



April 01, 2024

VIA ELECTRONIC MAIL

Bipartisan340BRFI@email.senate.gov

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, DC 20510

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

The Honorable Tammy Baldwin
United States Senate
709 Hart Senate Office Building
Washington, DC 20510

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

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

RE: Comments on Senate 340B Working Group SUSTAIN 340B Discussion Draft/RFI

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

The Health System Owned Specialty Pharmacy Alliance (HOSP) is a trade association for health systems and hospitals that have their own in-house specialty pharmacies, and the businesses that support them. HOSP advocates for its members in support of the improved patient care and clinical outcomes that are associated with fully integrated health system specialty pharmacies that serve their own patients in their own communities. HOSP develops and advocates for industry best practices to ensure that onsite health system specialty pharmacy operations have gold standard care models of excellence.

We are writing in response to the Bipartisan Senate Working Group's Discussion Draft of the *Supporting Underserved and Strengthening Transparency, Accountability and Integrity Now and for the Future of 340B Act* ("SUSTAIN 340B" Act) and related request for additional information on the 340B Program.

Our request is that the Program continue to be supported and protected. Fundamental to our comments is the premise that the 340B Program is already a success, but has been under threat from recent, unprecedented drug manufacturer actions that have undermined the Congress's intent in establishing

the Program. We request that any changes to the program be balanced in a way that builds on the success of the program. The status of the Discussion Draft is not complete, so we cannot provide comments as to whether the proposed changes would continue to support and protect the 340B Program in its totality. We submit these comments for your consideration on the outstanding questions in the RFI but we reserve judgment as to whether we support the proposal until the text is complete.

That said, we would like to express our gratitude for many proposals in the Discussion Draft that we do support. Specifically, the proposals that protect covered entities from harmful manufacturer policies such as refusing to offer or deliver 340B drugs to covered entities or their contract pharmacies, placing conditions on the ability of covered entities to purchase 340B drugs, and placing conditions on contract pharmacy use that would restrict distribution for 340B drugs or require sharing claims data directly with the manufacturer or related entity. A significant number of States have acted on this issue to pursue similar laws, signaling it is due time for a federal fix. We are also grateful for the proposals that protect covered entities from harmful payer and pharmacy benefit manager (PBM) policies that discriminate against covered entities based on their participation in the 340B program, often through lower reimbursement for 340B drugs or other discriminatory contract provisions. This too, is an area that states have taken the lead on with a patchwork of laws across the country.

We also are grateful for the codification of Congress' intent to continue to support the purpose of the 340B Program and to stretch scarce federal resources allowing for greater patient access to care. Congress made clear in the enactment of the 340B Program that certain safety net providers, such as disproportionate share (DSH) hospitals, should qualify for 340B discounted pricing by virtue of the critical services they provide to their underserved communities and for which they receive special federal funding. The program is not funded by taxpayers, yet it provides significant benefits to assist safety net providers serving the most underserved patients in our communities.

However, Congress did not dictate how these organizations should use their savings, and we believe that any changes that limit the use of savings to charity care only would run counter to the initial intent of the 340B statute. Indeed, such requirements would be unnecessary because safety net providers, by virtue of their "safety net" status, serve vital roles supporting uncompensated care and other un-/under-reimbursed services in their communities. In addition to being unnecessary, establishing specific requirements for the use of this revenue (beyond those otherwise required under myriad federal and state laws already in place) would place new administrative burdens on safety net providers and actually consume more scarce resources subverting the intent of the 340B Program.

Also, HOSP is disappointed that the legislative proposal does not modify the 340B statutory prohibition against obtaining covered outpatient drugs through a group purchasing organization (GPO), which is burdensome to manage in this age of drug shortages. Under the GPO prohibition, disproportionate share hospitals (DSH) and certain other hospitals participating in the 340B program may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." We respectfully request you consider including repeal of the GPO prohibition in your final legislation.

We appreciate the opportunity to share with you why continued support for the 340B Program helps our members improve patient outcomes, lowers the total cost of care, and provide critical services to our

communities. As a national coalition of covered entity providers, we have seen first-hand how this program positively impacts the ability to care for all of our patients, particularly the most vulnerable. Our members use 340B savings to meet the original intent of the program, reaching more eligible patients and providing more comprehensive services to the community at large. Any changes that Congress considers should remain true to the original intent of the Program to stretch scarce federal resources as far as possible, particularly in a time where healthcare providers face significant budget challenges and workforce shortages.

1. Congress must protect the existing patient definition issued in HRSA's 1996 guidance.

Arguably the most significant proposal would be any changes to the current patient definition from the 1996 guidance from the Health Resources and Services Administration (HRSA).

We strongly hold the view that HRSA's current enforcement of its patient definition from the 1996 guidance, should remain in place. Changes, after over twenty years of use, would not only potentially limit the use of the program but also cause significant confusion resulting in reduced care for the most vulnerable patients. Restricting 340B eligibility would reduce our members' ability to provide enhanced patient care, reduce the total cost of care for our patients, and strengthen our ability to serve our local communities. Additionally, shrinking the scope of patient eligibility would also reduce the amount of savings that go to supporting the uninsured or under-insured (including covering gaps in Medicaid and Medicare) and limit ancillary services such as, patient transportation, food, language services, and other services aimed at improving the patient's holistic care.. It is notable that these underserved patients also tend to be the sickest and often suffer from multiple chronic conditions and are more costly to treat.¹

It is important to emphasize that we also strongly disagree and oppose any adoption of any proposal similar to those changes proposed by HRSA to the patient definition in 2015 in its omnibus guidance. It was understood that the intent of that proposed guidance was an attempt to balance the intersecting interests of drug manufacturers and various categories of covered entities while adhering the original spirit of the program's intent. However, a number of provisions in the proposed guidance represented a drastic change to a twenty-year-old definition and only resulted in restricting eligibility and negatively impacting the Program as a whole. Specifically, the proposed guidance:

- Banned using 340B for discharge prescriptions which likely would have increased readmission rates.
- Requiring infusion orders to be written from the administering hospital to qualify for 340B discounts and restricting patient's accessibility and choice in care.
- Classifying any patient who received care within 72 hours of admittance as inpatient which would have resulted in administrative challenges and increased costs to care.
- Requiring prescriptions to be written by hospital employees or independent contractors such that the hospital may bill for services on behalf of the provider ignores the realities of the hospital setting and current system of care delivery and would make use of the 340B Program operationally impossible for many hospitals.

¹ <https://www.340bhealth.org/files/340B-Hospitals-What-the-Research-Says-FINAL.pdf>

The proposed guidance's cumulative burden would have devastated the majority of 340B hospitals, threatening access to necessary critical care to the most vulnerable patients contrary to the Program's intent. Restrictions on using 340B discounts for many drugs paid for by Medicaid would also be problematic, since the 340B program is intended for hospitals that treat high percentages of Medicaid patients. Similarly, the Discussion Draft's changes to the patient definition would also potentially significantly limit the scope of the program and negatively impact patient access to care.

It is critical that the cumulative impact of any other changes to the text beyond the patient definition section be considered in terms of how they may impact patient definition. For example, the proposed child site provisions limit eligibility by requiring the hospital's prescriber having clinical responsibility for health care services directly related to use of the 340B drug. The provisions appear to not only require prescriptions to originate in the covered entity, but also requires the hospital be directly responsible for the condition being treated by the 340B product. This ignores the reality of modern healthcare delivery in the hospital setting. Further, this would be operationally impossible for many hospitals to implement rendering the 340B program unusable. Other proposals limit child site eligibility to those sites that provide a "clinically meaningful range of services" by either hospital employees or "bona fide contractors." These provisions would result in significant limitations on the use of the 340B Program for discharge prescriptions, referrals (including those from clinics owned by the health system), and potentially for infusion clinics and medication therapy management. Pharmacists (and other prescribers) are important extensions of patient care provided in conjunction with the medical staff and these services should not be excluded from 340B eligibility.

Lastly, *Genesis v. Becerra*² found HRSA already has the authority and the obligation to issue guidelines to implement its interpretations of 340B negating the need to grant HRSA additional enforcement authority.

2. Congress must protect benefits the 340B Program provides to our local communities, including at child sites.

Child sites are locations that are part of our members' systems that allow them to serve patients directly in their local communities. Despite addressing other child site matters, the proposed draft leaves open a potential limitation of child sites based on their proximity to the hospital. These proximity restrictions would only serve to undermine the 340B program's intent by depriving patient access to care and reducing the total funds available to provide for each community's unique needs. Similarly, such restrictions would limit the ability to provide care in locations where it is most needed. systems to provide to the communities where they are most needed. Health system-owned specialty pharmacies, which make up our Membership, are local-regional in nature, providing a far better care model than distant options.

We also view proposals in the Discussion Draft that require covered entities to report on 340B savings in ways that are inconsistent with 340B's purpose as incongruent with the program's objectives. For

² *Genesis Healthcare, Inc. v. Becerra*, 39 F.4th 253 (4th Cir. 2022)

example, hospitals would be required to report only on the charity care provided on a child site-specific basis, Alleviating high uncompensated care costs (charity care + bad debt) is only one of many ways that hospitals use their 340B savings. Alone, it does not reflect the full spectrum of how covered entities use those savings to support their local communities. For example, many of our members provide wraparound services to help identify and support other needs, including transportation, translation, and food services. In addition, reporting charity care on a child site-specific basis is inconsistent with a tenet of 340B that savings from one location can be used in other locations, depending on the needs of the community.

The proposed reporting and transparency requirements will pose additional burdens on our members, who are already overwhelmed with budget challenges and workforce shortages. Also, covered entities would be required to report 340B savings based on a definition that does not reflect, and in fact would significantly overstate, the true savings. The Discussion Draft defines the savings as the wholesale acquisition cost (WAC) less the 340B acquisition cost. However, the true value of 340B savings is based on the GPO price of a drug, less the 340B acquisition cost. We urge a more accurate representation of the actual savings for covered entity reporting requirements. We reserve judgment on whether we support these requirements until we view the text in its entirety.

3. Congress must protect covered entities and their patients from harmful manufacturer 340B policies.

As we noted above, we are grateful for the provisions in the Discussion Draft protecting contract pharmacy arrangements since it permits increased access to care and a greater ability to treat the chronically ill. Unfortunately, manufacturer restrictions have only increased since last summer, and the restrictions are posing an insurmountable burden on our members.

The RFI also seeks input on possible contract pharmacy limitations, but we do not know of a clear policy reason to limit contract pharmacy by geography, number of arrangements, or by targeting specialty drugs. What we do know however is that increased patient access leads to better quality of care and improved patient outcomes. Our health systems represent multiple hospitals, but generally only own one integrated specialty pharmacy per system. Given the complexity and high cost of specialty drugs, these therapies are subject to strict payer restrictions and manufacturers' limited distribution requirements. This makes an in-house specialty pharmacy invaluable to a health system because the model provides integrated, high-touch care with electronic medical records shared with providers, which streamlines patient access and lowers costs, versus a mail-order specialty pharmacy fragmented model that is detached from patients and their providers.

While many hospitals do not have their own integrated specialty pharmacies and rely instead on outside mail-order specialty pharmacies, manufacturers have been tightening their contract pharmacy restrictions to a point that many now prohibit the number of contract pharmacy arrangements even within a health system, with no exception for wholly owned pharmacies that may have multiple “contracts” with hospitals owned by the same parent health system. In addition to restricting the number of contract pharmacies, they are placing distance restrictions on where a contract pharmacy is located, again without exceptions for wholly owned pharmacies that serve multiple hospitals and are located at

varying distances from the parent system. This significantly limits patient access to pharmacy options even within a health system because it treats the system’s own hospitals as “contract pharmacies.” Placing codified restrictions like these on the number, geographic location, or type of pharmacy would limit our systems’ ability to even use our own, integrated specialty pharmacies by our own hospitals for our own patients, not to mention patient access to drugs from contracted pharmacies closer to their location.

4. Congress must protect covered entities from harmful payer/PBM 340B policies.

As we noted, we are grateful for the provisions in the Discussion Draft that would prohibit discrimination against 340B entities. No federal protections exist to prohibit payers and pharmacy benefit managers (PBMs) from discriminating against providers based on their 340B participation, and our members are located nationwide, with a patchwork of state laws and enforcement mechanisms.

5. Congress should be clear about any regulatory authority provided to the Health Resources and Services Administration (HRSA) for oversight of the 340B Program.

HRSA has been successfully enforcing its statutory authority against covered entities for decades. For example, HRSA implemented its patient definition guidelines in 1996 and this guidance is still being followed today. Moreover, HRSA conducts at least 200 audits of covered entities per year, and findings requiring repayment to manufacturers are low. Ensuring that HRSA has the necessary rulemaking authority to develop, oversee and enforce the rules of the 340B Program is essential to maintaining the program. We believe that the notice and comment rulemaking process would allow the public and 340B stakeholders to bring important considerations to HRSA’s attention and to strengthen HRSA’s administration of the 340B Program.

However, any consideration to grant HRSA additional regulatory authority with respect to covered entities should be balanced and accompanied with clarifying guardrails that serve to support the fundamental scope of 340B without allowing it to restrict the scope of the program or impose additional undue burdens on covered entities. In the past, HRSA has proposed guidance that would have undermined Congress’ stated purpose of the 340B Program by significantly limiting the patients and facilities that could qualify. 340B is a critical program relied on by our members that should not be subject to changes by an administrative agency through the use of broad regulatory authority that could intentionally or unintentionally result in a dramatic reduction of 340B for providers.

6. Congress should protect covered entities from state Medicaid policies that limit covered entity access to 340B benefits.

Any changes to the 340B Program should serve to strengthen the Program’s ability to support entities and the eligible patients who they serve. Recent policy changes that “carve out” the managed Medicaid pharmacy benefit programs, such as those in California and New York,³ have done the opposite. Those

³ HOSP, *Letter to Sen. Krueger regarding Repeal of the Medicaid Pharmacy Benefit “Carve-Out” in FY23-24 Proposed Budget* (Feb. 27, 2023), <http://hospalliance.org/wp->

state policies have shifted the funding opportunities provided by the 340B Program from the intended beneficiaries, covered entities and their patient communities, to state coffers. Not only are covered entities deprived of the benefit of the 340B discount, but they are often forced to operate at a loss. This is critically important for specialty pharmacy drugs, which are complex and require much more pharmacy intervention than the simple dispensing of a traditional retail drug.

Congress should continue to preserve 340B use by covered entities for Medicaid managed care organizations (MCOs). However, the draft proposes to change federal law by shifting the obligation for preventing Medicaid managed care (MCO) duplicate discounts from states to covered entities. Covered entities would be liable and required to repay manufacturers for MCO duplicate discounts, without exceptions for errors made by the state or the MCO. Already, state Medicaid program requirements vary; some require point-of-sale identification with claim modifiers that most covered entities cannot meet. These proposed changes may effectively result in forcing most covered entities to carve-out Medicaid MCOs, even though serving Medicaid patients are the basis for a covered entity being eligible for the 340B program.

In that same vein, while a uniform process for preventing duplicate discounts through an independent claims data collection clearinghouse is appealing, we would like to see more details on how the data would be used. For example, who the data would be provided to and for what purpose, more clarity around the program integrity functions, and how the clearinghouse would actually prevent duplicate discounts. We also believe that the new claims data collection clearinghouse should be limited to Medicaid and used only to prevent Medicaid duplicate discounts. We do not believe that covered entities should be required to submit commercial claims data for the purpose of assisting manufacturers with their contracts with PBMs, such as providing commercial claims data so they can ensure that PBMs are complying with their voluntary agreements to provide rebates. We reserve further judgment on whether we support the concept until we view the text in its entirety.

7. Conclusion

The 340B statute and definitions currently allow HOSP's members the flexibility they need to provide services that are specifically designed to meet the needs of our communities. We are grateful for proposals in the Discussion Draft that support the premise of the 340B program. However, until a full text of the bill is complete, we are unable to fully assess the impact of the proposed changes.

We continue to be proud of our members' ability to deliver exemplary patient care and improved patient outcomes. These results are only achievable because our members are the best positioned to alleviate barriers in their own communities to accessing specialty medications for their chronically or severely ill patients. Allowing patients, especially disenfranchised individuals, to choose care provided through an integrated specialty pharmacy ensures they receive effective care coordination with their medical and pharmacy providers through frequent communication in-clinic or through shared electronic medical records. We believe that the local-regional care that patients receive from integrated system-owned

content/uploads/2023/03/health_system_owned_specialty_pharmacy_alliance_-_hosp_.pdf, last visited July 26, 2023.



Health System Owned
Specialty Pharmacy Alliance

specialty pharmacies is a far better model of care. None of this would be achievable without the 340B Program and any changes will reduce access to care and harm both providers and patients in local communities alike.

Sincerely,

A handwritten signature in blue ink that reads "Gary Kerr".

Gary Kerr
President
Health System Owned Specialty Pharmacy Alliance