The Honorable Bill Cassidy, MD
520 Hart Senate Office Building
Washington, DC 20510

February 16, 2018

Dear Dr. Cassidy:

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 provide some initial feedback on the Helping Ensure Low-income Patients have Access to Care and Treatment Act (HELP Act, S. 2312).

The AAMC appreciates the statement you made in your press release accompanying the bill, "The 340B program is an important resource for hospitals serving low-income areas." However, we must oppose S. 2312 because it would weaken and significantly change the 340B program. Specifically, we are concerned that linking charity care to program eligibility does not take into account the full range of other burdens that safety net hospitals bear due to the patient population they serve, establishing a moratorium on new hospitals and child sites would restrict hospitals' abilities to expand services to low-income populations, and the proposed additional reporting requirements are overly burdensome without providing any benefit to patients who rely on these services.

At no cost to taxpayers, safety net hospitals utilize the savings from the discounts that come from pharmaceutical companies to help strengthen access and programs that provide services 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.

Charity Care Should Not Be Linked to the 340B Program

This bill inappropriately ties the provision of charity care to the 340B program. Focusing solely on charity care would change the intent of the program and does not accurately reflect the many and varied financial burdens of disproportionate share hospitals (DSH), including bad debt, underpayment by public programs, and treating underinsured and insured patients. While 340B DSH hospitals represent just 29 percent of Medicare Inpatient Prospective Payment System hospitals, they bear 67 percent of charity care costs, 54 percent of bad debt costs, and 56 percent of Medicaid shortfalls.

Additional Reporting Requirements Will Increase the Burden on Hospitals Without Improving the Program's Effectiveness

The AAMC supports opportunities to strengthen program integrity. However, many of the new reporting requirements in S. 2312 are unnecessarily burdensome and have no commensurate benefit since the data obtained would not improve the program's support to low-income patients. Additional administrative reporting requirements as outlined in the legislation will require hospitals to report a modifier on all Medicare Advantage, Part D, and Prescription Drug Plans (PDP) claims, going far

beyond the current Center for Medicare and Medicaid Services (CMS) requirement for a modifier for certain Part B drugs. This would require hospitals to modify their claims systems to accommodate these changes, diverting scarce resources that could otherwise be used to provide needed health care services to vulnerable populations. For example, billing systems will need to be adapted to accommodate the inclusion of a modifier on all claims. Additionally, hospitals will need to allow time for additional testing to ensure the modifier is working correctly and to educate staff who must append the modifier. This process could take up to 12 months to test and implement. If the modifier does not appear on the claim automatically, it would have to be added manually by hospitals' billing staff, a time and labor intensive task. In addition to the administrative burden, this requirement will unfairly penalize hospitals that unknowingly fail to append the modifier.

Hospitals would also be required to report aggregate annual revenue from 340B drugs, and both hospitals and each child site would need to report the costs of charity care. Hospitals do not collect information in this way and the burden would be tremendous. For instance, if an outpatient clinic covers 10 floors in one building, and each floor is a different specialty, then the hospital would be considered to have 10 child sites, each of which would require reporting. Or if a hospital has a clinic that offers several specialty services, each service in that location would have to be reported separately. Current requirements for child site registration already are burdensome and require continuous monitoring. This additional reporting would provide little benefit and does not reflect the intent of the program.

We are also concerned that other reporting requirements in this legislation would force hospitals to report confidential reimbursement information. Reporting drug acquisition costs could violate confidentiality agreements hospitals maintain with drug manufacturers. Furthermore, revenue from drug reimbursements will likely breech confidential agreements that hospitals have with payers. Requiring hospitals to report patient mix broken down by expected payment source for each child site is extremely burdensome. Patients should not be singled out by type of health insurance coverage and hospitals should be not required to report this confidential information. Moreover, it is unclear how these new requirements would increase program integrity.

Additionally, S. 2312 unfairly imposes a higher reporting standard on hospitals than on drug manufacturers since it does not include any new reporting or transparency requirements for manufacturers. Specifically, this legislation allows manufacturers to keep ceiling prices from being published, even though the Health Resources and Services Administration (HRSA), which oversees the 340B program and has rulemaking authority over the issuance of drug ceiling price methodologies, published a final rule over a year ago (January 2017) 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. The Department of Health and Human Services has continued to delay implementation of this rule.

Concerns about transparency should also include more robust requirements for manufacturers, especially since manufacturer revenues continue to increase drastically. According to a recent report from the Government Accountability Office 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]

Imposing a moratorium will limit access for underserved populations

A moratorium on the registration of new DSH hospitals and child sites would lead to higher health care costs and less services to those who need them the most. Instituting a minimum two year moratorium would prevent some hospitals from expanding needed health care services to areas where access is already limited. It would also force other hospitals that provide a high level of care to underserved populations to cut back on some of these services, including preventive care. Often, covered entities use their savings from the 340B program to provide preventative services to vulnerable populations, with the goal of keeping these patients healthier and reducing overall health care costs by providing care in low cost settings. Reduced health care costs benefit not only patients, but also the federal and state governments, employers, and insurers, who bear the responsibility for paying for health care services.

When the moratorium finally ends, S. 2312 would limit child sites to "facilities that provide a full range of outpatient services, in addition to drugs." Many clinics offer services that are limited to a specific disease or type of service, including oncology, diabetes, and infusion clinics, all of which provide health care services beyond drugs. The ability of these clinics to specialize in a specific area improves the quality of the care delivered. Having hospitals provide a full range of services at every location they operate is inefficient. This proposed limitation would greatly reduce the number of child sites, thereby restricting the resources that safety net hospitals have available to help patients in their communities.

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 safety net 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

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