American Hospital Association

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December 22, 2017

The Honorable Larry Bucshon
United States House of Representatives
1005 Longworth House Office Building
Washington, DC 20515

The Honorable Scott Peters
United States House of Representatives
1122 Longworth House Office Building
Washington, DC 20515

Dear Congressman Bucshon and Congressman Peters,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) would like to comment on H.R. 4710, the 340B Protecting Access for the Underserved and Safety-Net Entities (PAUSE) Act. While we have heard many of the unfounded claims about abuses within the 340B Drug Pricing Program, we believe this bill misses the mark and therefore oppose H.R. 4710.

The AHA remains committed to ensuring the long-term sustainability of the 340B program and is willing to discuss additional transparency requirements in addition to the existing yearly recertification process and random audits required of 340B hospitals. However, transparency requirements should not place an excessive burden on hospitals that already bear a significant regulatory burden. 340B hospitals are large and complex organizations, providing care to thousands of patients in both inpatient and outpatient settings every day. They manage complicated financial payment systems comprised of numerous private and government payers. In contrast, 340B eligible federal grantees are smaller, less complex and typically serve very targeted populations. In addition, grantees are largely dependent on a single source of funding. If any new reporting requirements are to be considered, they must take into account the different capabilities of covered entities to ensure none are overly burdened.

Unfortunately, many of the reporting requirements outlined in the 340B PAUSE Act are clearly burdensome to 340B hospitals, involve major changes in hospital inventory practices and could prove to be unworkable in mixed-use settings. Placing such onerous hardships on hospitals that provide care to vulnerable populations seems unwarranted given the value the 340B program provides to the communities these hospitals serve. The

340B program also operates at virtually no cost to taxpayers, as it involves dollars from pharmaceutical companies, not taxpayers.

The 340B PAUSE Act requires data and recommendations for changes to the 340B program to align 340B eligibility with charity care levels. However, charity care is only part of a hospital's total community benefit. Alone, it does not account for the many programs and services that hospitals provide to meet the needs of their community. For example, hospitals not only provide financial assistance to those unable to pay for their own care, but absorb underpayments from means-tested government programs such as Medicaid. In addition, hospitals also provide benefits by bearing unreimbursed Medicare expenses and bad debt expenses attributable to low-income individuals. Hospitals also subsidize the high cost of essential services, such as burn and neonatal units, and many programs that improve community and population health. It also is worth noting that the 340B program was initially established to help hospitals that treat high numbers of Medicaid and low-income Medicare patients, not just the uninsured. Therefore, charity care is not the criteria on which to make an accurate judgment about the 340B program.

Any additional transparency requirements considered by Congress must be balanced, providing additional reporting for both covered entities and manufacturers. It is unfair and disappointing that your legislation targets only hospitals for additional requirements. For more than seven years, a provision passed by Congress requiring a 340B ceiling price calculation methodology and application of civil monetary penalties for manufacturers' violations of the ceiling price has remained unenforced. As a result, covered entities are unable to challenge drug manufacturers when manufacturers sell drugs above the 340B ceiling price. In fact, a Department of Health and Human Services Office of Inspector General report found that manufacturers overcharged for more than half of the drugs subject to the current program's penny pricing policy (designed to rein in drug pricing) with incorrect charges ranging "anywhere from $1.65 to $1,931 per purchase over the ceiling price." Any effort to add transparency to the 340B program should include more robust transparency requirements of manufacturers.

Finally, the 340B PAUSE Act would implement a two-year moratorium on certain new 340B hospitals and child sites. The AHA opposes efforts to restrict new hospitals and child sites that meet the eligibility requirements established by Congress from participating in the program. The increasing number of hospitals eligible for the program is a direct result of congressional action to expand the program to more hospitals serving vulnerable communities. In addition, preventing newly-eligible hospitals from benefitting from the program will prove more costly to the government. 340B savings allow covered entities to focus on preventive medicine, population health and care throughout the lifespan. These efforts help avoid other, more expensive medical interventions, the cost of which would be borne in large part by federal and state government funds if not for the 340B program.

For the reasons outlined above, the AHA respectfully opposes the 340B PAUSE Act. If you have any questions, please contact me or Aimee Kuhlman, AHA senior associate director of federal relations, at akuhlman@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President