510

The Honorable Shelly Moore Capito
United States Senate
Washington, DC 20510

The Honorable Tammy Baldwin
United States Senate
Washington, DC 20510

The Honorable Jerry Moran
United States Senate
Washington, DC 20510

The Honorable Ben Cardin
United States Senate
Washington, DC 20510

Dear Senators:

Thank you for the opportunity to comment on your request for information pertaining to the 340B drug discount program. As you know, this is a health equity area of growing concern to the Black community. Media reports over the last year have indicated that discounted medicines intended for safety-net hospitals and related facilities in poor ZIP codes have instead found their way to middle class or even affluent patients elsewhere, where they are sold at full price. We look forward to working with you on this issue, as it's of the utmost importance to those of us concerned about health equity issues.

To turn to your specific questions:

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?

HRSA plays a vital role in ensuring that Congressional intent is met in the 340B program. Unfortunately, this office lacks the resources and manpower to adequately investigate whether 340B participants are abiding by their end of the bargain. A great deal more transparency must be demanded by HRSA of 340B covered entities, both upon application and regular renewal of eligibility. In particular, these entities must show that they are using the discounted drugs of the 340B program where they are intended, and on the patients that are intended, by the Congress. HRSA should be required to testify annually before all its Congressional committees of jurisdiction and do an annual 340B report detailing their progress in increasing the program's integrity.

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

Like other 340B covered entities, contract pharmacies should be required to regularly prove to HRSA that they are using the discounted drug program to serve the communities Congress intended. Money and inventory is fungible, so it's important that HRSA make sure that 340B drugs are not being diverted to populations that were never intended to interact with them.

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?

Granular transparency on the part of covered entities reporting to HRSA is the only solution here. Covered entities like charity hospitals and contract pharmacies should show that specific 340B drugs were actually used at the facilities in question, and that they were used on the patient population Congress intended. Modern inventory accounting and reports should make this possible with the proper level of policing and accountability from HRSA. Congress should make clear that for-profit pharmacy chains and pharmacy benefit managers, many of which are on the Fortune top 50 list, should not be benefiting financially or driving shareholder profits from this charitable medicine program.

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

If multiple discounts are occurring, that again should be able to be solved with extremely granular inventory and invoice accounting which simply does not exist today in HRSA interactions. A covered entity should be able to say that a particular bottle of medicine was bought using the 340B program on a particular date, and it was dispensed at a particular hospital to a particular population at a particular time. The burden of proof needs to be on the covered entities, not HRSA.

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?

Since the 340B program became law three decades ago, major hospital and pharmacy systems have developed sophisticated inventory and invoicing technology that allows them to pinpoint when and how drugs were purchased and dispensed. There is no reason why this technology should not be brought to bear in HRSA disclosures and audits to ensure that the program's resources are directed properly.

340B participating Health Care organizations should be required to contract with non-profit healthcare organizations to provide educational and awareness services about the program to the communities that are being served by the 340B participants.

In March of 2023, the National Action Network convened a listening session with national and state leaders to discuss problems in the 340B program. Below are some selected quotes from that conversation:

"This affects everybody. If you are having people abuse government funds that should be reinvested, this is not a right wing or left wing issue...The data is very important, education is even more important, and now that we know, frankly, we can ask the question: where'd the money go?"

The Rev. Al Sharpton, Founder and President, National Action Network

"Recent reports have uncovered that some hospitals are not using these savings as intended...Robbing the underserved, black and brown communities, is just not acceptable...We need to make sure that we build in robust oversight, and that can only be done through the Energy and Commerce [committee], so we need to get them involved in another discussion like this."

The Honorable Shri Thanedar, U.S. Representative, MI-13

"I was really infuriated by the accounts of taking away resources intended for the east end community in Richmond, it is a predominantly Black community, and also a low-wealth community."

The Honorable Kathy Tran, State Delegate, VA-42

"We do not believe that when government programs are misused and they're particularly designed to help people in certain communities, and it is abused or perverted by industries – that's wrong."

Dean Nelson, Chair, Frederick Douglass Foundation

"We need to allocate these savings specifically to programs that are going to be to the benefit of the wellness and the health equity of black women, black people, BIPOC communities, native American communities, federally-qualified health centers"

Dr. Ifeoma Udoh, Executive Vice President of Policy, Advocacy, and Science, Black Women's Health Imperative



"For our health centers, reform of the 340B program, protecting the 340B program, it's something that cannot wait, or we won't be able to complete our mission of serving communities in need, which is why I think the folks at the health centers go to work every day."

Nick Widmyer, Director of Federal Affairs, NACHC

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?

Covered entities should document how much they have saved (both annually and over time) from participation in the 340B program. They ought to then be able to match those savings to discounted drugs to low-income patients, as well as demonstrate investments in poor rural and urban communities to help increase health equity and patient health outcomes in those underserved areas. Failure to show that 340B savings have been used to do so should be grounds for HRSA to consider removing the covered entity from eligibility to participate in the 340B program.

Sincerely,

<p>Bishop Dean Nelson, National Founder</p> <p>The Frederick Douglass Leadership Institute</p> 	<p>Dr. Benjamin F. Chavis Jr., CEO</p> 
<p>Linda Goler Blount, CEO</p> 	<p>Gus West, President</p> 
<p>Kevin B. Kimble, Chairman</p> <p>Southern Christian Leadership Global Policy Initiative</p> 	<p>Dr. Sylvia Bartley, President, Black Women Rising</p> 
<p>The Honorable Ed Towns, Former U.S. Congressman</p>	<p>The Honorable Michael Steele, Former Lieutenant Governor, Maryland</p>
<p>The Honorable William Bill Cleveland, Former Vice Mayor, Alexandria</p>	<p>Dr. Lorenzo Neal, Pastor, New Bethel AME Church</p>
<p>Kevin McGary, President/Chairman, Frederick Douglass Foundation, California Chapter</p>	