October 5, 2017

The Honorable Greg Walden
Chairman
Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

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

Dear Chairman Walden, Ranking Member Pallone, Chairman Murphy and Ranking Member DeGette:

In light of the Committee's continued interest in the 340B Drug Pricing Program, we are writing on behalf of the American Hospital Association and the Association of American Medical Colleges, to provide some additional background on the program's legislative history that we expect will be useful to the Committee as it pursues its work. In addition, we have provided some examples of how the program works in our institutions. Of key importance, is the fact that the 340B program is not federally funded and has enabled hospitals and health systems to support and expand access and services consistent with their mission and the program's original and ongoing charge.

340B Background

The 340B Program was created in 1992, two years after the adoption of the Medicaid Drug Rebate Program, which required pharmaceutical manufacturers to pay rebates to states based on the "best price" of the drugs purchased, as a condition of having their products covered by state Medicaid programs. H.R. Rep. 102-384(II), at 10 (1992). All or virtually all pharmaceutical companies participate in the program.

Under the Medicaid Drug Rebate Program, pharmaceutical manufacturers participating in Medicaid must sell their drugs at the lowest price they offered to other purchasers or at a fixed discount. The Medicaid "best price" standard, however, created a disincentive for manufacturers to offer the voluntary discounts that they had provided previously to federally-funded clinics and hospitals. This

caused a sharp increase in drug prices for these institutions, which offered vital health care services to some of the most vulnerable populations. *Id.* In response to this problem, Congress created the 340B Program—by adding section 340B to the Public Health Service Act, 42 U.S.C. § 256b—to provide these publicly-funded non-profit entities, with discounts on outpatient drugs that were comparable to those available to state Medicaid agencies.[1]

As the report of the House Committee on Energy and Commerce states, the purpose of the 340B Program is to allow certain non-profit hospitals and federally-funded clinics "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). This broad purpose has been consistently recognized by the Health Resources & Services Administration ("HRSA"), the Department of Health and Human Services agency responsible for administering the 340B Program, as well as the Government Accountability Office ("GAO").

As HRSA has explained, the 340B Program enables institutions serving vulnerable populations to stretch scarce Federal resources by "lower[ing] the cost of acquiring covered outpatient drugs," allowing the entities to generate "[a]dditional program resources." In this way, other than modest appropriations to administer the program, the 340B Program is self-sustaining; the financial support covered entities receive is derived from drug manufacturer discounts, rather than federal investments or other expenses to taxpayers. This intended revenue source "permits HHS programs to provide additional financial capacity to assist health care providers without increasing the Federal budget for the grant or other assistance programs."[2] Accordingly, since the 340B Program was first implemented, the covered entities have retained all revenue generated through the Program. According to HRSA, 340B Program sales are less than three percent of the total U.S. drug market.[3]

Recognizing the utility and importance of the 340B Program as a means to provide health care to vulnerable populations, Congress has steadily increased the categories of "covered entities" over the years. In 1992, "covered entities" included federally-funded health centers and clinics providing

[1] The rebate under the Medicaid Drug Rebate Program is the greater of the minimum rebate percentage (e.g., for innovator drugs, 12.5% in 1992 and 23.1% today) *or* the difference between the Average Manufacturer Price ("AMP") per unit and the best price per unit. *See* 42 U.S.C. § 1396r-8(c). A lower best price would thus create a larger differential between the AMP and the best price, increasing the rebate required if this difference is greater than the minimum rebate percentage. As a result, the "best price" standard created an incentive for manufacturers to cease offering deep discounts to nonprofit organizations, including public hospitals, which were then required to pay "full price" for pharmaceuticals.

[2] HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act*, at Part I.G. (July 2005), *available at* https://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm#2l (last accessed Sept. 18, 2017).

[3] https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf

family planning, AIDS intervention, and hemophilia treatment services, as well as public hospitals serving a large proportion of low-income or uninsured populations. *Id.* at 13. Later, additional categories of federally-funded clinics, as well as certain private non-profit hospitals serving vulnerable populations, were added as "covered entities." *See* 42 U.S.C. § 256b(*l*). Congress further expanded "covered entities" in more recent legislation to include several additional categories of hospitals, specifically certain children's hospitals, freestanding cancer hospitals, critical access hospitals and rural hospitals. *See* 42 U.S.C. § 256b(m)-(o).

Over the years, the covered organizations have used the revenue generated through the Program to maintain vital services and to provide additional services to their patients. In a 2011 report, the GAO found that all studied organizations "reported that the 340B program, including the up-front savings they realized on the cost of drugs, allowed them to support their missions by maintaining services and lowering medication costs for patients, which is consistent with the purpose of the program." Specifically, some organizations relied on the 340B revenue to, for instance, "offset losses incurred from [certain] patients . . . [to] help support the financial stability of the organization," maintain an outpatient pharmacy that it would otherwise have to eliminate, and/or "provid[e] lower-cost drugs to uninsured patients." Other entities that were able to generate a surplus through the Program "use[d] this revenue to serve more patients and to provide services that they might not have otherwise provided," including additional service locations, patient education programs, case management services that facilitate access to appropriate health care, and translation and transportation services.[4]

There are many examples of how hospitals and health systems have used savings from costly pharmaceuticals made possible by the 340B program in conformance with the program's purposes to maintain and expand access and services; here a just a few examples to illustrate that point:

- Support for a neonatal intensive care unit and training for physicians to care for these vulnerable newborns;

- Expansion of a stroke center;

- Addition of nurses, physician assistants, social workers and patient transporters for a local hospital;

- Support for the cost of pharmaceuticals for a range of patients in need, examples of this include expenditures of as much as a $1 million for a low-income elderly patient with co-morbidities and hundreds of thousands of dollars for a low-income pediatric patients;

[4] *See* U.S. Gov't Accountability Off., GAO-11-836, *Manufacturer Discount in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* (Sept. 2011), at 17-18.

- Provide low income patients with free outpatient drugs;

- Pharmacist counseling services for medication therapy disease management, including telephone consultations for outpatients with conditions such as diabetes, hypertension, and asthma; and

- Smoking cessation programs to help both uninsured and underinsured patients gain access to cessation drugs.

As briefly illustrated above, covered organizations are using the 340B Program as Congress intended and continue to rely on revenue generated by that Program to maintain or provide additional health care services to their patients.

If we can provide further information, please contact Tom Nickels at (202) 638-1100 or tnickels@aha.org or Karen Fisher at (202) 828-0400 or kfisher@aamc.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
American Hospital Association

Karen Fisher
Chief Public Policy Officer
Association of American Medical Colleges

cc: Members of the Oversight and Investigations Subcommittee