



U.S. House of Representatives Committee on Energy & Commerce

Health Subcommittee Hearing

“Examining the 340B Drug Discount Program”

March 24, 2015

Testimony for the Record

Submitted by:

The Alliance for Integrity and Reform of 340B

Chairman Pitts, Ranking Member Green and other Members of the Subcommittee, we thank you for holding this important hearing on the 340B Drug Pricing Program—the first such hearing in nearly a decade—and we appreciate the opportunity to submit testimony for the record. The Alliance for Integrity and Reform of 340B (AIR 340B) urges the Subcommittee to closely examine the current state of the program and whether and in what ways it continues to benefit patients. Notably, we ask the Subcommittee to consider the very real challenges facing this program today in meeting its original intent: to help vulnerable, underserved patients gain access to outpatient prescription medicines. Further oversight and action is needed to bring reform, transparency and accountability to the 340B Program and to ensure that this much-needed program is both sustainable and serves its intended goals.

AIR 340B is a coalition of patient advocacy groups, clinical care providers and biopharmaceutical innovators dedicated to reforming and strengthening the 340B Program to ensure it directly supports access to outpatient prescription medicines for vulnerable, underserved patients. Alliance members believe the 340B Program is critically important to these patients, and that attention is needed to address concerns over whether the program has deviated from its original purpose leading to unintended consequences for patients.

Background

Over the past two decades, participation in the 340B Program has expanded exponentially, particularly among 340B hospitals, and yet there is little direct evidence that needy patients are benefitting from 340B hospitals as they do from other 340B providers. These other providers, which include community health centers, Ryan White clinics, family planning centers and hemophilia treatment centers, are grantees of the Health Resources and Services Administration (HRSA), and are required, under the terms of these grants, to use all income, including that generated by 340B, to benefit patients of their programs. These organizations serve the most vulnerable populations and operate as stewards of the program. In hospital-based settings, however, patients have no assurance that the 340B Program will help them access lower cost medicines. Few patients, in fact, even know the program exists; hospitals

that participate in the program are neither required to inform patients of the discounts, nor pass any discounts on to those in need of assistance. These hospitals now comprise 80 percent of the purchasing volume in the 340B Program.

Recent research has revealed three critical findings that are cause for concern:

- 340B hospitals make up one-third of U.S. hospitals. A shocking two-thirds of these 340B-participating hospitals provide charity care at a level that is **lower** than the national average. Indeed, a quarter of 340B hospitals provide charity care valued at *one percent or less of their total patient costs*.
- In recent years, thousands of pharmacies have begun contracting with hospitals to dispense 340B drugs in higher-income areas, generating revenue for themselves. That said, there is virtually no correlation between the activities and placement of these so-called “contract pharmacies” and the locations and needs of the communities of patients they are intended to be serving.
- 340B hospitals are increasingly acquiring community-based outpatient treatment facilities, reducing the availability of vital services such as community cancer care, and in many cases driving up the cost of treatment for patients. Further, those acquisitions allow the hospitals to increase their 340B profits.

Such challenges in the 340B Program have been highlighted in numerous independent reports produced by, among others, many of the witnesses at today’s hearing, including the Department of Health and Human Services Office of the Inspector General (OIG) and the Government Accountability Office (GAO).

To ensure the long-term sustainability of the 340B Program and to realign it with the needs of today’s medically underserved, vulnerable patients, AIR 340B believes that there are three vital issues that can be explored in this hearing and beyond:

1. **Policymakers should improve transparency and accountability to ensure needy patients benefit.** 340B hospitals can access 340B pricing for all of their patients, regardless of patient income or insurance status, and are not required under the 340B statute to pass those discounts on to the patient or his or her insurer. As a result, these hospitals may absorb all revenue generated by billing insurers for drugs purchased through the 340B Program without transparency for the patient, the drug manufacturer, HRSA, or Congress. Meanwhile, the number of individuals with insurance has risen substantially since the 340B program was enacted in 1992, markedly increasing this potential revenue stream. These hospitals should be held accountable for the gains made through the 340B Program; such transparency would require them to demonstrate how their 340B savings directly benefit the economically challenged patients they treat. Clear, reasonable and auditable rules for hospitals could provide assurance for all program stakeholders.
2. **Eligibility criteria for participating hospitals should be modernized.** As noted above, the number of entities in the 340B Program has increased significantly in recent years, particularly among hospitals. Indeed, between 2003 and 2013 alone, the number of disproportionate share hospitals (DSH) enrolled in the 340B program increased from 185 entities to approximately 970. Yet, while the 340B Program aims to help vulnerable, underserved patients gain access to outpatient prescription medicines, the DSH metric by which these hospitals became eligible is a measure of *inpatient* care to Medicare and Medicaid enrollees. AIR 340B believes that the 340B

Program can only meet its intended purpose if it benefits true safety net hospitals serving high numbers of low-income, uninsured, indigent patients. To that end, Congress should ensure that a hospital demonstrates a measureable indicator of its safety-net function before it is allowed to participate in 340B.

- 3. The definition of a 340B patient should be clarified to ensure the program meets its intent.** Currently, the 340B statute does not define who qualifies as 340B-eligible patient. This has led to ambiguities regarding who can be served by the program. GAO has recommended that HRSA issue a stronger, clearer “patient” definition, as it would help to improve HRSA’s monitoring of covered entity compliance. Congress and HRSA should work together to clarify the definition and interpretation of the term “patient” to ensure that it corresponds to the intent of the 340B law.

Because AIR 340B believes in and wants to preserve the original intent of the 340B Program, we look forward to hearing from nonpartisan government investigators providing testimony at today’s hearing about the challenges facing this program in its current form. We applaud the Subcommittee for taking this critically important step to hold a hearing on the 340B Drug Pricing Program, and are eager to work with you to bring more transparency and oversight to ensure that this vitally important program remains sustainable, and is able to meet its public health objective of helping our nation’s most at-risk and underserved patients.