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Statement

of the

American Hospital Association

before the

Health Subcommittee

of the

Committee on Energy and Commerce

of the

U.S. House of Representatives

"Examining the 340B Drug Pricing Program"

March 24, 2015

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including more than 1,700 hospitals that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to comment for the record as part of the Subcommittee's hearing examining the 340B program.

The AHA strongly supports the 340B program and its proven track record of enabling eligible entities, including certain hospitals, to stretch scarce federal resources to expand and improve access to comprehensive health care services for more patients, especially low-income and uninsured individuals. 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 both increase the federal deficit, and have devastating consequences for patients and communities.

340B Program Increases Access to Care for Vulnerable Patients

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 that serve low-income and indigent populations.

The 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:

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

Saint Thomas Hickman Hospital, a 25-bed CAH serving residents of Centerville and Hickman counties in Tennessee, participates in the 340B program. The hospital is located in a high-poverty area and serves more than 10,000 patients annually – 20 percent of whom are uninsured. The hospital uses savings from the 340B program to improve patient care by having staff visit patients at their homes, providing transportation to the hospital for group meetings and appointments, and assisting patients with the cost of medication. For example, an uninsured patient who came to the emergency department received insulin for $17; if the hospital did not have the 340B savings, the insulin would have cost the patient $242.

The University of Utah Hospitals and Clinics (UUHC) – the state's only academic medical center – relies on the 340B program to help it improve the quality and number of health care services it provides to low-income and uninsured patients. For example, the program allows UUHC to increase patient access to pharmacy services and provide additional services to patients treated in its clinics. UUHC provided $46 million in charity care and $75 million in uncompensated care in fiscal year 2014; any reduction to the 340B program would compromise UUHC's ability to act as the safety-net for its region.

A SMALL PROGRAM WITH BIG BENEFITS

The 340B program accounts for only 2 percent – or $6.5 billion – of the $325 billion in annual drug purchases made in the U.S. In addition, 340B hospitals provided $28.6 billion in uncompensated care in 2013, which is four times the amount of drugs purchased through the 340B program.

While the number of hospitals participating 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. Even with this expansion, the drugs used by these hospitals account for only a small fraction of drugs sold under the 340B program.

SUPPORT FOR PROGRAM INTEGRITY EFFORTS TO STRENGTHEN 340B

Hospitals that participate in the 340B program are subject to oversight by the Health Resources and Services Administration (HRSA) 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, including resources from Apexus, which manages the 340B Prime Vendor 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 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, HRSA plans to issue this year comprehensive interpretive guidance that examines several areas pertinent to the 340B program. These include the definition of patient eligibility, contract pharmacy arrangements and mechanisms to prevent ineligible patients from receiving the benefit and duplicate discounts for Medicaid patients. The AHA looks forward to reviewing and commenting on the proposed guidance and working with HRSA to strengthen the 340B program.

SCALING BACK 340B WOULD HURT COMMUNITIES, ADD PROFITS FOR PHARMACEUTICAL COMPANIES

The 340B program has a long history of helping safety-net providers stretch limited federal resources to increase access to care for the vulnerable patients and communities they serve. However, some stakeholders and interest groups – financed by the pharmaceutical industry – continue to spread misinformation about the program. In 2013, 340B hospitals' average operating margin was 3.9 percent[i], and one out of every three 340B hospitals had a negative operating margin. Meanwhile, pharmaceutical companies averaged an 18 percent[ii] operating margin in 2013, and the price of pharmaceuticals continues to rise. Prescription drug prices rose 6.4 percent[iii] in December 2014, up from 4.6 percent in November, a rate not seen since 1992. 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.

In addition, the Pharmaceutical Research Manufacturers of America (PhRMA) filed a federal lawsuit to block HRSA from implementing a policy that allows rural and cancer 340B hospitals to purchase "orphan drugs" through the 340B program when the drugs are not used to treat the rare conditions for which the orphan drug designation was given. The AHA filed a friend-of-the-court brief supporting HRSA. It noted that PhRMA's argument should be rejected because:

- It would deprive America's rural and cancer hospitals of the medically necessary drugs that, in many cases, are unaffordable without 340B pricing.
- It would jeopardize 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.
- It is inconsistent with the text and purpose of the legislation that it purports to construe.

Providence Hood River (Ore.) Memorial Hospital is a 25-bed CAH that participates in the 340B program. More than 20 percent of its patients are Medicaid or self-pay and another 42 percent are Medicare beneficiaries. The hospital used 340B savings to establish a medication assistance program in which patients can receive co-pay assistance. This lowers an individual's out-of-pocket expenses and can make the difference between an individual completing the full course of a cancer drug treatment or skipping some purchases during difficult financial months. Scaling back the 340B program would force the hospital to eliminate the enhanced pharmacy services that help their patients.

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.

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[i] American Hospital Association Annual Survey, data for 2013.
[ii] Forbes, BBC News, Pharmaceutical Industry gets high on fat profits. November 6, 2014. http://www.bbc.com/news/business-28212223.
[iii] Altarum Institute Price Brief, February 12, 2015.