The 340B Drug Pricing Program:
Maintaining Critical Support to Safety Net Hospitals and Their Patients

Congress created the 340B Drug Pricing Program in 1992 under the Public Health Service Act to support certain safety-net hospitals and other providers that serve low-income, vulnerable patients. At no cost to taxpayers, the program allows these "covered entities" to purchase outpatient drugs at a discount from drug manufacturers to help "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

The 340B Program Provides Vital Support and Access to Vulnerable Patients and Communities

- Only hospitals that treat a significant share of vulnerable patients can qualify for 340B. These safety-net hospitals utilize the savings under the 340B program to provide access to programs and services for their communities, including low-income, rural, and other underserved patients. Some examples include:
    - Providing free or substantially discounted prescriptions to uninsured or low-income patients,
    - Creating multidisciplinary clinics to treat mental health and/or substance use disorders,
    - Bringing mobile health care units to communities with no local primary care provider or pharmacy, and
    - Improving access to specialized care previously unavailable in underserved areas.

The 340B Program Makes a Big Impact at No Cost to Taxpayers

- Because the 340B program allows safety-net hospitals and other eligible providers to leverage discounts from pharmaceutical companies to provide patients and communities with access to care they otherwise would not receive, there is no cost to taxpayers.
- Restricting the scope of the program would not result in additional funds for the federal government and could potentially leave patients who rely on these essential programs without necessary services.
- According to the Health Resources and Services Administration (HRSA), which administers the program, 340B sales are less than three percent of the total U.S. drug market.[2] Yet, the discounts generated from the program allow safety-net hospitals to provide crucial services to their patients.

Clarifying Misperceptions About the 340B Program

340B spending has remained relatively constant even with program expansion

- Congress expanded the 340B program in 2010 to include additional eligible providers due to the success of the program in helping safety-net providers provide access to health care services to the neediest patients.

[1] H.R. Rept. No. 102-384(II), at 12 (1992)
[2] Department of Health and Human Services Fiscal Year 2018, Health Resources and Services Administration, Justification of Estimates for Appropriations Committee: https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-2018.pdf

- Even with this increase, total 340B drug spending has remained relatively constant – having only increased one percentage point compared to total drug sales since 2012. At the same time, a recent GAO report shows that annual profit margins of the largest 25 pharmaceutical companies have increased between 15-20 percent since 2006.[3]

Closure of oncology practices and physician consolidation are not related to 340B

- Studies have shown that increased consolidation in the market for cancer care is part of a broader trend toward integration of health care systems, and is not related to the 340B program.[4]
- The trend for the shift in cancer care to hospital-based practices is due to a variety of factors, including changes in reimbursements and regulatory requirements related to information technology.[5]

Providers' prescription decisions are based on patient needs, not 340B discounts

- Many 340B hospitals are major referral centers with highly specialized expertise that serve a sicker, more complex, and more vulnerable patient population.
- New and emerging drug therapies, particularly infusion medicines, are more expensive because of the prices set by pharmaceutical companies and price inflation.
- For many patients, the most effective drug regimen consists of new, high-priced drugs.

Legislative Proposals Would Not Benefit Taxpayers or Patients

Recent legislation introduced in the House (H.R. 4710) and Senate (S. 2312) would weaken the 340B program by creating a moratorium on participation, changing eligibility requirements, and imposing burdensome reporting requirements.

A moratorium would limit access to care

- A moratorium that prevents newly eligible disproportionate share hospitals (DSH) and their associated outpatient clinics from enrolling in the program would restrict hospitals' ability to expand services for low-income patients. Since many of these services are preventative, this would lead to higher health care costs and less services to those who need them the most. Because 340B is not funded by taxpayers, these changes would not save the government any money; they would simply limit discounts pharmaceutical companies would be required to provide.

Focusing on charity care would change the intent of the 340B program

- Efforts to link charity care to the 340B program do not fully account for the magnitude of comprehensive services DSH hospitals provide for underinsured and uninsured patients, including bad debt and underpayment by public programs. This change would shift the focus of the program and reduce the amount of services hospitals are able to provide to low-income patients, while not saving taxpayers any money.

3 U.S. Government Accountability Office, "Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals." https://www.gao.gov/assets/690/688472.pdf

4 Alpert, Abby, et al. "Evaluating The Role Of Payment Policy In Driving Vertical Integration In The Oncology Market." Health Affairs, Vol. 36, No. 4, 2017, pp. 680–688.

5 Kantarjian, Hagop and Chapman, Robert. "Value of the 340B Drug Discount Program." JAMA Oncology, Vol. 1, No. 8, 2015, pp. 1029-1030.

- While 340B DSH hospitals represent just 29 percent of Medicare hospitals, they bear 67 percent of charity care costs, 54 percent of bad debt costs, and 56 percent of Medicaid shortfalls.

Reporting requirements increase burden on hospitals without helping patients

- The bills' proposed reporting requirements would be extremely burdensome for safety-net hospitals. Reducing the scope of the program would only reduce the ability of these hospitals to support low-income patients since manufacturers would not be required to provide discounts to as many entities.
- Many covered entities go beyond HRSA's program integrity requirements and invest additional resources to maintain compliance.
- Any effort to improve transparency should also include drug manufacturers.

The AAMC looks forward to working with Congress and the Administration to strengthen the 340B Drug Pricing Program to ensure that America's safety-net hospitals can continue providing important programs to low-income and vulnerable communities.

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