American Hospital Association

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

July 18, 2017

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Diane DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
2125 Rayburn House Office
Washington, DC 20515

Dear Chairman Murphy and Ranking Member DeGette:

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 Pricing Program, as well as 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) appreciates the opportunity to submit our comments on the 340B program.

For 25 years, the 340B program – which enjoys broad, bipartisan support – has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services to low-income and uninsured individuals in communities across the country. In addition, the AHA and its member hospitals support program integrity efforts to ensure that the 340B program remains available to safety-net providers. We have worked and continue to work with the Health Resources and Services Administration (HRSA) and its partners on these efforts.

Given the increasingly high cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build healthy communities. Scaling back the 340B program would only benefit drug companies, while both increasing the federal deficit and creating devastating consequences for the patients and communities who rely on this vital program.

340B PROGRAM INCREASES ACCESS TO HEALTH CARE

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include community health centers, children's hospitals, free-standing cancer hospitals, hemophilia treatment centers, critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations.

340B hospitals use the savings they receive on the discounted drugs and reinvest them in programs that enhance patient services and access to care, as well as provide free or reduced priced prescription drugs to vulnerable patient populations. For example, hospitals use the savings to:

- provide financial assistance to patients unable to afford their prescriptions;
- provide clinical pharmacy services, such as disease management programs or medication therapy management;
- fund other medical services, such as obstetrics, diabetes education, oncology services and other ambulatory services;
- establish additional outpatient clinics to improve access;
- create new community outreach programs; and
- offer free vaccinations for vulnerable populations.

For example, Childress Regional Medical Center (CRMC) is a rural health care organization located in an isolated town in the southeast corner of the Texas panhandle with a high Medicaid and uninsured population. CRMC is the primary health care provider for 30,000 residents in a five-county area, and it provides a diverse range of high-quality services, including home health and hospice. For years, CRMC wanted to provide chemotherapy treatments to patients since the nearest cancer treatment center is more than 100 miles away. In 2013, the hospital began partnering with the oncology program at Texas Tech in Lubbock. An oncologist from the Texas Tech group comes to Childress for a monthly cancer clinic and writes orders for patients to receive local treatments for diagnoses of lung, breast and colon cancers. Chemotherapy medications are expensive, but the 340B program, and the discounted drug prices it provides, makes it possible for CRMC to offer the cancer treatment program to 11 patients, as of today. Without the 340B program, Childress would not be able to offer the cancer program and patients would have to travel hundreds of miles to receive treatment.

Another example of the 340B program's many benefits is Providence Hood River Memorial Hospital, a 25-bed CAH, and the only hospital in Hood River County, Oregon. The hospital and associated clinics provided more than 140,000 patient-centered visits in 2016. More than 19 percent of the patients are Medicaid or self-pay and another 42 percent are Medicare. In 2016,

the hospital provided $7.9 million in community benefit and uncompensated care. Savings from the 340B program helped the hospital establish and support programs that increase access to care for patients and allow the hospital to provide the right care at the right time for its poor and vulnerable populations. The savings from the 340B program helped the hospital continue a medication assistance program (MAP), and in 2016 it had helped more than 100 patients procure $1.2 million worth of medications at no cost to them, and secure $120,000 in copay assistance.

340B ACCOUNTS FOR A SMALL PORTION OF DRUG SALES, BUT HAS BIG IMPACT FOR VULNERABLE INDIVIDUALS AND COMMUNITIES

Congress created the 340B program in 1992 to permit providers that care for a high number of low-income and uninsured patients "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." In 2015, the program accounted for only 2.8 percent of the $457 billion in annual drug purchases made in the U.S. However, hospitals were able to use those savings to support many programs that are improving and saving lives. In addition, in 2015, 340B hospitals provided $23.8 billion in uncompensated care.

Over the past 10 years, the volume of outpatient care has grown steadily, while inpatient volume has been on a downward trend, resulting in an increase in the number of 340B-eligible drugs. While the number of hospitals participating and the number of drugs sold in the 340B program has grown since its inception, some stakeholders, particularly those representing the pharmaceutical industry, continue to misrepresent the program's growth. In 2010, Congress expanded the benefits of the 340B program to additional safety-net hospitals to improve health care access for a greater number of low-income and uninsured patients. Those safety-net hospitals included CAHs, RRCs, SCHs and free-standing cancer hospitals. These hospitals now account for 54 percent [1]of 340B-eligible hospitals. Many of these hospitals are the lifelines of their community, and discounts they receive through 340B program play an important role in allowing these organizations to care for patients. In 2015, one out of every four 340B hospitals had a negative operating margin, and one in three 340B CAHs had a negative operating margin. Meanwhile, in 2015, pharmaceutical companies averaged a 25.4 percent net margin, and the price of pharmaceuticals continues to rise. Spending for prescription drugs[2] grew 9 percent in 2015 after a 12.2 percent increase in 2014. Scaling back the 340B program would hurt vulnerable patients and increase costs to the government in order to add to the already high profits of pharmaceutical companies.

MISINFORMATION ABOUT THE 340B PROGRAM

[1] HRSA 340B hospital enrollment data for 2017. [2]
CMS National Health Spending Data.

Some stakeholders claim incorrectly that the 340B program is a main driver of consolidation in the oncology field. In reality, larger market forces have influenced independent oncology practices to merge with their community hospitals. Hospitals are strengthening linkages to each other, and to physicians, in an effort to respond to new global and fixed payment methodologies, as well as incentives for improved quality and efficiency, implementation of electronic health records and care that is more coordinated across the continuum. In addition, unlike independent oncology practices, hospitals care for all patients who seek care, regardless of their insurance status or ability to pay; maintain standby disaster readiness capacity in the event of a catastrophic occurrence; and treat patients who are sicker and require more complex services than those treated by private oncology clinics.

In recent years, the Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) have issued reports regarding the Medicare Part B payments for 340B hospital purchased drugs. GAO's report claimed that financial incentives were driving 340B Medicare DSH hospitals to prescribe more expensive drugs to treat Medicare Part B patients. The AHA challenged GAO's conclusions citing, for example, the report did not appropriately account for certain differentiating factors and characteristics of 340B DSH hospitals. GAO acknowledged that 340B DSH hospitals treat sicker, more complex patients.[2] However, when examining Medicare Part B spending per beneficiary at 340B DSH hospitals, GAO did not adequately account for differences in patients' health status or outcomes – a point underscored by HHS in its comments on the report.[3] In addition, OIG issued a report attempting to quantify what Medicare Part B pays 340B hospitals for 340B discounted drugs. Yet OIG acknowledged limitations in its own analysis through a footnote in its report that states: "Because there is no identifier on Part B claims indicating that a drug was purchased through the 340B Program, we could not confirm that claims submitted by covered entities were in fact for drugs purchased at or below the 340B discount price."[4]

The Centers for Medicare & Medicaid Services (CMS) recently issued its proposed rule on the Medicare outpatient program making a recommendation that would drastically cut Medicare payment for drugs acquired under the 340B program. Specifically, CMS proposes to pay separately payable, non pass-through drugs (other than vaccines) purchased through the 340B program at the average sales price minus 22.5 percent, rather than ASP plus 6 percent. CMS cites the work of the Medicare Payment and Advisory Commission (MedPAC) and the analysis of the OIG as the basis of its recommendation.[5] CMS estimates that this proposal would reduce Part B drug payments by as much as $900 million.[6] While the agency proposes to implement the policy in an overall budget neutral way within the outpatient payment system, money currently going to vulnerable 340B hospitals would be distributed to all hospitals paid under the outpatient payment

[2] GAO-15-442, 340B Drug Pricing Program, p. 31
[3] , GAO-15-442, 340B Drug Pricing Program, p. 31
[4] Office of Inspector General: Part B Payments for 340B Purchased Drugs (OEI-12-14-00030), Nov. 2015. p. 6
[5] CMS-1678-P, Proposed Rule, Medicare Hospital Outpatient Prospective Payment Program, p. 300 (FR display version)
[6] CMS-1678-P, Proposed Rule, Medicare Hospital Outpatient Prospective Payment Program, p. 616 (Federal Register public inspection version)

system generally. CMS has not clearly articulated how such savings from this proposal would be distributed. Cuts of this magnitude would be devastating to the exact programs that 340B hospitals offer to improve access to care in their communities and meet the goals of the program. In addition, we are deeply concerned that shifting $900 million into other services reimbursed through the outpatient payment system could *increase* patient cost sharing for those services.

We have many questions regarding CMS's rationale for this policy recommendation and its potential impact. Most importantly: How would Medicare beneficiaries be affected? CMS further states that their goal is to reduce Medicare beneficiaries' drug copayments when seeking care from 340 hospitals.[7] Many Medicare patients, however, coming to 340B hospitals do not pay their own copayments. According to MedPAC's own analysis, 86 percent of all Medicare beneficiaries have supplemental coverage where their copayments are paid by others, of which, 30 percent have their copayments paid for by a public program, such as Medicaid, or by their Medigap plan.[8] We believe this recommendation would not directly benefit many Medicare beneficiaries, dually eligible Medicare beneficiaries included. In addition, this policy punitively targets 340B safety-net hospitals serving vulnerable patients, including those in rural areas, rather than addressing the real issue: the skyrocketing cost of pharmaceuticals. We oppose CMS's misguided proposal and urge the agency and Congress to abandon it.

SUPPORT FOR PROGRAM INTEGRITY EFFORTS TO STRENGTHEN 340B

Hospitals that participate in the 340B program are subject to oversight by HRSA's Office of Pharmacy Affairs. The AHA supports program integrity efforts to ensure that the 340B program remains available to safety-net providers. We have shared resources with our member hospitals to help them run a compliant 340B program.

Hospitals in the 340B program must meet numerous program integrity requirements. These include yearly recertification; audits from both HRSA and drug manufacturers; and maintaining auditable inventories of all 340B and non-340B prescription drugs. In recent years, HRSA has implemented additional program integrity efforts, and the AHA encourages HRSA to develop a process to help financially distressed providers meet the new program integrity provisions. In addition, we encourage HRSA to implement important program integrity requirements that Congress has passed. These requirements would hold drug manufacturers accountable for how 340B ceiling prices are set and establish a dispute resolution process for 340B-covered entities to bring forward challenges on whether drug manufacturers over charged the covered entity based on the 340B ceiling price.

[7] Ibid, p. 305 (FR display version)
[8] MedPAC, June 2016 Databook, Section 3, p. 27.

CLOSE THE ORPHAN DRUG EXCLUSION

The current orphan drug exclusion policy prevents 340B CAHs, SCHs, RRCs and free-standing cancer hospitals from purchasing some medically necessary drugs at the 340B price. The AHA supports H.R. 2889, the Closing Loopholes for Orphan Drugs Act, which would allow 340B 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.

Limiting the orphan drug exclusion for 340B-eligible rural and cancer hospitals is critical for some of the most vulnerable patients cared for by these safety-net hospitals, because, in many cases, these medically necessary drugs are unaffordable without 340B pricing. The current exclusion policy jeopardizes the financial sustainability of those hospitals, while at the same time providing a financial windfall to drug manufacturers for uses of the drug unrelated to the rare disease or condition for which it was designated. We urge Congress to pass this important legislation.

CONCLUSION

The AHA and the hospital field appreciate your consideration of these issues. Since Congress established the 340B program in 1992, it has helped hospitals stretch limited resources to expand and improve access to comprehensive health care services to low-income patients. Given the increasingly high cost of pharmaceuticals, the 340B program remains critical. The AHA looks forward to working with all stakeholders to ensure that this vital program continues to help the patients and communities who depend on it.

Sincerely,

/s/
Thomas P. Nickels
Executive Vice President

cc: Members of the Subcommittee on Oversight and Investigations