340B Program: MYTH vs. FACT

AIR 340B
Alliance for Rx Integrity and Reform

Congress created the 340B program in 1992 to help uninsured or vulnerable patients gain better access to prescription medicines.[1] To that end, the law requires pharmaceutical manufacturers to provide discounts on outpatient prescription drugs to select health care providers. Congress expected that the 340B program would be targeted to safety net providers that served large numbers of uninsured or vulnerable patients.However, a growing body of evidence indicates that the program is not benefiting these patients and that its growth has become unsustainable, highlighting the need for policymakers to adjust current 340B eligibility criteria so that the program is able to benefit uninsured or vulnerable patients in the future.

340B is an important safety net program for patients, but there are growing concerns that in many instances, patients may not benefit as Congress intended. Moreover, there are concerns that its rapid growth is unsustainable. Testifying at the Senate Finance Committee in 2014, former Health and Human Services Secretary Kathleen Sebelius noted that the program "had expanded beyond its bounds." Critical to the mission and sustainability of the 340B program is reform. Without reforms, entities could continue to profit from the 340B program while providing minimal free or discounted care to uninsured or vulnerable patients. This is evidenced by recent analyses, including a spring 2016 study by AIR340B which documented that most 340B hospitals provide little charity care to low-income or uninsured patients.

MYTH	FACT
The 340B program should be expanded because it provides discounted drugs to patients with the greatest need.	The 340B program currently does not require that 340B discounts be passed on to patients. While clinics eligible for 340B on the basis of a federal grant typically must show that they reinvest 340B revenue into care for vulnerable patients, hospitals typically have no such requirements. Evidence suggests that in some cases, the program's benefits flow to 340B hospitals rather than patients. The Government Accountability Office, concluded in 2015 that Medicare Part B drug spending at 340B participating hospitals was higher than at hospitals that do not participate in the program, stating that, "…on average, Medicare beneficiaries were prescribed more drugs, more expensive drugs, or both, at 340B DSH hospitals." Additionally, the program may displace non-340B providers who serve a key role in furnishing health care services, typically at lower cost than 340B hospitals, which could cut patient access to these local, community providers (e.g., community pharmacies, independent oncologists).
Only hospitals that primarily serve an indigent patient population participate in the program.	Unfortunately, there is a gap between the eligibility criteria for certain types of facilities' participation in the 340B program and the mission Congress established for the program The metric generally used to qualify 340B hospitals is based on a measure of low-income insured patients and does not account for the uninsured patients a hospital treats. Eligibility is also not tied to the degree to which a hospital provides free or discounted care to low-income patients who qualify for its charity care program. In fact, recent research shows that many 340B hospitals are providing very little charity care. Reevaluation of hospital eligibility criteria is needed to ensure the 340B program is meeting its intended purpose and aiding those hospitals providing a true safety net function by serving high numbers of low-income uninsured patients.
AIR340B is seeking to dismantle the 340B program.	AIR340B would like to work with Congress and policy makers to develop a more appropriate set of eligibility criteria for hospitals, accompanied by strong oversight, that will help ensure vulnerable patients directly benefit from the program. Our goal is to improve the 340B program, by working with others to develop hospital eligibility standards that channel the program's benefits to low-income and vulnerable patients, not to cut a certain number of entities from the program or to weaken the program in any way.

MYTH	FACT
There are numerous examples of how the covered entities have used 340B program financial incentives to directly benefit patients.	AIR340B applauds covered entities that use the program to the direct benefit of patients but remains concerned about those that do not. For example, evidence shows charity care represents 1 percent or less of patient costs at 37% of 340B hospitals, and for almost two-thirds of 340B hospitals, charity care as a percent of patient costs is less than the national average of 2.2% for all hospitals. There are critical ambiguities in the standards governing multiple areas of the 340B program, and hospitals are not required to use the net income they derive from the program to benefit low-income or vulnerable patients. This has made it difficult to monitor and assure program integrity. Additional transparency is needed to validate how 340B hospitals use the 340B program to improve access and expand services for uninsured and vulnerable patients.
The enormous costs of 'uncompensated care' are borne by 340B hospitals and these costs far outweigh the value of the 340B discounts.	Various government programs exist to help hospitals meet the cost of uncompensated care. In fact, Avalere's analysis found that the total value of inpatient outlier payments, indirect medical education (IME) payments and Medicare DSH payments totaled $8.5 billion for 340B disproportionate share hospitals in 2014. Congress did not create the 340B program to compensate hospitals for situations where patients are unwilling or unable to pay their bills.
The primary critics of the 340B program are big drug companies losing money through the program.	AIR340B supports 340B and its original intent to provide discounted drugs to uninsured or vulnerable patients. In fact, the industry is on record stating its support of this critical program. However, it is unclear whether the original goals of the program are being met, even as the program continues to grow dramatically. We should all be concerned where the program fails to target true safety net providers or to ensure that vulnerable and uninsured patients reap the benefits of the program.
AIR340B is a front for 'Big PHARMA' who wants to dismantle and get rid of the program.	AIR340B is a coalition of patient advocacy groups, clinical care providers and biopharmaceutical organizations that are dedicated to reforming and strengthening the 340B program to ensure it directly supports access to outpatient prescription medicines for uninsured or vulnerable patients. AIR340B members support the program but believe that it has deviated from its original purpose.
The Health Resources and Services Administration (HRSA) – the agency responsible for overseeing the program – is liable for problems in the program.	A 2011 GAO study found that HRSA's past oversight of the program was inadequate because it primarily relied on participants' self-policing to ensure compliance. HRSA has subsequently taken significant steps to improve oversight, and such efforts to ensure program integrity must continue and expand. Adequate funding is needed to ensure that HRSA has appropriate resources to oversee the 340B program. Additionally, Congress has a role to play in reevaluating hospital eligibility criteria and other requirements to ensure that the program is targeted at supporting access for needy patients.

BOTTOM LINE

Bottom Line: Congress and executive branch policymakers should conduct a thorough examination of the 340B program to determine how it can best support uninsured or vulnerable patients who need the program, and to build in increased transparency and oversight

A diverse group of health care stakeholders have come together because they believe in the importance of 340B but recognize the need for improving this safety net program to ensure that it is helping those it was intended to help, namely uninsured or vulnerable patients.

Footnote: [1]2H.R. Rep. No. 102-384 (II) (1992).