

**Statement
of the
American Hospital Association
for the
Committee on Health, Education, Labor and Pensions
of the
U.S. Senate**

“Perspectives on the 340B Drug Pricing Program”

March 15, 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, the American Hospital Association (AHA) appreciates the opportunity to submit for the record our comments on the 340B program.

For 25 years, the 340B program has been critical in helping hospitals expand access to lifesaving prescription drugs and comprehensive health care services in vulnerable communities across the country, including to low-income and uninsured individuals. The AHA and its member hospitals support program integrity efforts to ensure that the 340B program meets the Congressional objective of the program: “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 initially 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 this challenge; scaling back the program would have devastating consequences for these vulnerable communities while only driving more revenue to drug manufacturers.



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 for vulnerable populations; and
- provide access to specialty care, such as oncology care, not otherwise available to low-income individuals in the community.

For example, the 340B program helps Henry Ford Health System embed pharmacists in primary care and specialty clinics in Detroit to treat chronic diseases, and to provide additional services for all patients. Providence Cancer Center in Oregon has used 340B savings to provide life-saving infusion treatment for uninsured and marginally insured patients referred from private practice medical staff members and expand its social work and spiritual care support. Johns Hopkins Hospital in Maryland uses 340B savings to provide low-income patients with free and discounted outpatient drugs and other services, including telephone consultations, home visits and transportation services.

Despite the program's many benefits, 340B is under threat, especially because of a recent change in Medicare payment policy that reduces by nearly 30 percent, or \$1.6 billion, payments to certain hospitals for outpatient drugs purchased under the 340B program. This change is contrary to the Medicare statute and falls outside of the scope of the Secretary's authority to make. Cuts of this magnitude negate the intent of the program, reducing resources that hospitals use to expand access to care and services to vulnerable communities. We urge Congress to pass H.R. 4392, which would prevent these cuts that are reducing critical health care resources in vulnerable communities.

340B ACCOUNTS FOR A SMALL PORTION OF DRUG SALES, BUT HAS 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. In 2015, the program accounted for only 2.8 percent of the \$457 billion in annual drug purchases made in the U.S. Despite this discount program, drug

manufacturers were able to achieve double-digit margins. Also in 2015, 340B hospitals provided \$23.8 billion in uncompensated¹ care and \$51.7 billion² in total benefits to their communities. Hospitals were able to provide these benefits despite significant fiscal pressures. 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.³

MISINFORMATION ABOUT THE 340B PROGRAM

We would like to take the opportunity below to clarify some common misinformation being spread about the 340B program.

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 vulnerable communities, much of the program growth can be attributed to drug manufacturers' dramatic price increases for outpatient drugs, as more and more hospital care is provided in 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 safety-net hospitals included CAHs, rural referral centers (RRCs), sole community hospitals (SCHs) 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 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 increases, the value of the discounts correspondingly increase; therefore, the "growth" in the program is self-generated by the drug manufacturers. For example, cancer pills 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 going to be bigger 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, 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. The 340B program also helps these clinicians access the drug therapies they need to treat their patients.

¹AHA 2015 Annual Survey Data

²AHA 340B Community Benefit Analysis, March 2018 <https://www.aha.org/system/files/2018-03/340b-community-benefit-analysis.pdf>

³AHA 2015 Annual Survey Data

Government Studies Miss the Mark. 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 Medicare Part B payments for 340B hospital purchased drugs. GAO’s report claimed that financial incentives were driving 340B Medicare disproportionate share hospitals (DSH) to prescribe more expensive drugs to treat Medicare Part B patients. The AHA challenged GAO’s conclusions citing, for example, that 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. 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. In addition, when the OIG issued a report attempting to quantify what Medicare Part B pays 340B hospitals for 340B-discounted drugs, it had to acknowledge that it could not confirm that claims submitted by covered entities were in fact for drugs purchased at or below the 340B discount price.

NEJM Study’s Conclusions Lack Validity. A recent study published in the *New England Journal of Medicine* (NEJM) claimed that the 340B program does not expand access to care to low-income populations or improve their mortality rates, while driving hospital/physician consolidation. The study, as designed and executed by its authors, fails to draw meaningful, valid conclusions about the program due to constraints and serious flaws in the methodology used. Some of the concerns we have with the study include:

- using a limited sample set – just 20 percent of 340B hospitals – to make expansive statements about the implications of the program;
- relying on fee-for-service Medicare data only to make claims about the impact of the 340B program on low-income individuals, thereby ignoring that the vast majority of low-income people are not enrolled in Medicare. Only 23 percent of low-income individuals are elderly or disabled and, therefore, potentially eligible for Medicare;
- the study authors put forward their own beliefs of how the 340B program should work, not Congress’s intention for the program, which, as previously stated, is to “stretch scarce Federal resources as far as possible;” and
- failing to account for changes in coding of physician practices during the study period. Beginning in 2011, HRSA required that all outpatient and other community-based sites of care that intended to use 340B drugs for their patients register separately for the 340B program, along with other requirements. By ignoring this HRSA reporting change, the study authors fail to acknowledge that the increase in the registration of hospital-owned outpatient clinics and services in the 340B program may simply be a matter of changes in reporting.

A more detailed review of the study is available on our website, along with information on how 340B hospitals tailor programs to meet local community needs.⁴

⁴ AHA Blog, Tom Nickels, Feb 5, 2018 <https://www.aha.org/news/blog/2018-02-05-major-methodological-flaws-negate-findings-recent-340b-study>; AHA Blog, Tom Nickels, Feb 9, 2018 <https://www.aha.org/news/blog/2018-02-09-what-authors-recent-study-would-have-learned-about-340b-program-had-they-asked>

SUPPORT FOR PROGRAM INTEGRITY EFFORTS TO STRENGTHEN 340B

The AHA remains committed to ensuring the long-term sustainability of the 340B program. We appreciate policymaker interest in increased transparency and believe that 340B-participating hospitals can provide information to support how they use the program to benefit their communities through the yearly recertification process and the randomized audits required of them. However, we urge caution.

The 340B program is working as intended. Under some transparency proposals, the program would not function better, it would simply reduce the number of 340B hospitals by increasing the burden of compliance. As a result, vulnerable 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 sky-high margins by forcing hospitals to pay higher prices for a portion of their drugs.

Transparency requirements must acknowledge that 340B hospitals are large and complex organizations, providing care to thousands of patients every day in both inpatient and outpatient settings. They manage complicated financial payment systems comprised of numerous private and government payers. Hospitals cannot be compared to 340B-eligible federal grantees, which are smaller, less complex and typically serve targeted populations. Any effort to require additional reporting requirements must take into account the different capabilities of covered entities to ensure no covered entities are overly burdened.

In addition, any additional transparency requirements considered by Congress must be balanced, providing additional reporting for both covered entities and manufacturers. 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. As a result, covered entities are unable to challenge drug manufacturers when these manufacturers sell drugs above the 340B ceiling price. In fact, an HHS 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 over the ceiling price." Any effort to add transparency to the 340B program should include more robust transparency requirements of manufacturers.

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.