



July 28, 2023

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 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 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 Senate's request for 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 under threat from recent, unprecedented drug manufacturer actions that undermine the Congress's intent in establishing the Program.

The 340B Program was established in 1992 by Congress in response to the dramatic increase in drug prices following establishment of the Medicaid Prescription Drug Rebate Program in 1990. The Drug Rebate Program requires drug manufactures to provide state Medicaid programs with rebates for covered outpatient drugs. In the two years following implementation of the Medicaid Drug Rebate Program, drug manufacturers dramatically increased drug prices to compensate for revenue lost to Medicaid drug rebates. In 1991, drug manufacturers increased prices by approximately 23%, and then

by another 25% in 1992.¹ The 340B Program, established by Congress in 1992, served to protect safety net healthcare providers from these drug price increases, implemented to protect manufacturer revenue in the face of the Medicaid Drug Rebate Program.

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 provided to their underserved communities and for which they received special federal funding. The 340B Program is not funded by taxpayers, yet it provides significant benefits to safety net providers serving the most underserved patients in our communities. Congress did not dictate how these organizations should use their savings. Indeed, such requirements would have been unnecessary because safety net providers, by virtue of our “safety net” status, serve vital roles supporting uncompensated care and other un-/under-reimbursed services in our communities. Establishing specific requirements for the use or disclosure of revenue (beyond those otherwise required under myriad federal and state laws already in place) would have been not only unnecessary, but such requirements would have placed new administrative burdens on safety net providers, actually consuming our scarce resources in opposition to the purpose of the 340B Program. These same considerations still exist today.

We disagree with the inference in many of the RFI’s questions that there are material concerns surrounding oversight of 340B covered entities or covered entity compliance with the 340B Program’s requirements. These suggestions are simply not supported by the facts, and we respectfully urge you to consider the lack of evidence supporting these suggestions. These suggestions distract from the real and growing threat to the 340B Program, that being manufacturers’ express disregard for their obligation under the 340B statute to provide discounted prices to covered entities.

We appreciate the opportunity to share with you why continued support for the 340B Program helps our members improve patient outcomes, lower the total cost of care, and provide critical services to our communities. As a coalition of providers in many states who provide specialty pharmacy care within our hospitals, we have seen first-hand how this program positively impacts the ability to care for all patients in our communities, and importantly, those who are the most vulnerable. As covered entities, our members use 340B savings to meet the original intent of the program, reaching more eligible patients and providing more comprehensive services. Any changes that Congress considers should remain true to the intent of the Program to stretch scarce federal resources as far as possible, particularly following the COVID-19 pandemic, which has resulted in significant budget challenges and workforce shortages for our members.

1. Congress must protect the benefits the 340B Program provides to our local communities.

Contrary to what some stakeholders may say, 340B is not limited to funding care for the uninsured, covering the costs of uncompensated care, or providing discounts on drugs, though it certainly plays a

¹ See, e.g., Health Care Finance Review, Vol 25, Iss. 3, 5-23 (2004) (citing data from the Centers for Medicare and Medicaid Services), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194863/> (last visited July 18, 2023).

significant role helping to fund those activities. We rely on the Program as a sustained and reliable source of flexible funds our members reinvest locally to meet the unique needs of our communities. Specifically, the program ensures that patients from our communities have the continuity of care from their provider through to their pharmacy for the most difficult, specialty conditions to treat, rather than being sent or redirected to an out of area/out of state mail order specialty pharmacy. Health system-owned specialty pharmacies are local-regional in nature, providing a far better care model. The Program helps our members serve uninsured and/or low-income patients who need access to specialty clinics that provide lifesaving treatments such as organ transplants, complex cancer care, immunological care (including bone marrow transplants), neurological and neurosurgical care, cardiovascular care and cardiothoracic surgery. The Program also supports critical services for chronic care management, including for HIV and Hepatitis C patients, as well as transportation services, nutrition and diabetes education programs, among many others. Because of the 340B Program, our members' integrated specialty pharmacies help hospitals provide a higher quality of care, measurably improved outcomes, faster times to therapy, reduced readmissions, and broad community support that helps break down barriers to health inequities – all at a reduced total medical expense.²

Our members are mostly 340B DSH hospitals, which are a mix of urban and rural hospitals, and they provide 77% of the hospital care provided to Medicaid patients and 67% of all hospital uncompensated care while having extremely tight operating margins.³ 340B savings support much more than care for Medicaid patients and those unable to pay. For all types of hospitals, 340B supports a wide range of programs and services targeted to meet the health and social needs of underserved populations as well as the broader community, many of which would not otherwise be financially sustainable.⁴

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

Even with the success of the Program, 340B hospitals are hurting due to the increasing number of drug manufacturers placing severe restrictions and policies that limit access to 340B pricing. 340B Health estimates the 21 manufacturers restricting contract pharmacy as of June 1, 2023 are responsible for a combined \$8.4 billion in lost 340B savings for hospitals.⁵ Without action to stop this behavior, the

² HOSP, Best Practices, The Health System Specialty Pharmacy Integrated Care Model: Delivering Patient-Centric Care (Aug. 24, 2022), http://hospalliance.org/wp-content/uploads/2022/08/Best-Practices-The-Health-System-Specialty-Pharmacy-Integrated-Care-Model-Delivering-Patient-Centric-Care-HERO-Committee_8.24.2022.pdf?utm_source=website&utm_medium=download&utm_campaign=whitepaper, last visited July 26, 2023.

³ Dobson and DaVanzo Health Economics Consulting. 340B DSH Hospitals Serve Higher Share of Patients with Low Incomes (Sep. 2022), https://www.340bhealth.org/files/340B_and_Low_Income_Populations_Report_2022_FINAL.pdf, last visited July 26, 2023.

⁴ 340B Health. *340B Health Annual Survey 2022: Vital 340B Supported Patient Services Threatened as Manufacturer Restrictions Cut Into Savings* (July 2023), https://www.340bhealth.org/files/340B_Health_Survey_Report_2022_FINAL.pdf (last visited July 26, 2023).

⁵ 340B Health, *Drugmakers Pulling \$8 Billion Out of Safety-Net Hospitals*, https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf (July 2023), last visited July 20, 2023.

trend will lead to all manufacturers adopting these restrictions. The restrictions are a patchwork of requirements that vary by manufacturer and drug, posing an insurmountable burden on our members. These issues are hitting 340B hospitals at a time when they are still recovering from the COVID-19 pandemic and dealing with severe workforce shortages. These restrictions are taking money away from covered entities and the patients they serve and putting it directly in the pockets of manufacturers, who generate billions of dollars in profit without any obligations or restrictions on how these profits are used. As noted above in more detail, we believe that Congress needs to act to prevent these discriminatory practices.

Many of these manufacturers appear to be intentionally targeting the kinds of high-cost specialty drugs that our members administer and dispense. Our members provide unique and high-impact wrap-around pharmacy services for these drugs, which often include same-day delivery, unique packaging to improve adherence, and 24x7 access to a clinical pharmacist. Such actions remove a significant share of the drug market from 340B – all impacting our health systems’ patients the hardest. While many hospitals do not have their own specialty pharmacies and rely instead on contract specialty pharmacies or pharmacies owned by their parent systems, manufacturers have been tightening their restrictions to a point that many are now prohibiting contract pharmacy entirely for hospitals, with no exception for system-owned pharmacies, and/or placing distance restrictions on where a contract pharmacy is located relative to the hospital, which significantly limits specialty contract pharmacy options. Our health systems represent multiple hospitals, but generally only own one integrated specialty pharmacy per system. Manufacturer restrictions are now limiting our systems’ ability to even use our own, integrated specialty pharmacies by our own hospitals for our own patients.

Congress should protect covered entities, particularly those that own their own specialty pharmacies in-house, from restrictive and disparate manufacturer policies through legislation that clarifies that manufacturers are required to offer 340B pricing for drugs dispensed at our own pharmacies and prohibit manufacturers from implementing conditions or restrictions that are designed to dissuade or inhibit a covered entity’s ability to purchase drugs at the 340B price.

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

No federal protections exist to prohibit payers and pharmacy benefit managers (PBMs) from discriminating against providers based on their 340B participation. Examples of payer policies that directly or indirectly discriminate against 340B providers include lower reimbursement based on 340B participation, 340B claim identification requirements (other than for Medicaid programs to prevent duplicate discounts), and “whitebagging” requirements that limit a patient’s ability to fill prescriptions at a 340B pharmacy in our hospitals by requiring that drugs be filled by outside mail order specialty pharmacies and shipped directly in to hospitals, clinics and physician offices, interfering with chain of custody controls and adding unnecessary management burdens on those receiving locations.

Congress should consider enacting the PROTECT ACT (H.R. 2534⁶) to protect covered entities from

⁶ PROTECT 340B Act of 2023 (H.R. 2534), <https://www.congress.gov/bill/118th-congress/house-bill/2534/text> (last visited July 26, 2023).

discriminatory payer policies at the federal level. If enacted, the PROTECT ACT would prohibit payers from lowering reimbursement for 340B providers, requiring 340B claims identification, removing 340B providers from the payer’s network solely because they participate in 340B, or taking any action that would interfere with the covered entity’s ability to use 340B for its eligible patients. The 340B program is intended to allow participating entities to support patient care services, not financially benefit for-profit insurers.

4. Congress should be clear about any changes to the Health Resources and Services Administration (HRSA) oversight of 340B.

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 carefully considered, and accompanied with clarifying guardrails that serve to support the fundamental scope of 340B without imposing additional undue burdens on DSH covered entities, including health system-owned specialty pharmacies, clinicians, and other providers. 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 for the Program. 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.

It is equally important for HRSA to have sufficient resources to properly administer the Program, but also for HRSA to efficiently utilize its resources for the betterment of the 340B Program. For example, devoting resources to auditing almost 200 covered entities in 2022 while auditing only five manufacturers in the same time period would not appear to be the most appropriate use of HRSA’s resources. This is further exemplified by the continued and increasing instances of manufacturer violations of the 340B Ceiling Price Rule.⁷

5. Congress should enact legislation that prohibits state Medicaid “carve out/carve in” 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

⁷ 83 Fed. Reg. 55135 (Nov. 2, 2018); HRSA, *Program Integrity*, <https://www.hrsa.gov/opa/program-integrity> (July 2023), last visited July 20, 2023 (citing manufacturer violations).

pharmacy benefit programs, such as those in California and New York,⁸ have done the opposite. Congress should prohibit state Medicaid carve-in/carve-out policies that take away covered entities' ability to benefit from the 340B Program. Those state policies shift the funding opportunities provided by the 340B Program from the intended beneficiaries, covered entities and their communities, to the state coffers, either through requiring 340B providers to use 340B for Medicaid patients, and then reimbursing them only at cost for the drugs or prohibiting covered entities from using 340B for Medicaid patients altogether (i.e., mandatory Medicaid carve-in policies and/or mandatory Medicaid carve-out policies). In both situations, the covered entity is not only deprived of the benefit of the 340B discount but is 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 retail drug.

6. Congress should refrain from enacting legislation that reduces hospital participation in 340B or places unnecessary burdens on 340B providers.

340B Program critics have advocated for cuts to 340B, including removing certain hospitals or hospital locations from 340B participation or limiting patients that currently qualify for 340B drugs. Some stakeholders are advocating for hospitals to be required to report data for each registered child site, including 340B savings, payer mix, and charity care. Such irrelevant and unworkable data reporting requirements would pose an excessive burden on 340B hospitals. Post-pandemic recovery at many systems is also proving extremely difficult. Hospitals are treating patients amid high inflation, increased labor costs, significant budget constraints, and other factors. These challenges have hit especially hard for 340B hospitals, many of which are operating at negative margins. 340B cuts and/or new reporting requirements would only exacerbate these challenges. Moreover, all hospitals already report extensively on finances through the Medicare Cost Report, and non-profit hospitals have additional reporting requirements via the IRS Form 990, their community health benefits report, and their community needs assessment.

Covered entities currently undergo substantial HRSA audits that ensure transparency in the program. HRSA requires all covered entities to be recertified each year to assure integrity, compliance, transparency, and accountability. Providers and manufacturers are also subject to audits to ensure they are in compliance with 340B program requirements, but since 2012, HRSA has conducted more than 1,800 audits of 340B providers and only 36 audits of pharmaceutical manufacturers. We recommend that Congress require HRSA to increase the number of audits on manufacturers to ensure that manufacturers are complying with program rules and requirements, and not consider additional burdens for covered entities that are already subject to extensive reporting and auditing activity.

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 concerned that additional policies that require complex reporting mechanisms would limit our ability to serve patients. We recommend that Congress be cautious of implementing administratively complex and new reporting

⁸ 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-content/uploads/2023/03/health_system_owned_specialty_pharmacy_alliance_-_hosp_.pdf, last visited July 26, 2023.



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requirements, which can be duplicative of existing reporting requirements, or require significant investment in the development of new information technology to comply with new reporting requirements. Importantly, any new reporting requirements will divert our resources from providing patient care and community benefits with minimal, if any, practical purpose.

7. Conclusion

Our members' integrated specialty pharmacies deliver exemplary patient care and improved patient outcomes because they are best positioned to alleviate barriers to accessing specialty medications for their 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. This local-regional care patients receive from integrated system-owned specialty pharmacies is far better. Patients are treated in their own communities, rather than receiving complex treatments and defragmented care from mandatory mail-order pharmacy entities who are often out of state. None of this would be achievable without the 340B Program. Any changes that reduce access to care as a result will harm 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