Catholic Health Association of the United States

*We Will Empower Bold Change to Elevate Human Flourishing.*SM

April 1, 2024

The Honorable John Thune
United States Senate
511 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow
United States Senate
731 Hart Senate Office Building
Washington, D.C. 20515

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

The Honorable Tammy Baldwin
United States Senate
141 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 L. Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

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

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of more than 665 hospitals and 1,600 long-term care facilities and other health facilities in all fifty states, I am writing in response to your request for feedback on the SUSTAIN 340B Act discussion draft.

As a health care ministry of the Catholic church, CHA and its members are committed to respecting the human dignity of each person, promoting the common good, having special concern for low-income and other vulnerable persons, and being responsible stewards of resources. These foundational beliefs drive our long-standing commitment to ensuring that every patient has access to quality care regardless of ability to pay and that all persons in our communities reach their highest potential for health. The 340B program plays a vital role in supporting the work of more than 386 CHA member 340B providers as they work to meet these commitments to their communities.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers that participate in the Medicaid program to provide covered outpatient drugs at a discounted rate to nonprofit safety-net and other health care facilities serving low-income, vulnerable communities or remote rural areas. The pharmacy discounts available under the program allow hospitals to continue to provide and expand needed services that otherwise would not be available in these communities. To be eligible, a hospital must be nonprofit, owned or

operated by or under contract with state or local governments, and provide significant care to low-income patients or serve rural communities.

CHA commends your commitment to strengthening and protecting the 340B program. We welcome this opportunity to provide feedback on the SUSTAIN 340B Act discussion draft and look forward to working with you to ensure the 340B program continues to support the vital needs of patients and communities. **To that end, we strongly support the SUSTAIN 340B Act's reiteration that Congress's goal of the 340B program is to stretch scarce federal resources by requiring drug manufacturers, as a condition of participation in the Medicaid and Medicare programs, to provide discounts to covered entities that serve a disproportionate share of low-income patients. In addition, we welcome the efforts to address the egregious behavior of drug manufacturers in unilaterally restricting the use of contract pharmacies and imposing new requirements on participation in the program. However, we are concerned that some of the Act's proposals around the patient definition, new and duplicative reporting requirements, and other operational aspects of the 340B program would undermine the program's goal to "stretch federal resources" to serve patients and communities serving low-income individuals.** We look forward to working with you to address these concerns and ensure the 340B programs remain critical to the healthcare safety net.

I. Intent of 340B program (Section 2 of SUSTAIN Act)

For over 30 years, the 340B program has supported the health care safety net by requiring drug manufacturers, as a condition of participation in Medicaid and Medicare, to provide discounts to covered entities that serve a disproportionate share of low-income patients. These discounts support the underlying goal of the 340B program (42 U.S.C. 256b) to provide "scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] Savings from 340B allow providers, for example, to run free and low-cost clinics to provide services in remote or low-income areas, offer generous financial aid policies, provide low-cost or free prescriptions, maintain critical services that operate at a loss, and support community programs meeting the identified needs of their service areas.

We **welcome the effort in Section 2 of the SUSTAIN 340B Act to provide further clarity on the intent and purpose of the 340B program a**t a time when drug manufacturers and broader community perceptions continue to misunderstand and distort

[1] "340B Drug Pricing Program - Official website of the U.S. Health Resources & Services Administration". *Hrsa.gov*. retrieved 20 October 2020. *See* H. Rep. No. 102-384, Pt. 2, at 12 (1992); *See also* See H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). See also Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act).

the purpose of the 340B program. Clearly, reiterating the long-established current law on the purpose and goal of the 340B program helps to address some of the abuses taking place by those seeking to change the program's role.

II. Contract pharmacies and restrictions on participation (Section 3 of SUSTAIN Act)

Contract pharmacies serve as an extension of the 340B provider and provide patients critical access to prescription drugs outside of the four walls of the hospital or community clinic. These arrangements, where a 340B covered entity contracts with a local pharmacy with 340B providers and community and specialty pharmacies, have been recognized by HRSA since 1996 and are a crucial tool for allowing patients to receive drugs rather than travel long distances to pick up prescriptions. These contract pharmacies also promote patient access by allowing hospitals to help patients access drugs that may be in limited distribution or supply.

340B hospitals have long partnered with local and specialty pharmacies to promote patient access to prescribed medications. This arrangement provides patients with access to needed medication at their local community pharmacy or through mail-order specialty pharmacies. Nearly half of all Americans live within one mile of a pharmacy, and 89% live within five miles.[2] This accessibility provides patients with convenience and a familiar and consistent source of care.

The importance of local pharmacies is even more critical in rural communities where half of all people live more than 10 miles from their nearest hospital and, therefore, rely on pharmacies that are local or easily accessible.[3] As a result, 80% of rural counties had a local 340B contract pharmacy and 74% of counties with higher-than-average uninsured populations had 340B contract pharmacies serving their communities.[4]

Despite the success of the 340B contract pharmacy arrangements in expanding access to necessary medications, drug manufacturers continue to take unlawful unilateral actions to restrict access to 340B drugs purchased through established arrangements with community and specialty pharmacies.

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[2] Lam, O., Broderick, B., & Toor, S. (2018, December 12). *How far Americans live from the closest hospital differs by Community Type*. Pew Research Center. https://www.pewresearch.org/short-reads/2018/12/12/how-far-americans-live-from-the-closest-hospital-differs-by-community-type/#:~:text=Rural%20Americans%20live%20an%20average,to%20a%20new%20Center%20analysis

[3] *Id.*

[4] American Hospital Association, *340B Arrangements with Community and Specialty Pharmacies Provide Essential Services to Underserved Communities* https://www.aha.org/system/files/media/file/2024/02/340B-Contract-Pharmacies-Infographic-20240212.pdf

These restrictions have dramatically limited the availability of the 340B program to cover prescriptions filled by patients. In rural communities, these restrictions mean patients must travel many miles to access a pharmacy for their medications. This restriction has resulted in critical access hospitals reporting annualized losses of over $500,000 and disproportionate share hospitals (DSH) losing nearly $3 million annually.[5] As of June 1, 2023, these unilateral restrictions on contract pharmacies have resulted in more than $8.4 billion in annual 340B savings facing further restrictions or elimination.[6]

In addition to limiting the use of contract pharmacies, drug manufacturers have also sought to undermine the 340B program by imposing new restrictions and conditions on participation in the 340B program, such as attempting to turn the 340B program into a rebate program or requiring additional claims reporting by providers. These efforts highlight the critical importance of ensuring that any reforms of the 340B program provide strong enforcement tools that allow the HHS Secretary to prohibit any and all inappropriate restrictions or conditions on the distribution or access to 340B priced drugs.

Recommendation: The SUSTAIN 340b Act takes a critical first step in providing such protections by prohibiting drug manufacturers from refusing to offer or deliver 340B drugs to covered entities or their contract pharmacies, prohibiting unilateral restrictive distribution policies, and prohibiting drug manufacturers from requiring covered entities to submit data directly to themselves. In addition to this promising start, **we encourage you to further protect the 340B program by giving the HHS Secretary additional authority to restrict any and all efforts by drug manufacturers to provide new restrictions or conditions on the distribution of 340B-priced drugs. Such authority would help to sustain the underlying goal of the 340B program and future-proof the 340B program from efforts by drug manufacturers to create loopholes that harm the 340B program.**

A. Response to request for information regarding proposals for geographic or other restrictions on contract pharmacies.

As stated, contract pharmacies are a critical component of the 340B program and fundamentally vital tools for supporting the 340B program's effort to maintain and expand access to care. These networks of local and specialty pharmacies provide easily accessible means for patients to access their prescriptions. This ease of access is particularly critical given that patients visit their local pharmacy more often than they visit their physician or other health care provider.[7] For senior citizens, individuals with mobility challenges, those

[5] https://www.aha.org/news/headline/2022-11-14-aha-survey-drug-companies-reduce-access-care-limiting-340b-community-pharmacies
[6] https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf
[7] Valliant SN, Burbage SC, Pathak S, Urick BY. Pharmacists as accessible health care providers: quantifying the opportunity. J Manag Care Spec Pharm. 2022 Jan;28(1):85-90.

who rely on public transportation and those living in rural communities, this access is essential to ensure patient access to care. Because of this highly varied way individuals access their prescriptions, there is a need for maximum flexibility for covered entities to contract with pharmacies to meet their patient's needs in both urban and rural areas.

Changes in practice and the increasing role of specialty drug pharmacies also demonstrate how geographic or other contract pharmacy restrictions are likely to harm access to care and undermine the goal of the 340B program. Currently, over half of all drug spending and 80% of new drug approvals by the Food and Drug Administration (FDA) are for specialty drugs. The use of contract and specialty pharmacy contracts will be required for the 340B program to meet its goals of supporting safety net hospitals and maintaining access to care.[89]

Recommendation: Efforts to impose geographic or other contracting restrictions would undermine the ability of local hospitals and providers to work with their patient community and local pharmacies to tailor access in a way that best meets their needs. Changing networks of providers and pharmacies, lack of in-house pharmacies, specialty drug handling requirements, transportation changes, or changing needs of patients all demonstrate why a one-size-fits-all geographic limitation is likely to harm patient access in urban and rural communities. **Therefore, geographic or other limitations on the ability of providers to use contract or specialty pharmacies in the SUSTAIN 340B Act would directly and negatively impact patient access and create future financial challenges for providers and safety net hospitals, which would no longer have the flexibility they need to meet the changing demands of patients.**

III. Patient Definition (Section 4 of SUSTAIN Act)

Since 1996, the Health Resources and Services Administration (HRSA) has issued guidance on the definition of the patients under the 340B program. Under this guidance, the definition of a patient relies largely on whether the patient has a relationship with the 340B covered entity as assessed by looking at whether the individual (1) receives services from a health care professional who has an arrangement with a 340B covered entity; (2) whether the covered entity is responsible for the care and (3) whether the covered entity maintains the records for the care.[10] For nearly thirty years, this definition has provided the flexibility needed for covered entities and the 340B program to evolve and change to meet new and emerging challenges. For example, the flexibility of the patient definition has been critical for providing the flexibility needed for telehealth to grow and become a vital aspect of patient access to care.

[8] https://blog.navitus.com/specialty-pipeline-2022-0

[9] https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf

[10] https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf

Recommendation: As you consider potential changes or limitations on the "patient" definition or creation of a "meaningful relationship" standard, we urge you to consider how such changes would correspond with the stated goal of the 340B program, as expressed in Section 2 of the SUSTAIN 340B Act. The goal of the 340B program, as stated in Section 2 of the SUSTAIN 340B Act, is to "maintain, improve, and expand patient access to health care services." Providing a narrower patient definition than the 1996 HRSA guidance would result in the SUSTAIN 340B Act having the opposite impact of the stated goal of the program and would result in restrictions and limitations to patient health care services, rather than their maintenance or expansion. **Rather than narrowing the patient definition, Congress should instead focus on fully implanting the 340B Administrative Dispute Resolutions (ADR) process established 14 years ago, which still has not been implemented to adequately protect against the diversion of drugs or disputes in the program. CHA, therefore, continues to support the existing HRSA guidance on patient definition as sufficient and would have concerns over legislating the issue in a way that results in undermining the goal of the 340B program and in turn limiting access to care.**

IV. Child Site Requirements (Section 5 of SUSTAIN Act)

The growth in child site locations as part of the 340B program is a direct result of the work to improve health by shifting care from hospital-based care to outpatient care. This shift in care has been driven by patient needs and government efforts to improve health outcomes and address rising costs by moving low-cost and less complex services from inpatient to outpatient settings. This trend in outpatient care is expected to continue with a projected growth of 19% in hospital outpatient visits in the next five years.[11] As a result, the use of child sites within the 340B program will likely continue to be a critical part of addressing patient demands and expanding access to care (the stated goal of the 340B program). While we understand concerns raised about the expanded use of child sites within the 340B program, the reality is that this expansion directly corresponds to efforts by safety net providers to "maintain, improve and expand patient access to health care services" (Section 2 of the SUSTAIN Act).

The proposals in the SUSTAIN 340B Act would largely create new restrictions and requirements that would increase the regulatory compliance costs of operating a 340B program while at the same time creating barriers to the ability and desirability for providers to participate in the 340B program. Both of these realities go directly against the goal of the 340B program. For example, the restrictions related to joint ventures would discourage

[11] https://www.businesswire.com/news/home/20210604005089/en/Sg2-Impact-of-Change-Forecast-Predicts-Enormous-Disruption-in-Health-Care-Provider-Landscape-by-2029

partnerships and collaborations among providers to address local health needs. These jointly owned collaborations are particularly critical in rural areas where the lack of specialty care or providers requires greater collaborations amongst providers to meet health needs.

The SUSTAIN 340B Act would also require that covered entities and their child sites be clinically and financially integrated and that the same financial assistance policy and patient assistance policies be applied to the child sites operated by the covered entity. Under the existing child site registration requirements, they are already able to demonstrate how the child site is an integral part of their services through Medicare cost reporting rules. We agree that as a matter of best practices financial assistance policies should extend to child site facilities. However, we remain concerned that the SUSTAIN 340B Act would use the 340B program to make substantial changes and create confusion with existing 501(r) tax code provisions. Therefore, this potentially creates confusion and unintentionally limits critical services where needed.

Similarly, the SUSTAIN 340B Act's proposals around "clinical responsibility for care," "clinically meaningful range of services" and "bona fide contract" requirements all raise substantial questions as to the goal of these provisions and how such provisions would be implemented by providers or enforced by HRSA. While hospitals and child sites are clinically integrated, it is not clear how these new requirements would impact the delivery of care, and it is difficult to see how these provisions would help expand access to care under the 340B program.

Finally, in response to your question about the use of 340B savings in the communities where the child site is located, we continue to support allowing 340B hospitals the flexibility they need to determine how best to allocate their savings to meet community needs. This means these hospitals and child sites are clinically and financially integrated in a way that allows low-income child sites to benefit from the financial support and clinical specialty that the parent hospital provides. **Accordingly, to achieve the goals of the program as set forth in Section 2 of the discussion draft, hospitals should be given the flexibility to determine how best to allocate their savings.**

V. Transparency (Section 6 of SUSTAIN Act)

Catholic hospitals are committed to transparency in the 340B program to ensure its integrity and that the program serves its stated goals. As nonprofit hospitals they are already one of the most regulated aspects of the health care system, with requirements to report prices, uncompensated care, charity care, and community benefit spending through Medicare cost reports and the IRS 990 form Schedule H for tax-exempt hospitals. This includes spending on charity care, community health improvement programs, subsidized health services, health professional education, and coverage of unreimbursed Medicaid. This spending is in addition

to Medicare shortfall expenditures, uncollected bad debt, and other community anchor institution investments that they make that are not collected on the IRS 990 Schedule H.

Catholic hospitals also continue to work to keep hospitals and facilities open at a significant financial loss, which is regularly reported through quarterly financial disclosure statements. In addition, many Catholic health providers have also voluntarily committed to the AHA Good Stewardship Principles that focus on showing how 340B savings benefit their patients and communities. Nonprofit hospitals, including Catholic hospitals, clearly are doing their part to support the health care safety net across the country.

The proposed transparency-related changes in Section 6 of the SUSTAIN 340B Act would create new reporting obligations that are redundant and distract from the true goal of the 340B program to "maintain, improve and expand access to care." One such proposal is the SUSTAIN 340B Act's proposal to require new reporting related to "charity care." This requirement would be on top of the already existing requirement for nonprofit hospitals to report this information in their Medicare S-10 cost reports and in their Schedule H 990 tax filings. This requirement would compound the already sizeable confusion and differences in the current charity care calculations between the S-10 and the Schedule H 990.[12] It would also fundamentally change the 340B program by implicitly prioritizing charity care spending over spending on other community-prioritized needs, such as running free and low-cost clinics to provide services in remote or low-income areas, public health improvement, providing low-cost or free prescriptions, maintaining critical services that operate at a loss, and supporting community programs that meet the identified needs of their service areas.

If the goal of the 340B program as stated in Section 2 of the SUSTAIN 340B Act is to "maintain, improve, and expand access to care" then prioritizing "charity care" would fail to capture when covered entities are using their 340B savings to sustain or expand current health services such as maintaining a behavioral health treatment program, opioid treatment clinic or other health services that are critical to patient needs and may not exist without these efforts. Therefore, we do not support using the 340B program to introduce new "charity care" reporting requirements.

Finally, in order to strengthen the transparency of the 340B program, the discussion draft must look not only at hospitals or covered entities but the entirety of the 340B program. The

[12] See, for example, most recently available "IRS Report to Congress on Private Tax-Exempt, Taxable, and Government-Owned Hospitals," which shows nonprofit hospital charity care as $12,635,759 under the IRS 990 reporting requirements (table 5) and $14,360,441 under Medicare S-10 cost reports (table 1). https://www.grassley.senate.gov/imo/media/doc/3-24-20%20CY%202016%20Hospital%20Report%202020.pdf.

current SUSTAIN 340B Act's transparency requirements are focused exclusively on providers or pharmacies, with no similar requirements related to shared information by drug manufacturers. The 340B program was established as a way to give drug manufacturers access to large Medicare and Medicaid-funded programs in exchange for these drug manufacturers contributing their small part to the health care safety net.

Only requiring transparency for hospitals and health care providers, who are already providing Medicare cost reports on IRS 990 schedule H forms, while requiring no transparency on behalf of drug manufacturers as it relates to their pricing decisions places an even greater burden to support the health care safety net onto hospitals and providers. **If the SUSTAIN 340B Act is going to require new, costly, and burdensome transparency requirements, we urge you to do the same for drug companies.**

VI. Program Integrity (Section 7 of SUSTAIN Act)

HRSA currently has significant authority to oversee the 340B program's implementation and integrity. For 340B covered entities, these program integrity requirements include an annual recertification for 340B providers and an ongoing process for covered entities to evaluate and correct aspects of their 340B program. In addition, covered entities such as hospitals are subject to audits of their 340B program by HRSA and drug manufacturers. As a result of these requirements, HRSA has conducted audits of 1,720 340B health care providers since 2012. The SUSTAIN 340B Act's proposal would dramatically expand the scope of issues covered by 340B audits and would subject contract pharmacies to government audits. Currently, covered entities are responsible for maintaining program integrity and working with government auditors to address deficiencies or concerns. Expanding the scope of issues covered by the audits, increasing punitive sanctions and expanding these audits to contract pharmacies will have a chilling impact on the desire for providers and pharmacies to participate in the 340B program, yet again undermining the goal of the 340B program to "maintain, improve, and expand access to care." **CHA believes that HRSA's current auditing authorities are sufficient to ensure program integrity and do not believe expanding this authority would serve the goals of the 340B program.**

If Congress is concerned about addressing program integrity, then drug manufacturers should also be subject to similar compliance requirements. Currently, drug manufacturers and Pharmacy Benefit Managers face far less scrutiny and oversight of their 340B practices. Providing greater transparency and accountability for all stakeholders in the 340B program would be one way to significantly strengthen the program's integrity. For example, HRSA only audits around five to six drug manufacturers per year to ensure compliance with 340B requirements (31 audits since 2015). At the same time, over 200 covered entity providers

faced audits. **To address this imbalance and promote greater trust and integrity in the 340B program, CHA recommends equalizing the oversight of drug manufacturers and covered entities.** In so doing, we would build trust in the program and ensure that both drug companies and 340B covered entities are held to the same level of accountability.

We have strong concerns over the draft Act's proposal to go beyond the current 501(r)(4)(A) tax requirements for hospital financial assistance policies by extending the implementation of these financial assistance policies to the point of sale at all sites of care, including contract pharmacies. The legislation would also amend the current financial assistance policies established in the tax code by adding a numerical floor at 200% of the federal poverty level for financial assistance policies under 501(r). While the draft legislation intends this change to apply only to the 340B program, the practical reality is that it will fundamentally change how nonprofit hospitals in the 340B program operate by essentially establishing a new financial assistance floor to their 501(r) requirements. The Catholic health ministry has long been a leader in developing community benefit and financial assistance policies. However, discussion drafts proposing changes to financial assistance policies and tax code requirements would create new, highly complex systems to ensure compliance at all point-of-sale sites. It also sets a dangerous precedent of using the 304B program to make changes to the Tax Code. It would also further shift the goal of the program away from allowing local providers the flexibility needed to respond to use their 340B savings in a way that expands access to care and addresses the unique needs of local communities.

Regarding duplicate discounts, current law already prohibits duplicate discounts and manufacturers are not required to provide a discounted 340B price and Medicaid drug rebate for the same drug (see 42 USC 256b(a)(5)(A)(i)). As a result, providers have significant requirements for ensuring that claims are accurate and duplicate discounts do not occur. **The SUSTAIN 340B Act's proposal to establish a third-party national claims clearinghouse is one way to improve program integrity by preventing duplicate discounts between the 340B program and Medicaid. We look forward to working with you to further improve the clearinghouse proposal to mitigate against unintentional duplicated 340B and Medicaid drug rebates on the same drug while at the same time limiting further burdens and expenses on 340B hospitals and other covered entities.**

Finally, CHA also urges Congress to continue to ensure that HRSA has funding to ensure compliance with the 340B program requirements. More resources are needed so that HRSA is able to conduct audits of drug manufacturers to ensure greater oversight and audit parity. **However, the proposed user fee program in the SUSTAIN 340B Act would take away resources intended to support the goal of the 340B program. Instead, we urge you to**

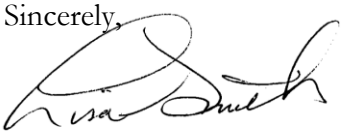
find a different means for funding the program that does not directly take from the financial resources the 340B intended to create.

VII. <u>Conclusion</u>

In conclusion, CHA thanks you for your continued work to strengthen and protect the 340B program. We welcome this opportunity to share our perspective on the discussion draft and look forward to working with you to ensure that 340B continues to serve its critical role in supporting the health care safety net.

If you have any questions, please feel free to reach out to me or to our Senior Director for Government Relations, Lucas Swanepoel, at Lswanepoel@chausa.org.

Sincerely,



Lisa Smith, MPA
Vice-President, Advocacy & Public Policy
Catholic Health Association of the United States