Executive Summary: 340B Reform - Recommendations to Support Healthy Aging & Health Innovation

Overview

The 340B Drug Pricing Program was established by Congress in 1992 to help low-income and uninsured patients access their treatments. The program enables eligible healthcare providers (known as "covered entities"), such as hospitals and local health clinics, that serve a significant proportion of those patient populations to purchase outpatient drugs from biopharmaceutical manufacturers at a significant discount. The program was designed with the intent that 340B covered entities would use savings from drug discounts to provide patients in need with more affordable and accessible care.

However, there is inconsistency in how covered entities that participate in 340B demonstrate how they use savings from the purchase of discounted drugs to provide care to the patients the program was intended to serve. At the same time, for-profit pharmacy benefit managers (PBMs), through their ownership of and affiliation with pharmacies that contract with 340B entities (known as "contract pharmacies"), are silently siphoning away critical dollars and increasing the burden on American patients, families, and employers, instead of passing savings to the low-income populations the program was designed to support.

The lack of transparency and accountability in 340B has fueled abuses of the program and allowed 340B covered entities, national pharmacy chains, and for-profit middlemen to exploit the program for financial gain.

340B is the second-largest prescription drug program in the country, expected to surpass Medicare Part D, Medicaid Part B, and Medicaid in size by 2028.

In 2023, discounted drug purchases under 340B totaled over $66.2 billion.

Key Challenges: Misuse of 340B

Lack of Reporting Requirements:
The 340B program does not mandate that covered entities disclose how they use revenue generated from drug discounts or how these funds benefit patients.

Lack of Charity Care:
Evidence suggests that some participating hospitals may not reinvest 340B savings into safety-net care as intended.

Expansion in Affluent Neighborhoods:
Due to a lack of oversight within the 340B program, there is a perverse incentive to maximize revenue by gaining access to a larger pool of well-insured patients.

Increased Burden on American Employers, Health Plans, and Families: Exploitation of the 340B program also drives up costs for and increases burdens on American employers, health plans, and families.

Impacts on Healthy Aging & Innovation

Abuse of the 340B program has an impact on opportunities for healthy aging and the ability of older adults to access their medications. Treatments for conditions that disproportionately impact older populations make up significant percentages of the total sales within the 340B program. In turn, abuse of the 340B program by covered entities and middlemen, and the lack of transparency in the charity care provided to patients as a result, disproportionately impacts aging adults.

As covered entities often fail to use 340B drug discounts to benefit patients, these funds also are not flowing back into the life sciences ecosystem that brings innovative treatments to patients and enables healthier aging. The absence of transparency into how these dollars are used to help patients allows the funds to be diverted into profits for bad actors rather than being invested into the development of innovative healthcare solutions that will bring better health outcomes and longer, healthier lives for patients.

> Nearly 95 percent of Americans age 60 and older are living with at least one chronic condition and nearly 79 percent are living with two or more chronic conditions.

> Rates of chronic conditions in older Americans are set to double by 2050.

Policy Solution: Comprehensive Federal Reforms

In recent years, a growing number of state legislatures have introduced legislation pertaining to the federal 340B program – creating a confusing patchwork of policies across the country which make an already complex system even more difficult to navigate and exacerbating the opportunity for for-profit middlemen to exploit loopholes in 340B for their own financial benefit.

Only through comprehensive federal reforms can the necessary transparency and accountability measures be instituted to 340B to ensure it is carrying out its original intent and mitigate negative impacts on the supply chain.

Key Takeaway

*By **increasing transparency and accountability through comprehensive federal reform,** the 340B program could better align with its original mission of supporting vulnerable populations, while fostering equitable access to care and innovation.*

To address these issues, several federal policy reforms could be considered:

Mandatory Reporting: Require 340B claims transparency and covered entities to disclose detailed information on how 340B savings are used, including specific investments in patient care and community health programs.

Stricter Eligibility Criteria: Narrow eligibility requirements to ensure that only truly safety-net providers benefit from the 340B program.

Enhanced Oversight: Implement regular audits and compliance checks by federal agencies, such as the Health Resources and Services Administration (HRSA) and the Centers for Medicare & Medicaid Services (CMS), to prevent misuse of funds.

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