

340B PATIENTS ACT DRAFT LEGISLATION

Proposed bill to reform the 340B drug pricing program.

Purposes

- Clarify that drug manufacturers must offer 340B pricing regardless of how or where drugs are dispensed.
- Allow covered entities to contract with pharmacies to dispense 340B drugs, generating savings to provide more comprehensive patient care.

Clarifications on 340B Pricing

Requirement for Drug Manufacturers:

- Must offer 340B pricing regardless of dispensing method or location.
- Prohibited from placing conditions on the purchase or use of 340B drugs without the Secretary's approval.

Enhanced Manufacturer Compliance

Penalties for Non-Compliance:

- Imposes civil monetary penalties for violations that are committed both knowingly and intentionally, excluding overcharges.
- Penalties can reach up to \$2,000,000 per day based on the nature and extent of the violation.
- Continued daily penalties until compliance is achieved.

Support for Contract Pharmacies

Contract Pharmacy Agreements:

- Covered entities can contract with pharmacies for dispensing 340B drugs.
- These pharmacies must comply with the same requirements as the covered entities.

Regulations and Claims Process

- Within 180 days of the legislation's enactment, the secretary will establish regulations to address claims of violations submitted by covered entities.

118TH CONGRESS
2D SESSION

H. R. _____

To amend title III of the Social Security Act to ensure the accessibility of drugs furnished under the 340B drug discount program.

IN THE HOUSE OF REPRESENTATIVES

Ms. MATSUI introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title III of the Social Security Act to ensure the accessibility of drugs furnished under the 340B drug discount program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. SHORT TITLE.**
4 This Act may be cited as "The 340B Pharmaceutical
5 Access To Invest in Essential, Needed Treatments & Sup-
6 port Act of 2024" or "The 340B PATIENTS Act of
7 2024".

