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Statement
of the
American Hospital Association
for the
Committee on Health, Education, Labor and Pensions
of the
United States Senate
“Examining Oversight Reports on the 340B Drug Pricing Program”
May 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 our comments on the 340B program for the record.

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 vulnerable 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 vulnerable 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 for vulnerable populations; 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 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 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. 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

MISINFORMATION ABOUT THE 340B PROGRAM

Despite the program's many benefits, 340B is under threat. Opponents of the program continue to spread misinformation to further their effort to decrease the number of hospitals and, therefore, patients that benefit from this program. We would like to take the opportunity below to clarify some common misinformation being spread about the 340B program.

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. Both of these reports have overlooked key facts regarding the program.

GAO's 2015 report claimed 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. The AHA was not alone in its critique of the report, HHS in its comments to GAO, also noted that GAO's methodology did not support its conclusion that financial incentives were driving 340B Medicare DSH to prescribe more drugs or more costly drugs to treat Medicare Part B patients. HHS further noted that a high volume of drugs in 340B DSH hospitals could lead to better clinical outcomes. GAO did note that 340B DSH hospitals had lower outpatient Medicare margins compared with other hospitals and provided more uncompensated care as a percent of revenue.

OIG's 2015 report attempted to quantify what Medicare Part B pays 340B hospitals for 340B discounted drugs and proposed options for ways Medicare could share in 340B savings by reducing Medicare Part B payments to 340B hospitals. In the report, OIG acknowledged limitations in its own analysis by stating, "We did not review Part B claims, pricing data, or covered entity enrollment data for accuracy. 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." In addition to OIG not verifying the accuracy of the underlying data, it noted that the report did not examine the impact the proposed payment reductions would have on covered entities' ability to provide services to their communities. While OIG proposed ways Medicare could share in 340B savings, it did caution that any change in payment methodology needed to provide enough financial incentives to ensure that covered entities continue to purchase Part B drugs through the 340B program.

Despite the shortcomings of these reports, the Centers for Medicare & Medicaid Services (CMS) in its final rule for 2018 Medicare outpatient payment used both the OIG and GAO reports to justify a dramatic 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 remove these cuts that are reducing critical health care resources in vulnerable communities.

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, 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 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 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, unlike independent oncology practices, hospitals care for 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.

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 intent 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.^v

SUPPORT FOR PROGRAM INTEGRITY EFFORTS TO STRENGTHEN 340B

The AHA remains committed to ensuring the long-term sustainability of the 340B program and appreciate policymaker interest in providing oversight of the program. We believe 340B-participating hospitals provide information to support their use of the 340B program through the yearly recertification process and the randomized audits required of them. While more can and should be done to improve the overall transparency of the program, we urge caution.

The 340B program is working as intended. Under some of the transparency proposals before Congress, 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 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. While federal grantees are subject to report requirements on how they use federal grant funds they have no specific reporting requirement on how they use 340B savings.

In addition, any additional transparency requirements considered by Congress must be balanced, providing additional oversight of manufacturers as well. 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 with additional implementation delays requested. 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.

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>.

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