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Statement

of the

American Hospital Association

for the

Energy and Commerce Subcommittee on Health

of the

U.S. House of Representatives

"Opportunities to Improve the 340B Drug Pricing Program"

July 11, 2018

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including more than 1,900 hospitals that participate in the 340B drug savings program, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – the American Hospital Association (AHA) appreciates the opportunity to express our strong support for the 340B program.

For more than 25 years, the 340B program has been critical to expanding access to life-saving prescription drugs and comprehensive health care services in communities across the country, including to low-income and uninsured individuals. The AHA and its member hospitals and health systems support efforts to ensure that the 340B program meets the objective set by Congress: "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." We continue to work with the Health Resources and Services Administration (HRSA) on that effort.

The AHA believes the 340B program is working as it was originally intended and support legislation that would enhance the mission of this program. We continue to oppose efforts to decrease the size and scope of the program or that add overly burdensome and unworkable reporting requirements on covered entities that do not improve access to care for vulnerable communities.

With these objectives in mind, we submit the following comments on bills pending before the Committee to alter the 340B program.

H.R. 4392. The AHA strongly supports this bill to reverse a Centers for Medicare & Medicaid Services (CMS) final rule that reduces by nearly 30 percent, or $1.6 billion, Medicare reimbursement to certain public and non-profit hospitals for outpatient drugs purchased under the 340B program. CMS's decision to cut Medicare reimbursement in this way threatens access to health care for many patients, including uninsured and other vulnerable populations, who rely on services that are available in part because of the 340B program. It is not based on sound policy and punishes hospitals and patients for participating in a program outside of CMS's jurisdiction.

H.R. 6071, the Stretching Entity Resources for Vulnerable (SERV) Communities Act. The AHA strongly supports this bill that also would reverse CMS's reimbursement cut to certain 340B hospitals and increase parity in transparency requirements between covered entities and drug manufacturers by requiring implementation of the long-delayed 340B ceiling price calculation methodology and application of civil monetary penalties for manufacturers' violations of the ceiling price. For more than seven years, these provisions passed by Congress have not been implemented, and, as a result, covered entities are unable to challenge drug manufacturers when they sell drugs above the 340B ceiling price.

H.R. 2889, the Closing Loopholes for Orphan Drugs Act. The AHA supports this bill, which would allow 340B-eligible hospitals subject to the orphan drug exclusion to purchase orphan drugs through the 340B program when the drugs are used to treat an illness other than the rare conditions for which the orphan drug designation was given. The current orphan drug exclusion policy prevents 340B-eligible critical access hospitals, sole community providers, rural referral centers and free-standing cancer hospitals from purchasing some medically necessary drugs at the 340B price. The AHA has long supported efforts to allow these 340B eligible hospitals to access 340B pricing for these drugs as a means to improve access and quality of care.

H.R. 4710, the 340B Protecting Access for the Underserved and Safety-Net Entities (PAUSE) Act. The AHA opposes this bill because its onerous reporting requirements would simply add burden to the program while doing nothing to expand access to care in vulnerable communities. This bill would involve major changes in hospital inventory practices and could prove to be unworkable in mixed-use settings. Placing such hardships on hospitals without demonstrating any benefits to vulnerable patients is unwarranted. The 340B PAUSE Act also requires changes to the 340B program, including new data reporting, to align 340B eligibility with charity care levels. This approach ignores that charity care is only part of a hospital's total community benefit, and does not account for the many programs and services that hospitals provide to meet the needs of their community.

In addition, the bill 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 would prove more costly to the government. Savings from the 340B program allow covered entities to focus on preventive medicine and population health interventions. These efforts help avoid other, more expensive

medical interventions, the cost of which would be borne in large part by the federal government and state governments through the Medicare and Medicaid programs.

H.R. 5598, 340B Optimization Act. The AHA opposes this bill because it imposes reporting requirements on 340B disproportionate share hospitals (DSH) without a stated purpose. The bill would require that 340B DSH hospitals report, on an annual basis, the rate of low-income patients served in all their 340B outpatient eligible sites, including child sites. The bill bases the definition of low-income utilization rate on the Medicaid DSH statute. In the Medicaid DSH program, while states have flexibility to determine which hospitals receive DSH payments, the federal statute requires that hospitals meeting certain thresholds be eligible. The low-income utilization rate based on a hospital's inpatient utilization is one of those thresholds. This bill references the existing Medicaid statute regarding this threshold but changes the data required for calculating the low-income utilization rate from inpatient to outpatient. It then imposes on 340B DSH hospitals the obligation to report this utilization rate to HRSA. This new reporting requirement imposes considerable burden on 340B DSH hospitals with no stated purpose or direction to HRSA on how to evaluate this new reported information except to report the information to Congress annually.

H.R. 6240, User Fees under the 340B Drug Discount Program. The AHA opposes imposing a user fee on 340B hospitals to fund basic HRSA program responsibilities. This bill would impose on 340B DSH, children's and free-standing cancer hospitals a user fee of 0.1 percent of the hospital's total payments to drug manufacturers for 340B drugs. According to this proposal, the user fees are intended to fund program integrity and oversight functions. These oversight responsibilities are ones that Congress has already mandated the agency perform, and as such, Congress has embraced the responsibility to fully fund the agency and not rely on stakeholders to do so, particularly when such resources will come at the expense of vulnerable patients who benefit from services and programs funded in part through 340B savings.

H.R. __, Protect Safety-Net 340B Hospital Act. The AHA strongly opposes the discussion draft proposal to raise the eligibility threshold for hospitals that qualify for the 340B program based on their Medicare DSH adjustment percentage from 11.75 to 18. The Medicare DSH adjustment percentage is an indicator of the level of low-income and other vulnerable individuals served by a hospital. The AHA continues to believe that the current Medicare DSH threshold is an appropriate eligibility threshold for the 340B program. The congressional intent for the 340B program is to allow 340B hospitals and clinics to *stretch scarce federal resources* to provide patients and communities with more comprehensive health care services. Raising the threshold to 18 percent is designed to reduce the number of eligible hospitals. It ignores the impact that reducing eligible hospitals would have on patients and communities, particularly for the most vulnerable populations. Reducing the eligibility threshold achieves drug manufacturers' objective to reduce the discounts they provide, thus increasing their own profits.

H.R. __, Defining the term "Patient" for Purposes of the 340B Drug Discount Program. The AHA opposes this discussion draft to alter the definition of "patient" as it applies to the 340B program. The current 340B patient definition is based on the relationship the eligible patient has with his or her hospital. It includes patients who receive health care services from a health care

professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity. Narrowing the definition of patient would significantly reduce the volume of drugs eligible for 340B drug discount pricing, and jeopardize hospitals' ability to serve the most disadvantaged patients in their communities. The bill would further limit the availability of 340B discounts by excluding patients who receive infusion services only. These changes would significantly reduce access to 340B discounts for outpatient drugs. For example, hospitals could not access 340B discounts for discharge prescriptions intended for outpatient use. Many 340B hospitals have relied on HRSA's current policy that permits discharge prescriptions as they develop programs to reduce avoidable readmissions, particularly for their low-income patients. The ability to use 340B drug pricing for these discharge prescriptions is consistent with the objectives of the 340B program to provide access to pharmaceuticals to low-income populations.[1] It also is consistent with the national health care objective to reduce avoidable readmissions.

In addition, excluding patients receiving "only" infusion services from the definition of eligible 340B patient could harm patients' access to needed care. For example, critical oncology drugs have undergone extraordinary price increases. One study found that the average launch price of oncology drugs, adjusted for inflation and health benefits, *increased by 10 percent annually, or an average of $8,500 per year, for almost 20 consecutive years* – from 1995 to 2013.[2] 340B hospitals that provide cancer and other costly infusion services for underserved communities depend on 340B drug discount pricing to provide these vital services. This is particularly true in rural communities. About half of 340B hospitals are located in rural areas, and almost half of them offer vital chemotherapy services to their patient populations.[3] Access could be endangered by this change in patient definition. Patients in rural areas may be unable, due to their medical condition, age or other factors, to travel to urban areas to receive these services. Having these services available near their home vastly improves their quality of care and quality of life.

H.R.__, Require Certain 340B Covered Entities to Report Charity Care Expenditures. The AHA opposes this discussion draft because it would impose new reporting burden for 340B hospitals without any benefit to vulnerable communities. This discussion draft is similar to the PAUSE Act in that it would involve major changes in hospital reporting, tracking and inventory practices. Like the PAUSE Act, it looks at only certain financial metrics regarding the level of care provided by 340B hospitals that is compensated and uncompensated. It ignores the many programs and services that hospitals provide to meet the needs of their community that are not captured in these narrowly defined financial metrics. In 2015, 340B hospitals provided $23.8 billion in uncompensated care[4] and $51.7 billion in total benefits to their communities. [5]

H.R. __, Limitation on Amount Charged to Low-income Patients. This discussion draft would limit what a covered entity could charge a low-income patient. While we appreciate the Committee's interest in ensuring low-income patients have access to affordable drugs, we are

[1] U.S. House, Committee on Veterans Affairs, "Establishment of Limits on Prices of Drugs Procured by the Department of Veterans Affairs (to accompany H.R. 2890)," H. Rept. 102-384, Pt. 2, 1992.
[2] David Howard, Peter Bach, Ernst Berndt, and Rena Conti, "Pricing in the Market for Anticancer Drugs," Journal of Economic Perspectives, vol. 29, no. 1 (Winter 2015): 139-162.
[3] American Hospital Association 2017 Annual Survey.
[4] AHA 2015 Annual Survey Data
[5] AHA 340B Community Benefit Analysis, March 2018 https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf

concerned this approach is not workable. Hospitals do not collect income information from the patients they serve unless that patient is applying for the hospital's charity care policy. Systematically collecting this information for all patients would require significant hospital resources, including to ensure that such processes adhered to all state and federal privacy requirements. We look forward to working with the Committee on ways Congress can provide assurance that low-income patients have access to affordable drugs or other health care services.

H.R.__, Require that 340B audits follow Generally Accepted Government Accounting Standards. Central to HRSA's 340B program integrity efforts are audits of covered entities and drug manufacturers. The AHA believes that HRSA's current 340B audit process could benefit from ensuring that the process adheres to generally accepted government accounting standards. However, the AHA believes that HRSA should make a more concerted effort to audit drug manufacturers to ensure their adherence to program rules, in particular the appropriate setting of 340B ceiling prices. The Committee noted, in its own study of the 340B program, the need for greater audit parity between 340B covered entities and drug manufacturers.[6]

H.R. __, Granting HRSA regulatory authority. The Committee is reviewing a discussion draft regarding HRSA's authority over the operation of the 340B program. This proposal would clarify that HRSA has authority to issue regulations in its management of the 340B program. Congress already provided HRSA with clear authority and resources to implement important safeguards for the 340B program. Safeguards such as:

- ensuring drug manufacturers sell 340B drugs at the ceiling price or face penalty;
- establishing a web-based portal for 340B covered entities so they could verify that drug manufacturers are selling 340B drugs at the mandated ceiling price; and
- providing a dispute resolution process for 340B covered entities to hold drug manufacturers accountable.

The AHA believes additional congressionally-mandated directives of this nature would not ensure better oversight or program management.

H.R.__, To Require the Secretary of Health and Human Services to implement the Government Accountability Office (GAO) Report on 340B Contract Pharmacy Arrangements. This proposal calls on HRSA to implement a series of oversight recommendations made by GAO in how HRSA manages 340B contract pharmacy arrangements. The agency recommends that HRSA improve its oversight of these arrangements and specifically recommends more reporting, registration and auditing of 340B covered entities that have such arrangements. In its response to the report, HRSA voiced concern that some of the recommendations made by GAO, such as the registration of all child sites with contract pharmacy arrangements, could impose administrative burden on HRSA, as well as some covered entities. HRSA further notes that its own audit protocols already place an emphasis on the review of all contract pharmacy arrangements for child sites. The Committee should review carefully any measure that adds administrative and regulatory burden with a focus on whether and to what extent the measure actually helps expand access to care for vulnerable populations.

[6] https://energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf House Energy and Commerce: Review of the 340B Drug Pricing Program, February, 2018

The AHA appreciates the opportunity to provide these comments, and we look forward to a continued dialogue with the Committee.