The PROTECT ACT: Protect 340B Safety Net Providers & Communities from Discriminatory PBM/Insurer Practices

OVERVIEW

The federal 340B Drug Pricing program offers a lifeline to the neediest and most underserved patients in this nation. Established by Congress in 1992, this program requires pharmaceutical companies to provide drugs at discounted prices to specified clinics and hospitals – Federally Qualified Health Centers (FQHCs), Ryan White HIV/AIDS clinics (RWCs), Medicare Disproportionate Share hospitals, rural hospitals, children's hospitals, and others.

> The 340B savings earned by safety net providers enable them to serve more patients with more comprehensive services (the stated intention behind the original law). The Government Accountability Office (GAO) said, *"Providers use 340B to: offset losses incurred from treating some patients, continue providing existing pharmaceutical and clinical services, lower drug costs for low-income patients and serve more patients, and provide additional services, such as case management to facilitate access to appropriate care."*

ISSUE: DISCRIMINATORY TREATMENT BY PBMS AGAINST 340B SAFETY NET PROVIDERS

PBMs/insurers reimburse safety net providers for drugs that pharmacies dispense to patients. Through their contract terms, PBMs/insurers have found creative ways to take the 340B benefit away from safety net providers. As a result, the savings accrue to these for-profit, third-party middlemen at the expense of vulnerable patients for whom they were intended.

HOW DOES THIS 340B DISCRIMINATION HAPPEN?

The most common form of discrimination occurs when a for-profit PBM or other third-party payor forces safety net providers to accept contract terms that unfairly discriminate against 340B safety net providers, among other unfair practices. <u>For example, some PBMs/insurers reimburse safety net providers for drugs at lower rates than non-340B providers, exclude 340B safety net providers from networks, interfere with patient choice of provider, impose onerous reporting requirements, or simply refuse to contract with 340B safety net providers.</u> Most safety net providers do not have the market power to successfully push back against these huge, for-profit companies. If 340B providers refuse the terms offered, they will jeopardize their ability to serve their patients and communities.

MS. JONES: UNINSURED PATIENT AT 340B PROVIDER	MR. SMITH: INSURED PATIENT AT 340B PROVIDER

• Takes heart medication that normally costs $100.
• Because of 340B, heart medication is $70, instead of the $100 regular price.
  ○ *Even with this discount, the safety net provider still loses $60 when charging Ms. Jones $10 for her medication ($70 purchase price - $10 copay).*
• **Ms. Jones PBM/insurer discriminates against 340B providers by paying them only $70.**
• <u>Without the 340B savings, the safety net provider can longer afford to provide Ms. Jones with affordable medication.</u>
• **The PBM/insurer has taken the benefit away from the safety net provider and patients they serve.**
	• Takes heart medication that normally costs $100.
	• PBM/insurer normally pays providers $100 for his heart medicine.
	  ○ *This allows the safety net provider to retain $30 in savings ($100 payment - $70 purchase price) to help offset the cost of providing the medication.*
	• **Mr. Smith's PBM/insurer discriminates against 340B providers by paying them only $70.**
	• <u>Without the 340B savings, the safety net provider can no longer use the benefit of the program to provide discounts to Ms. Jones or other patients.</u>
	• **The PBM/insurer has taken the benefit away from the safety net provider and patients they serve.**

Summary of the PROTECT 340B Act of 2021

Supported by: 340B Health, America's Essential Hospitals, National Association of Community Health Centers, Ryan White Clinics for 340B Access

Protections related to private insurance plans: Adds a new Section 2730 to the Public Health Service Act, which applies to private insurance plans:

(a) **General Prohibition:** Generally prohibits health insurers and Pharmacy Benefit Managers (PBMs) from discriminating against 340B providers or their contract pharmacies on the basis of their status as providers or pharmacies that dispense 340B drugs by imposing different rules or reimbursement terms than are imposed on other providers or pharmacies.

(b) **Specific Prohibited Actions:** Specifically prohibits insurers and PBMs from:

- Treating 340B providers and their contract pharmacies differently from other similarly-situated providers and pharmacies with regards to:
    - Reimbursement (1)
    - Fees (including professional dispensing fees), adjustments, etc. (2)(A) & (B)
    - Participation in standard or preferred networks – (2)(C)
    - Audits and inventory management systems – (2)(D)
- Interfering in patients' choice to receive drugs from a 340B pharmacy, whether in person or by mail (3)
- Requiring 340B providers or pharmacies to identify 340B drugs, other than for Medicaid purposes (4)
- Refusing to contract with a 340B provider or contract pharmacy (5)
- Imposing "Any other restrictions, conditions, practices, or policies that, as specified by the Secretary through rulemaking, interfere with the ability of a covered entity to maximize the value of discounts provided under section 340B." - – (2)(E)

(c) **Enforcement.**

- For PBMs: The HHS Secretary will impose civil monetary penalties.
- For insurers: Section XXVII of the Act already contains enforcement mechanisms.

Protections for Medicare Parts C & D plans: Applies the above rules (Section 2730 of the Public Health Service Act) to Medicare Parts C and D plans.

National clearinghouse to prevent duplicate discounts under Medicaid: Instructs HHS to contract with a neutral third party to serve as a clearinghouse for data needed to prevent duplicate discounts under Medicaid. The contractor will collect data on 340B drugs reimbursed by Medicaid and state rebate data and ensure that those drugs are not included in States' Medicaid rebate requests.