340B DRUG PROGRAM

THE SOLUTION:

Protect the 340B Prescription Drug Program. Section 340B of the U.S. Public Health Service Act provides that pharmaceutical manufacturers that choose to participate in Medicare and Medicaid sell certain outpatient drugs to safety-net providers at a discount.



WHY IS 340B IMPORTANT?

Every American uses the health care system in one way or another. For people who are elderly or who live in poverty, the U.S. government helps pay for their health care costs through the Medicare and Medicaid programs. Most hospitals, clinics, doctors and pharmaceutical companies participate in both programs because they cover such a high percentage of Americans.

The 340B program helps hospitals and other providers procure medications from drugmakers for Medicare and Medicaid patients at a discount. It helps share the burden of costly medications and treatments. Without the 340B drug program, hospitals will be forced to absorb the entire cost of a patient's care. This may lead to catastrophic outcomes for hospitals like service lines discontinued and facility closures.

WHAT ARE DRUGMAKERS DOING TO AVOID THEIR RESPONSIBILITIES?

Drugmakers make an end run around 340B in many different ways. They include:

- Deciding not to cover certain drugs but cover others, often in confusing and ever-changing ways.
- Dictating that a hospital use only one pharmacy to process 340B claims, thus undermining local pharmacies and confusing patients who now have to figure out which pharmacy they should visit.
- Requiring hospitals to submit onerous amounts of paperwork to process 340B claims.
- Asking for excessive amounts of records from hospitals to verify that they meet their standards (not the federal government's) for receiving 340B discounts.

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These actions result in disruptions to patients, increased costs to the system, degrading of hospitals' finances and increased profits for them. For all intents and purposes, drugmakers are making money off the backs of the poor by building mountains of red tape.

A CONGRESSIONAL SOLUTION

In September 2022, the U.S. District Court of the District of Columbia issued an order to HHS to resolve their 340B payment guidelines to the full amount prior to reductions enacted in 2018. HHS has ruled that they will pay affected hospitals back what they are owed, but only by lowering future hospital Medicare reimbursements. This is fundamentally unfair.

Passing a bill like the Protect 340B Act (H.R. 2534) would fully address imbalances that both drugmakers and HHS are unwilling to challenge. In general, any Congressional solution should do the following:

- Give either HHS-HRSA or CMS complete enforcement authority over 340B non-compliance.
- Prohibit drugmakers from limiting which pharmacies hospitals can contract with for 340B purposes.
- Prohibit discriminatory actions by Pharmacy Benefit Managers against 340B entities and their pharmacy partners.
- Allow hospitals that are not operating with negative margins to use common documents for 340B reporting purposes like their S-10s and IRS Form 990s.





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