AIRx340B
Alliance for Integrity and Reform

340B Program: MYTH vs. FACT

Overview: 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 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 and vulnerable patients. However, a growing body of evidence indicates that the program has vastly over-expanded, highlighting the need for policymakers and stakeholders to review and adjust current 340B eligibility criteria so that at-risk patients can benefit from the program.

340B is an important safety net program for patients, but there are rising concerns that in many instances, patients may not benefit as Congress intended. Moreover, there are concerns that its expansive growth is unsustainable. Testifying at the Senate Finance Committee in April, 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. Absent improvement, entities that fail to serve predominantly indigent and vulnerable patients will continue to reap program benefits to the detriment of true safety net facilities and vulnerable needy patients. This is evidenced by recent analyses, including a March study by AIR340B which documented that most 340B hospitals provide little charity care to vulnerable patients.

MYTH	FACT
The 340B program should be expanded because it provides discounted drugs to patients with the greatest need.	There is little concrete evidence of how and whether benefits of the 340B program are reaching the intended beneficiaries of the program – uninsured or vulnerable patients. Growing evidence suggests the expanded 340B program has deviated significantly from its original intent, and may incentivize conduct that leads to unintended and potentially harmful consequences for patients. Anecdotal evidence suggests that in some cases, the 340B program can skew patient care and clinical decision-making for financial incentives that may flow to the covered entities, but not to patients. Treatment decisions and clinical care pathways should always be guided by the best interest of the patient and not by access to deep discounts in the 340B program. The program may lead to displacement of non-340B providers who serve a key role in providing important health care services, typically at lower cost than 340B hospitals, which could cut patient access to these local, community providers (i.e. community pharmacies, oncologists). The need for the program will diminish as more and more Americans gain access to insurance. By 2016, for example, the ACA is expected to cause a 45% decline in the number of uninsured patients, according to the most recent Congressional Budget Office estimate.

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 metrics used to qualify 340B hospitals may not be calibrated to ensure proper identification of those safety net facilities that serve large numbers of low-income uninsured patients. In fact, recent research shows a major discrepancy between the amount of charity care that DSH hospitals provide compared to true safety net facilities. The findings show many 340B hospitals are providing very little charity care to the uninsured. Reevaluation of hospital eligibility criteria is needed to ensure 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 change eligibility criteria in ways that would cut 80 percent of hospitals and other covered entities from this program.	AIR340B would like to work with Congress and policy makers to develop a more appropriate set of eligibility criteria, accompanied by strong oversight, that will help ensure vulnerable patients directly benefit from the program. As with any specific policy proposal, it's always important to consider the details on broad program changes. The coalition agrees that a new metric on entity eligibility may provide a better way to capture true safety net providers that provide the majority of care to indigent vulnerable patients. The Coalition looks forward to working with Congress to come up with specific reform policies that will address the program's short-comings.
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 do not. For example, evidence shows charity care represents 1% or less of patient costs at approximately one-quarter of 340B hospitals, and for more than two-thirds of 340B hospitals, charity care as a percent of patient costs is less than the national average of 3.3% for all hospitals. There are critical ambiguities in the standards governing multiple areas of the 340B program, and a number of covered entities have no formal requirement governing use of funds to benefit the low-income uninsured 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.
340B discounts are not intended to go directly to patients; they are intended to help offset the broader costs of serving at-risk patients and providing other important community services.	The original intent of the program was to lower drug costs so that federal grantees and true safety net hospitals could use their federal grant money to buy more drugs or other items they needed to serve vulnerable uninsured patients. There is no definitive evidence that Congress meant that these entities should charge patients or insurers higher rates.
The enormous costs of 'uncompensated care' are borne by 340B hospitals and these costs far outweigh the value of the 340B discounts.	Medicaid and other programs help hospitals meet the cost of uncompensated care. 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.	The biopharmaceutical industry 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 program fails to target true safety net providers or 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 recently 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 supports access for needy patients.

Bottom Line: Because of the potentially serious consequences that could evolve from these and other findings, Congress and other federal policymakers should conduct a thorough examination of the 340B program to ensure it is meeting its original goals through increased transparency and oversight to best support uninsured or vulnerable patients who need the program.

A diverse group of health care stakeholders, including BIO, the Community Oncology Alliance (COA), the Pharmaceutical Care Management Association (PCMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), 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.

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