The Honorable Larry Bucshon, MD
1005 Longworth House Office Building
Washington, DC 20515

The Honorable Scott Peters
1122 Longworth House Office Building
Washington, DC 20515

January 9, 2018

Dear Dr. Bucshon and Congressman Peters:

On behalf of the Association of American Medical Colleges (AAMC), which represents all 149 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and more than 80 academic societies, I am writing to comment on the 340B Protecting Access for the Underserved and Safety-Net Entities Act (340B PAUSE Act, H.R. 4710).

The AAMC agrees with Dr. Bucshon's statement in his press release that, "The 340B program is an important tool that helps hospitals and other covered entities meet the healthcare needs of patients." However, as outlined below, we have serious concerns with and oppose H.R. 4710 because it would weaken the 340B program by creating unnecessary, burdensome requirements for safety net hospitals while imposing a moratorium on new hospitals from entering the program – changes that would provide no additional benefits for patients who rely on services that hospitals provide from the program's savings.

At no cost to taxpayers, the 340B Drug Pricing Program allows safety net hospitals and other eligible providers to leverage discounts from pharmaceutical companies to provide patients and communities with access to critical, life-saving programs. Safety net hospitals, including many teaching hospitals, utilize the savings under the 340B program to help strengthen care for low-income, rural, and other underserved patients. Some examples of these services include identifying and treating patients with substance use disorders, providing free or substantially discounted prescriptions to uninsured or low-income patients, and operating community clinics.

The AAMC supports efforts to strengthen the 340B program so that safety net hospitals can continue to provide patients with access to these valuable programs as well as the other services provided by these institutions. We are concerned that this bill unfairly targets these hospitals while not addressing issues that arise with manufacturers failing to comply with program requirements. At a time when the need for reductions in regulatory burden have been recognized by both Congress and the Administration, H.R. 4710 imposes burdensome oversight requirements on all hospitals that appear to seek to address unsubstantiated claims of abuse within the program. This bill also inappropriately ties the 340B program to the provision of charity care rather than, as was intended, to hospitals that provide a disproportionate share of care to Medicaid and low-income Medicare populations.

While the AAMC is open to discussing additional measures to strengthen the 340B program, many of the new reporting requirements in H.R. 4710 are impractical and unnecessarily burdensome, especially since the savings are being used to expand health care services to vulnerable populations

and do not come from taxpayer dollars. For example, the bill is extremely prescriptive regarding the way in which information is to be reported. It requires that hospitals identify whether an individual's health insurance plan is "coverage offered in the individual or group market or a group health plan." Patients should not be singled out by where they purchase their health insurance coverage and this information is not currently collected by hospitals. It is also unclear how such information would improve transparency.

Additionally, the bill's requirement for hospitals to report acquisition cost and gross reimbursement for drugs purchased through contract pharmacies is unfeasible since the insurer pays the contract pharmacy, not the hospital, for those drugs. In most cases, hospitals do not know how much the contract pharmacy is paid for a 340B drug since pharmacies keep these payment rates confidential.

The bill also contains a requirement for the reporting of charity care. As was noted earlier, the purpose of the 340B program is to benefit hospitals that treat a disproportionate share of Medicaid, low-income Medicare populations, and low-income individuals who do not qualify for Medicaid and Medicare. Furthermore, all 501(c)(3) hospitals are already required to complete an Internal Revenue Service Schedule H form annually, which is appended to their 990 tax forms to report not only on charity care, but also on community benefit as a recognition that there is much that hospitals do beyond providing free care that improves the health of their communities. Hospitals also must make a community benefit report public available and have an Implementation Strategy on a triannual basis.

Additionally, it is concerning that H.R. 4710 unfairly imposes a higher standard on safety net hospitals than on drug manufacturers since there are no new reporting or transparency requirements for manufacturers. This bill calls for the Office of the Inspector General (OIG) and Government Accountability Office (GAO) to issue new reports on covered entities and their use of the 340B program, but does not include similar reports to review whether or not drug manufacturers are meeting their legal obligations under the program. This comes at a time when the Department of Health and Human Services continues to delay the implementation date for the calculation of the 340B ceiling price and the application of civil monetary penalties for drug manufacturers that intentionally charge above the ceiling price, contrary to the requirements of the law. Concerns about transparency should include more robust transparency requirements for manufacturers.

According to a recent GAO report on the profits of the drug industry, worldwide pharmaceutical and biotechnology sales revenue for drug companies grew from $534 billion to $775 billion between 2006 and 2015. During this time period, the annual average profit margin for the largest 25 companies increased between 15-20 percent, while margins for the top non-drug companies increased just 4-9 percent.[1]

Instead of addressing rising drug costs and intentional overcharging from manufacturers, H.R. 4710 seeks to limit hospitals' ability to provide vital services to vulnerable patients by creating a two-year moratorium that prevents additional safety net hospitals and child sites from joining the program. Safety net hospitals that participate in the 340B program provide a disproportionate share of care to Medicaid and low-income patients, while also providing a high level of uncompensated care. A moratorium would prevent these hospitals from expanding services and prohibit other hospitals that provide a high level of care to underserved populations from benefitting from the program.

[1] United States Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals," November 2017

Often, covered entities use their savings from the 340B program to provide preventative services to vulnerable populations and on population health measures, with the goal of keeping these patients healthier and reducing overall health care costs. This benefits not only patients, but also the federal and state governments that do not have to use their own funding for such efforts. A moratorium would lead to higher health care costs and less services to those who need them the most.

This bill also appears to address an unsubstantiated concern about growth in the 340B program. Due to the success of the program for so many patients and communities, Congress expanded the 340B program in 2010 to allow additional hospitals and other entities to participate in the program. This resulted in increased access to care and services to needy patients. Even with the addition of these new covered entities, 340B sales grew by less than 1 percent between 2012-2016 compared to total drug sales. In other words, while the program has grown and served more patients, it is not responsible for increased drug costs.

The Health Resources and Services Administration (HRSA), which oversees the 340B program, already has extensive measures in place in order to maintain program integrity. To participate and remain in the program, covered entities must go through an initial certification process, recertify annually for the program, and prevent diversion to ineligible patients. HRSA also conducts random audits and posts a summary of the findings on its website for transparency. The AAMC strongly believes that HRSA oversight is important to ensure that all 340B participants – both covered entities and manufacturers – are abiding by the program's strict guidelines.

In addition to HRSA's oversight, hospitals invest in their own internal program integrity efforts to maintain compliance with the 340B program. This includes purchasing or creating sophisticated software to ensure that 340B drugs are identified within their pharmacy systems and dispensed only to eligible patients, internal audits, drug order verifications, targeted chart reviews, and other policies.

The AAMC welcomes the opportunity to work with you on our mutual objective of strengthening the 340B program so that it continues to provide vital support to hospitals and other health providers as they work to serve vulnerable patients in their communities.

If you have questions or would like to discuss further, please contact me at kfisher@aamc.org or Jason Kleinman, senior legislative analyst, at jkleinman@aamc.org.

Sincerely,

Karen Fisher, JD
Chief Public Policy Officer