Ryan White Clinics for 340B Access

WHY MAKING 340B A DIRECT PATIENT BENEFIT WOULD HARM RYAN WHITE HIV PATIENTS

ISSUE

Some critics of the 340B program argue that the program is not benefitting patients because the discounts required under the 340B statute are not being directly passed through to individual patients. While such an argument may sound benign or even pro-patient, it is potentially harmful to the health and wellbeing of patients, especially patients of Ryan White clinics (RWCs).

HOW 340B WORKS

The 340B program was established in 1992 as a bipartisan solution to rising drug prices. As a condition of having their drugs reimbursed by Medicaid and Medicare Part B, manufacturers are required to give significant discounts on the outpatient drugs that they sell to qualified nonprofit safety net hospitals and clinics, referred to under the 340B law as "covered entities."

The 340B program is structured so that drug discounts are provided to 340B safety net providers, not to individual patients. In fact, Congress was very clear that price reductions would flow to the covered entities when it described the intent of the program.

> *"In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."*

For over 25 years, the 340B program has been working as intended with the express goal of enabling safety net hospital and clinics to provide more patients with more comprehensive services – at virtually no cost to taxpayers and at relatively low cost to pharmaceutical manufacturers.

HOW 340B WORKS FOR RYAN WHITE CLINICS

RWCs are community-based organizations on the front lines of fighting the AIDS epidemic. They have the necessary experience and infrastructure to provide the full continuum of care to low income and other vulnerable patients in an outpatient setting. When an HIV/AIDS patient achieves viral suppression, the disease cannot be transmitted to another individual, thereby avoiding the increased health care spending that would be needed to treat that individual.

To achieve viral suppression, RWCs provide many services – prevention, testing, linkage and adherence to care – which, in turn, enables people living with HIV/AIDS to access and remain in care so that they can lead healthy and productive lives. These critically important services are not reimbursed by any payer.

The 340B program is instrumental in helping RWCs care for people living with HIV/AIDS and reduce their viral loads because of the following factors.

- The 340B program allows safety net providers to generate both savings and revenue to underwrite the cost of care for the uninsured, underinsured, and other vulnerable populations. Without this resource, RWCs would not have sufficient support to provide the comprehensive care that their patients need.
- The 340B program gives RWCs the flexibility to determine how to use 340B program savings and revenue to meet the public health needs of individuals with HIV in their communities.
    - For example, certain prevention and adherence methods that work in some rural areas, cities, or states may not be successful in other areas. And, while some communities are in dire need of pharmacists, others need more mental health care or addiction treatment services.
    - Further, some individuals living with HIV/AIDS face the dual stigma of also being homeless, unemployed, facing addiction issues, uninsured and/or dependent on financial assistance including Medicare and Medicaid.
- RWC-340B supports the President's goal of eradicating the HIV/AIDS epidemic, a goal which is attainable only through the delivery of comprehensive HIV services.
    - Providing the full continuum of care is often expensive and requires special expertise.
    - The 340B program gives RWCs the resources they need to achieve significantly higher rates of viral suppression and ultimately reduced transmission of HIV to other individuals.

DANGERS OF ADMINISTERING 340B AS PATIENT ENTITLEMENT PROGRAM

The need for comprehensive care for HIV/AIDS patients would not diminish if pharmaceutical manufacturers only gave drug discounts directly to patients. Limiting 340B to simply drug discounts for individual patients would completely eliminate the reasons why 340B works for RWCs for the reasons outlined below.

<u>Discounts Alone Would Not Make Care Affordable or Comprehensive</u>

- Even the discounted 340B price for most brand name drugs is still unaffordable for most patients. The cost of some new HIV/AIDS medications is so high even with a 340B discount (more than $2,300 per month) that RWC patients would still find the drugs unaffordable.
- RWCs provide drugs at little or no cost to patients who cannot afford them, but also use the 340B program more broadly to provide the comprehensive care that is so important to stopping the spread of HIV/AIDS.
    - For many individuals living with HIV/AIDS, access to non-pharmacy services made possible by 340B discounts – primary and specialty care, case management, housing, transportation, nutrition, and other support services – is equally as important to achieving desired health outcomes as access to low cost drugs.

<u>Detrimental to Health Care Outcomes</u>

- According to peer-reviewed literature, access to free or low cost drugs can be ineffective or even detrimental to patient health if not accompanied by a broader system of care. In fact, access to discounted drugs is only one relevant factor among many for addressing patient health outcomes, quality of care, and health care costs.

- In order to lower health care costs and improve patient outcomes, interventions must address patient knowledge, attitudes, complexity of prescription regimens, and other difficulties in accessing medications.
- Studies show that merely eliminating cost-sharing requirements, without a broader system of support, has a negligible impact on patient outcomes and overall health care costs and may even reduce compliance with medication regimens.[1]
- Patients who have no out-of-pocket expenses are less adherent to their medication regimens, indicating that patients with no out-of-pocket expenses may place less value on their medications than do patients who must pay even a small amount.[2]

Threatens Fight Against HIV/AIDS Epidemic

- Covered entities would serve fewer patients and provide fewer services because they would receive little to no 340B revenue to help pay for those patients and services, contrary to Congressional intent.
- Such a dramatic policy shift would inevitably and substantially diminish RWCs' ability to serve the HIV/AIDS population and to protect against the spread of the epidemic.
- RWCs are often the first and last line of defense in getting and keeping patients in care, providing them with the full complement of services to keep them from spreading the virus to others.

Taxpayers Forced to Pick up Cost of Care

- If the 340B program became simply a patient assistance program without the broader resources necessary to fight the HIV/AIDS epidemic, the epidemic could spread.
- States or the federal government would be forced to step in, shifting the cost of HIV care from pharmaceutical manufacturers to taxpayers.

Only Helps Manufacturers

- It does not make sense to upend a program that has worked for 25 years simply to lessen pharmaceutical manufacturer's responsibility to provide support to safety net providers.
- In fact, discounts provided by manufacturers only represent less than 2% of total drug spend in the U.S. As such, this attack on the 340B program is clearly a distraction campaign away from high drug prices.

RWC-340B is a national association of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program.

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[1] Niteesh K Choudhry et al., *Full Coverage for Preventive Medications after Myocardial Infraction*, 365 New Engl. J. Med. 2088 (2011); Francois Despres et al., *Impact of Patient Reimbursement Timing and Patient Out-of-Pocket Expenses on Medication Adherence in Patients Covered by Private Drug Insurance Plans*, 22 J. Manag. Care Pharm. 539 (2016).

[2] Francois Despres et al., *Impact of Patient Reimbursement Timing and Patient Out-of-Pocket Expenses on Medication Adherence in Patients Covered by Private Drug Insurance Plans*, 22 J. Manag. Care Pharm. 539 (2016).