

## ***340B Prescription Drug Program Anti-Discrimination Model Act***

***This draft language was submitted for discussion purposes by the National Association of Community Health Centers (NACHC) and 340B Health.***

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### **Section 1. Title**

This act shall be known as and may be cited as the “340B Prescription Drug Program Anti-Discrimination Model Act.”

### **Section 2. Purpose**

The Legislature hereby finds and declares that:

- (A) The 340B program enables safety-net providers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
- (B) Section 340B of Public Health Service Act requires pharmaceutical manufacturers to provide 340B discounts in order to have their drugs covered by Medicaid and Medicare Part B.
- (C) To participate in 340B, providers must meet strict eligibility criteria.
- (D) 340B savings support hospitals, clinics, and health centers’ care for patients who have low incomes, including those with low incomes enrolled in Medicaid and Medicare.
- (E) Over the last several years, some pharmacy benefit managers and health plans have used unique 340B participation agreements or addenda when contracting with 340B providers and their contract pharmacies.
- (F) Some of the agreements offer reimbursement rates below the rates paid to non-340B pharmacies, depriving providers of part or all of the financial benefit that Congress intended for them to receive when 340B was established.

- (G) Payers sometimes impose 340B claim identification requirements on 340B providers that are burdensome and impede covered entities' ability to use 340B drugs.
- (H) 340B providers should not be subject to payer practices that undermine the use of 340B drugs.
- (I) 340B providers should not be subject to burdensome requirements for the purpose of accommodating private contractual arrangements of payers and pharmaceutical manufacturers.
- (J) There is a need in the state to protect providers' 340B benefit from discriminatory payer practices in order to preserve the state's health care safety-net.

### **Section 3. Definitions**

- (A) "340B covered entity" means an entity described in section 340B(a)(4) of the "Public Health Service Act," 42 U.S.C. 256b(a)(4).
- (B) "340B drug" means a drug that is—(1) a covered outpatient drug (as defined for purposes of section 340B of the Public Health Service Act); and (2) purchased under an agreement in effect under such section.
- (C) "340B pharmacy" means: (1) a covered entity participating in the 340B drug discount program; (2) a pharmacy of a covered entity participating in the 340B drug discount program; or (3) a pharmacy contracting with a covered entity participating in the 340B drug discount program to dispense drugs purchased through the 340B drug discount program.
- (D) "Third party" means a group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager that reimburses a 340B covered entity for drugs. Third party includes Medicaid managed care organizations, employee benefit plans under the Employee Retirement Income Security Act of 1974, or Medicare Part C or D plans. Third party does not include drugs reimbursed under Medicaid fee-for-service or a self-pay patient.

### **Section 4. Prohibited Actions**

A third party may not discriminate against a 340B pharmacy by imposing requirements, exclusions, reimbursement terms, or other conditions on the 340B pharmacy that differ from those applied to entities or pharmacies that are not 340B pharmacies. Prohibited actions by third parties include, but are not limited to, the following:

- (A) Reimbursing a 340B pharmacy for drugs at a rate lower than that paid to non-340B pharmacies or lowering reimbursement for a claim on the basis that the claim is for a 340B drug

- (B) Imposing any terms or conditions on 340B pharmacies with respect to any of the following that differ from such terms or conditions applied to non-340B pharmacies on the basis that entity is a 340B pharmacy or that the drug dispensed is a 340B drug:
- (1) Fees, chargebacks, clawbacks, adjustments, or other assessments.
  - (2) Dispensing fees that are less than the dispensing fees for non-340B pharmacies.
  - (3) Restrictions or requirements regarding participation in standard or preferred pharmacy networks.
  - (4) Requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles.
  - (5) Any other restrictions, conditions, practices, or policies that are not imposed on non-340B pharmacies.
- (C) Requiring identification, billing modifiers, attestation, or other indication that a drug or claim is for a 340B drug unless the drug or claim is being billed to Medicaid fee-for-service or a Medicaid managed care plan and the state requires 340B claim identification
- (D) Requiring a 340B pharmacy to reverse, resubmit, or clarify a claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing
- (E) Excluding a 340B pharmacy from a network on the basis of the pharmacy's participation in 340B or refusing to contract with a 340B pharmacy for reasons other than those that apply equally to non-340B pharmacies
- (F) Imposing any provision that prevents or interferes with an individual's choice to receive a prescription drug from a 340B pharmacy, including the administration of the drug, in person or via direct delivery, mail, or other form of shipment, or creation of a restriction or additional charge on a patient who chooses to receive drugs from a 340B pharmacy
- (G) Using a definition of "pharmacy" that factors in a pharmacy's participation in 340B
- (H) Requiring or compelling the submission of ingredient costs or pricing data or pertaining to drugs purchased under section 340B

## **Section 5. Enforcement**

Upon enactment of this law, any provision of a contract that is contrary to this section is void and unenforceable. A civil monetary penalty shall be imposed on any third party that violates the requirements of this section. Such penalty shall not exceed \$5,000 per violation per 340B pharmacy per day.

A violation of any provision of this article by a third party constitutes an unfair or deceptive act or practice in the business of insurance under [insert state reference] and is considered void and unenforceable.

**Section 6. Rules**

The [chief State insurance regulator] shall propose and adopt regulations to implement this Act.

**Section 7. Effective Date**

This Act shall become effective immediately upon being enacted into law.

**Section 8. Severability**

If any provision of this Act is held by a court to be invalid, such invalidity shall not affect the remaining provisions of this Act, and to this end the provisions of this Act are hereby declared severable.