

**Statement
of the
American Hospital Association
for the
Committee on Health, Education, Labor and Pensions
of the
United States Senate**

“Effective Administration of the 340B Drug Pricing Program”

June 19, 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 Pricing 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 submit our comments on the 340B program.

For more than 25 years, the 340B program has been critical in helping hospitals expand access to lifesaving 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 program integrity 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) and its partners on these efforts.

Congress established the 340B program in response to the pressure high drug costs were putting on providers serving vulnerable communities. High drug costs were straining provider budgets and challenging their ability to invest in a wide array of services to meet the health care needs of their communities. The 340B program provided critical relief to address this challenge; scaling back the program now would have devastating consequences for these communities while only driving more revenue to drug manufacturers.



THE 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. Participating hospitals use the savings they receive on the discounted drugs to invest in programs that enhance patient services and improve access to care, especially for vulnerable patient populations. 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;
- offer free vaccinations; and
- provide access to specialty care, such as oncology care, not otherwise available to many low-income individuals in the community.

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

The 340B program represents a very small portion of drug spending nationally. Only some outpatient drugs are subject to 340B discounts, while all inpatient drugs, many other outpatient drugs and all retail drugs are not eligible. According to HRSA's most recent data, the program accounted for only 3.6 percent of the total drug market in the U.S. in 2016. Despite this discount program, drug manufacturers were still able to achieve double-digit margins. Also in 2015, 340B hospitals provided \$23.8 billion in uncompensated careⁱ and \$51.7 billionⁱⁱ in total benefits to their communities. Hospitals were able to provide these benefits despite significant fiscal pressures thanks in part to the 340B program. In 2015, one out of every four 340B hospitals had a negative operating margin, and one in three 340B critical access hospitals (CAHs) had a negative operating margin.ⁱⁱⁱ

340B has Grown as Congress Intended. Drug manufacturers consistently misrepresent growth in the program. While the 340B program expanded as a result of Congressional extension of the program to support more communities, much of the program growth can be attributed to drug manufacturers' dramatic price increases for outpatient drugs and the appropriate move of more hospital-based care to the outpatient setting.

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 hospitals included CAHs, rural referral centers, sole community hospitals and free-standing cancer hospitals. These hospitals now account for 54 percent of 340B-eligible hospitals. Many of these hospitals are the lifelines of their community, and the discounts they receive through the 340B program play an important role in allowing these organizations to care for patients.

Meanwhile, drug manufacturers have significantly increased drug prices, which gives the appearance that the 340B program has grown. As the cost of drugs increase, the value of the discounts correspondingly increase; therefore, the “growth” in the program is self-generated by the drug manufacturers. For example, cancer medications approved in 2000 cost an average of \$1,869 per month compared to \$11,325 for those approved in 2014. The 340B discount for an \$11,325 drug is thereby greater than the discount off a \$1,869 drug. Many stakeholders have questioned the rationale and validity of these drug price increases. Such dramatic price increases underscore the importance of the 340B program in preserving access to care.

Oncology Patients Benefit from 340B. 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 and incentives for improved quality, efficiency and coordination across the continuum of care. The implementation and cost of electronic health records also has fueled closer relationships among providers. In fact, several economists studying market consolidation have concluded that mergers in the oncology field are not driven primarily as a way for hospitals to get access to discounted drugs.^{iv}

In addition, closer relationships between oncologists and hospitals can help these physicians care for their patients. Unlike independent oncology practices, hospitals care for all patients who seek care, regardless of their insurance status or ability to pay, thus enabling affiliated providers to serve more individuals in their communities. The 340B program also helps these clinicians afford the drug therapies they need to treat their patients.

SUPPORT FOR PROGRAM INTEGRITY EFFORTS TO STRENGTHEN 340B

The AHA remains committed to ensuring the long-term sustainability of the 340B program. Over the past few years, HRSA has made significant progress in improving compliance and program integrity. Since 2011, HRSA has implemented a multitude of program integrity efforts, including an annual recertification process that requires covered entities to attest that they meet eligibility requirements and maintain compliance with program rules and guidance. In addition HRSA has established risk-based audits based on covered entities length of time in the program, number of outpatient facilities, number of contract pharmacies, complexity of the program and volume of purchases.

Despite the increased effort to improve transparency on the part of covered entities, much remains to be done to increase manufacturer transparency. 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. These rules were intended to shine needed light on drug manufacturer price increases and hold drug manufacturers accountable for price overcharging. As a result of these continued delays, covered entities are unable to challenge drug manufacturers when these manufacturers sell drugs above the 340B ceiling price. A Department of Health and Human Services (HHS) Office of Inspector General (OIG) 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.”

Unfortunately earlier this month, HHS decided to once again delay implementing the final rule on 340B drug ceiling prices and civil monetary penalties for manufacturers. This time the agency delayed implementation until July 1, 2019. We continue to be disappointed in the delays of the final rule – including five times since the beginning of last year alone –and in the short shrift given to the review of the latest public comments.

Despite the lack of parity in transparency requirements, several hospital-only transparency proposals have been introduced in Congress. These proposals would not help the program function better but would simply reduce the number of 340B hospitals by increasing the burden of compliance. As a result, communities could be harmed and implementation costs could increase for the federal government. The sole beneficiaries would be drug manufacturers, who could drive up already high margins by forcing hospitals to pay higher prices for a portion of their drugs.

CONCLUSION

We appreciate the Committee's attention to this important program and the opportunity to provide these comments. 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.

ⁱ AHA 2015 Annual Survey Data

ⁱⁱ AHA 340B Community Benefit Analysis, March 2018, accessed at <https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf>.

ⁱⁱⁱ AHA 2015 Annual Survey Data

^{iv} Alpert, A; His, H; and Jacobson, M; “Evaluating The Role of Payment Policy in Driving Vertical Integration in the Oncology Market;” *Health Affairs*, April 2017. No.4. p. 686 and <https://www.forbes.com/sites/peterubel/2018/02/08/whos-to-blame-for-the-high-cost-of-cancer-care-the-federal-government-or-justin-bieber/?source=bloomberg#c472d176da57>.