April 1, 2024

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
170 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 Ben Cardin
United States Senate
509 Hart Senate Office Building
Washington, DC 20510

Dear Sens. Thune, Stabenow, Capito, Baldwin, Moran, and Cardin:

On behalf of the Association of American Medical Colleges (AAMC), thank you for the opportunity to comment on the Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B (SUSTAIN 340B) Act and related request for information (RFI). We appreciate your continued interest in the 340B program and look forward to working with you on policy solutions that enhance, rather than limit, the scope of the 340B program, while strengthening covered entities' fundamental role in the health care safety-net.

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

The 340B Drug Pricing Program is critical to AAMC member institutions and the patients and communities they care for. Academic medical centers (AMCs) are a vital part of the nation's health care safety-net, ensuring access to cutting-edge technology, research, and health expertise

for the most medically and socially complex patients. AAMC member institutions provide highly specialized health care services that are often unavailable in other settings, including oncology services, transplant surgery, trauma care, pediatric specialty care, and treatment for rare and complex conditions. For example, although they account for just five percent of all short-term, non-federal hospitals nationwide, AAMC members comprise over 20% of all hospital beds, including 100 percent of all National Cancer Institute (NCI)-designated comprehensive cancer centers, 72 percent of all burn unit beds, 61 percent of all level-one trauma centers, and 63 percent of pediatric ICU beds.[1] AAMC member institutions share a common mission to care for the underserved and train the nation's future health care workforce, making life-saving health care services available to all patients, regardless of their ability to pay. This commitment to high-quality care, regardless of a patient's insurance coverage or socioeconomic status, can create significant financial challenges. The 340B program helps our members to navigate these challenges, supporting their ability to maintain, improve, and expand access to care.

Thank you for the tremendous time and effort you and your staff have invested into this discussion draft legislation. We appreciate your ongoing efforts to engage 340B stakeholders and develop bipartisan, consensus-driven legislative solutions to address the long-term sustainability of the program for covered entities and the patients they serve. To better understand the potential impact of this legislation on our members and their patients, the AAMC convened four focus group sessions during the week of March 4th. The sessions, which drew an average of 80-100 attendees from the academic medicine community, revealed valuable insights into the feasibility and potential effects of implementing policies included in the SUSTAIN 340B Act on AMCs and the patients and communities they serve. Based on the feedback we have received through this process, we offer the following comments for your consideration:

***Sense of Congress***

We greatly appreciate Sec. 2 of the legislation, which reaffirms Congress' purpose for the program: "to stretch scarce Federal resources and help safety net providers maintain, improve, and expand access to health care services." Congress' original intent for 340B has been repeatedly misconstrued and misrepresented by opponents of the program, including the pharmaceutical industry. These stakeholders continue to erroneously claim that the program was established to "help low-income and other vulnerable patients access more affordable medicines." This deliberate misrepresentation of 340B's original intent leads the public to assume that it is a medication access program, which is not the case. To address this confusion, we thank you for weighing in to clarify Congress' true intent for the program: to support safety-net providers in their efforts to maintain and improve patients' access to care. We urge Congress

[1] AAMC analysis of FY2022 American Hospital Association data, American College of Surgeons Level 1 Trauma Center designations, 2023, and the National Cancer Institute's Office of Cancer Centers, 2022. AAMC membership data, March 2024.

to uphold and adhere to the stated intent of the 340B program and to continue to reject attempts to alter the purpose of the program.

***Patient Definition***

We are greatly concerned by Sec. 4 of the legislation, which seeks to provide a definition of "patient" in 340B statute. **We believe the Health Resources and Services Administration's (HRSA's) 1996 guidance is sufficient in defining a 340B patient and that this issue does not necessitate legislation.**

We would emphasize that proposed restrictions on patient definition are tantamount to restrictions on the program, which inherently reduces the savings available to covered entities, and, by extension, bolsters the pharmaceutical industry's profits at the expense of safety-net providers and the patients and communities they serve. As affirmed in Sec. 2 of the legislation ("Sense of Congress"), the 340B program is intended to support safety-net providers, and as such, eligibility for the program is determined at the facility-level, rather than the patient-level. Efforts to further define "patient" in the context of the program contradict this mission and are unnecessary given covered entities' demonstrated commitment to complying with the statutory prohibition on diversion. Covered entities have robust policies and procedures in place to ensure they are dispensing 340B drugs to their patients. Additional requirements under consideration do not comport with how AMCs deliver care to their patients throughout their health systems and further compound administrative burdens that contribute to the already high cost of health care.

We do not believe that the existence of a "meaningful relationship" between a patient and a covered entity is the appropriate benchmark for whether a patient should qualify for the program. The concept of a "meaningful relationship" is inherently subjective — a patient may consider their relationship with a covered entity to be meaningful if it results in a treatment or cure, regardless of the duration of said relationship. In addition, patients may have relationships with multiple covered entities to fulfill their health care needs. For example, a patient may go to a community health center for their primary care needs and an AMC for specialized health care services (such as cancer treatment). In this case, both covered entities — the community health care center and the AMC — play an equally important role in promoting the health of the patient. Restricting the AMC from accessing 340B pricing for this patient would necessarily limit their ability to provide this patient with the wrap-around services they need, such as high-cost oncology drugs, care management, mental health supports, and transportation assistance. Furthermore, such a policy would have community-level impacts by limiting the AMC's investment in programs and services to address the upstream social determinants of health and advance health equity. Such a policy would unavoidably limit access to care for patients, while producing no savings for the federal government.

***Contract Pharmacy***

We greatly appreciate and support Sec. 3, which would clarify and codify covered entities' ability to employ contract pharmacy partnerships to distribute covered outpatient drugs. The AAMC remains deeply concerned by pharmaceutical manufacturers' increasingly prevalent restrictions on covered entities' use of contract pharmacies to distribute discounted medications. As outlined in our response to your June 16 request for information, these restrictions pose an existential threat to the 340B program, impeding access to care for patients and diverting critical financial resources away from our nation's health care safety-net. Over the past four years, pharmaceutical manufacturers' restrictions on our member institutions' use of contract pharmacies have resulted in mounting financial losses, further exacerbating the acute financial pressures facing teaching health systems and hospitals as they continue to recover from the COVID-19 pandemic and its financial ramifications. The AAMC adamantly maintains that the current 340B statute requires manufacturers to offer covered outpatient drugs to covered entities, regardless of their mode of delivery. To that end, we have joined the hospital community as *amici* in support of the federal government's enforcement of the statute.[2] The AAMC would support alleviating these financial losses and litigation costs by directing the HRSA to compel manufacturers to remedy hospitals' lost savings from the past four years. We recognize the urgency of the financial challenges facing safety-net hospitals, and therefore support efforts to quickly and efficiently restore covered entities' use of contract pharmacies.

To further strengthen this section, we urge you to reconsider the proposed requirement that covered entities annually register all contract pharmacy arrangements with the HHS Secretary. We believe that after initial contract pharmacy registration, additional registration requirements should be limited to only new contract pharmacies — requiring hospitals to re-register existing contract pharmacy arrangements would impose an undue administrative burden on both the covered entity and the federal government, demanding in significant staff time and resources. We further believe that this cumbersome process would produce little to no meaningful information to support program integrity efforts, as 340B hospitals are already required to register each contract pharmacy arrangement with HRSA. Furthermore, requiring HRSA to annually re-review written contracts between a hospital and a contract pharmacy could create significant delays, which would jeopardize hospitals' ability to maintain, improve, and expand access to care. In summary, this language would duplicate existing program requirements, impose a significant administrative burden on 340B hospitals and the federal government, introduce delays into the contract pharmacy registration process, and potentially restrict hospitals' 340B program savings.

While we greatly appreciate and recognize your continued support of the covered entity community on the contract pharmacy issue, we are deeply concerned by your consideration of potential limitations upon these partnerships. As we have emphasized previously, AMCs play a

[2] https://www.aamc.org/news/340b

critical role in our nation's health care safety-net, offering highly specialized health care services that are simply unavailable in other settings, including cancer care, transplant surgery, and treatment for rare and complex services. Because of the invaluable services they provide, AAMC-member institutions serve as quaternary and tertiary facilities, attracting patients from across their state and region. Our members' large, geographically dispersed service areas mean that potential limitations upon their use of contract pharmacy arrangements would unavoidably restrict access to care, particularly for rural, low-income, and historically underserved patients. These patients already face significant barriers to care, including inadequate transportation, a lack of reliable childcare, and inflexible working hours. Restricting their ability to fill their prescriptions at a location that is most convenient to them would further exacerbate these challenges.

We are concerned that geographic limitations on covered entities' use of contract pharmacy arrangements would effectively negate the protections provided under Sec. 3, even for those hospitals that operate an in-house pharmacy. As we established in our response to your June 16 RFI, even those hospitals that enjoy access to an in-house pharmacy may choose to partner with contract pharmacies because of pharmacy benefit managers' (PBMs) proclivity for patient steering. In other words, PBMs and other payers will often direct patients towards certain in-network pharmacies. The determination of which pharmacies qualify as "in-network" is outside the control of hospitals, which is reflected in the fact that these networks often exclude hospital-operated retail and specialty pharmacies. If Congress were to introduce geographic limitations on hospitals' use of contract pharmacy arrangements — for instance, requiring a pharmacy to be within a certain distance of the covered entity — this would incentivize PBMs to steer patients to pharmacies outside of this radius, restricting their ability to fill prescriptions at a convenient and accessible location. This is especially concerning considering the financial relationships that exist between payers, PBMs, and pharmacies.

It is also worth noting that geographic limitations would disproportionately impact covered entities' use of specialty pharmacies. AMCs, which care for a more medically and socially complex patient population, rely on the use of specialty drugs, which are used to treat rare, complex, and chronic health conditions. Specialty drugs represent an increasing proportion of the U.S. prescription drug market; these drugs accounted for virtually zero percent of market share when the 340B program was first established in 1992 but have since expanded to over half the market in 2023. Because of the challenges inherent in operating a specialty pharmacy, many hospitals do not operate these pharmacies in-house, instead relying upon contract pharmacy partnerships to distribute these drugs to patients. This is reflected in a July 2023 analysis conducted by 340B Health, which found that specialty drugs accounted for over 60% of the $8.4 billion in savings lost due to pharmaceutical manufacturers' restrictions on contract pharmacy arrangements.[3]

[3] https://www.340bhealth.org/files/Contract_Pharmacy_Financial_Impact_Report_July_2023.pdf

Given the increasingly important role of specialty drugs in the 340B program, we are concerned that geographic limitations would significantly restrict our members' ability to arrange for these specialty drugs to be dispensed via contract specialty pharmacies. Because specialty pharmacies are increasingly comprised of large, national chains, geographic limitations would unavoidably limit our members' ability to forge and maintain relationships with these partners. This would not only seriously reduce our members' 340B savings, but more importantly, disadvantage those patients who require specialty drugs to treat or manage their health conditions.

***Child Sites***

Offsite outpatient departments, also known as "child sites," play a critical role in the 340B program. These sites are part of a broader shift in health care delivery from the inpatient setting to outpatient, community-based clinics. This evolution towards ambulatory care has many benefits, including greater accessibility and enhanced patient satisfaction. In the case of the 340B program, child sites allow patients to receive care at a location that is most convenient to them, rather than having to travel long distances to the covered entity itself. This is particularly meaningful for patients living in rural or other underserved areas, or who otherwise face transportation barriers.

The AAMC has concerns regarding HRSA's current system for registering child site locations, which we believe imposes an undue administrative and financial burden on 340B hospitals. The agency's current requirement that a child site appear as a reimbursable line on a hospital's most recently filed Medicare cost report (MCR) before it is eligible for 340B pricing results in registration delays, which can impact operational decision-making. For example, a hospital with a fiscal year beginning on October1 that opened a child site in late 2022 would be unable to list that site on its cost report until the next MCR filing period, which would begin in October 2023. Once the MCR is filed, which could be as late as February 2024, the hospital would be required to wait until the beginning of the next quarter (April 2024) to register the child site. The hospital would then be eligible to dispense 340B drugs to patients of that child site in July 2024. In this case, the 18-month delay between when a site opens and when it becomes eligible for 340B pricing can result in significant forgone savings for the hospital, along with added financial pressure. The added logistical and financial barriers of the current registration process can impact a hospital's decision about the feasibility of opening a child site location. For these reasons, we welcome the discussion draft legislation's proposed shift away from the current MCR-based registration system. We believe that child sites should be eligible for 340B pricing as soon as they are registered with HRSA, and we appreciate your support in this matter.

The AAMC has significant concerns regarding certain eligibility requirements for child site locations proposed in Sec. 5 of the discussion draft legislation. For example, language included on page 14 would require child sites to provide a "clinically meaningful range of services" to patients. We believe that this "clinically meaningful" metric is ambiguous, as it lacks a clear definition in the current legislative text. Moreover, one of the strengths of the 340B program is

the flexibility it affords covered entities to tailor their programs and services to meet the unique needs of the patients and communities they serve. We feel that this arbitrary requirement would potentially constrain child sites' ability to do just that.

The AAMC also objects to efforts to further define "patient" in the context of child locations, including proposed requirements that a provider have clinical responsibility for services directly related to the use of the covered outpatient drug, as well as in the case of disproportionate share (DSH) hospitals, that the prescription be written by an employee or bona fide contractor of the covered entity. As we previously emphasized in this letter, efforts to define "patient" are inimical to the intent of the program as outlined in the "Sense of Congress," which reaffirms that program eligibility is determined at the facility-level. Restricting the use of 340B drugs to prescriptions written by employees or bona fide contractors of the covered entity is a significant and unnecessary departure from current patient definition guidelines. This proposal ignores the complex and interdependent relationships that exist between AMCs, outpatient facilities, and faculty practice plans. For example, current patient definition guidance allows prescriptions to be written by providers under other arrangements with the covered entity, including referrals for consultation. Prescriptions for patients of AMCs are often written by a provider that is employed or contracted by an entity that is commonly owned with the covered entity by a parent organization. The changes would preclude the use of 340B drugs for patients of the covered entity when the prescription is written by a referring provider or a provider who is not directly owned or contracted by the covered entity.

***Transparency and Reporting***

As we have stated, the AAMC supports commonsense, meaningful transparency that advances Congress' goal for the 340B program, whilst holding pharmaceutical manufacturers accountable for their abuses. For this reason, we have endorsed the American Hospital Association's "340B Good Stewardship Principles," which encourage hospitals to publicly share how they use their savings to benefit patients and communities. We look forward to continuing to collaborate with you on these transparency measures going forward.

In addition to the overall administrative burden this discussion draft legislation would place on 340B hospitals, we are concerned that certain transparency and reporting requirements are irrelevant to the congressional intent of the 340B program. As emphasized earlier, we greatly appreciate Sec. 2 of the discussion draft legislation ("Sense of Congress"), which reaffirms the Congress' purpose for the program: "to stretch scarce Federal resources and help safety-net providers maintain, improve, and expand access to health care services." This language validates and corroborates the hospital community's longstanding position that the program is intended to support covered entities and their ability to care for patients with vital programs and services. However, many of the reporting requirements outlined in Sec. 6 of the legislation are, in our view, misaligned with this stated goal. For example, although 340B eligibility is determined at the facility-level, rather than the patient-level, many of the reporting requirements are focused on

individual patient characteristics, rather than the programs and services offered by covered entities.

For example, Sec. 6 would require hospitals to report policies to "promote access and adherence to prescribed medication." As emphasized in the "Sense of Congress," 340B is not a medication access or adherence program — it is designed to financially bolster our health care safety-net. Therefore, we maintain that this reporting requirement is not aligned with the mission of 340B. Furthermore, this requirement is duplicative of other requirements included in Sec. 6, as hospitals that choose to use their savings to support medication adherence and access could easily capture these data in their "description of the covered entities' use of the savings received through participation."

In some cases, these reporting requirements are not just administratively burdensome, but logistically infeasible. As we have repeatedly emphasized to lawmakers, requiring hospitals to report charity care costs for each child site location would require investments in entirely new software systems. The costs associated with complying with this mandate would be difficult to bear for many health systems and hospitals, particularly considering the financial challenges facing our members. Furthermore, this requirement improperly suggests that savings accrued to a particular child site should be used to support charity care at that location. In reality, hospitals use their 340B savings to support a variety of systemwide programs, not just charity care, which benefit the patients and communities they serve, not just those treated at a particular child site location. In addition, we are unclear how to reconcile this requirement that hospitals report these data by individual child site location with your stated intent to ensure that these sites are "financially and clinically integrated into the covered entity."

Finally, we are concerned that these reporting requirements as currently written would fundamentally misrepresent the financial benefit hospitals receive from their participation in the program. For example, Sec. 6, pg. 26 of the discussion draft would require hospitals to report the "estimated discount received by the covered entity as a result of participation," which is defined as the difference between "the covered entity's cost of acquiring drugs at the discounted price under this section with the wholesale acquisition cost of such drugs." The AAMC has serious questions and concerns with this proposed methodology as it fundamentally misrepresents the volume of savings hospitals derive under the 340B Program. This approach presupposes that the wholesale acquisition cost (WAC) is the correct benchmark for what a hospital would have paid for a drug absent their participation in 340B. In reality, hospitals that do not participate in the program pay the group purchasing organization (GPO) price for drugs, which is often lower than the WAC. As such, this proposed methodology would misrepresent hospitals' savings, creating an unrealistic benchmark against which to measure their investments in patient care and community benefit.

These are just a few of many examples where we feel the transparency measures included in Sec. 6 should be reconsidered. We would welcome a dialogue with you regarding what constitutes

meaningful transparency in the program and how we can accurately capture and convey 340B hospitals' continued commitment to the program.

The AAMC is grateful for lawmakers' bipartisan efforts to support the 340B program, which plays a crucial role in supporting our nation's health care safety-net and increasing access to care for low-income and underserved patients. We remain steadfast in our commitment to working with Congress to support covered entities' ability to care for patients and ensure the program's longevity. We look forward to continuing to work with you and your staff on these proposals. Please contact me, Len Marquez (lmarquez@aamc.org), Senior Director of Government Relations and Legislative Advocacy, or Sinead Hunt, Legislative Analyst (sihunt@aamc.org) if you have any questions or concerns.

Sincerely,

Danielle P. Turnipseed, JD, MHSA, MPP
Chief Public Policy Officer
Association of American Medical Colleges

CC: David J. Skorton, MD
President and CEO
Association of American Medical Colleges

CC: Jonathan B. Jaffery, MD
Chief Health Care Officer
Association of American Medical Colleges