LAWS OF DELAWARE VOLUME 84 CHAPTER 408 152nd GENERAL ASSEMBLY FORMERLY HOUSE SUBSTITUTE NO. 1 FOR HOUSE BILL NO. 383 AS AMENDED BY HOUSE AMENDMENT NO. 1 AND HOUSE AMENDMENT NO. 2 AND SENATE AMENDMENT NO. 1

AN ACT TO AMEND TITLES 18 AND 24 OF THE DELAWARE CODE RELATING TO PROHIBITING DISCRIMINATION AGAINST 340B DRUGS AND COVERED ENTITIES BY MANUFACTURERS AND PHARMACY BENEFITS MANAGERS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF DELAWARE:

Section 2. Amend Subchapter VII, Chapter 33A, Title 18 of the Delaware Code by making deletions as shown by strike

through and insertions as shown by underline as follows:

§ 3374A. Prohibition of discrimination against 340B entities by pharmacy benefits managers.

(a) For purposes of this section:

(1) "340B drug" means a drug that is a covered outpatient drug under 42 U.S.C. § 256b.

(2) "340B drug program" means the federal drug pricing program under 42 U.S.C. § 256b that limits prices on drugs

purchased by covered entities.

(3) "Claim" means a request from a covered entity or the covered entity's contracted pharmacy to be reimbursed for

the cost of filling or refilling a prescription for a drug or for providing a medical supply or device.

(4) "Covered entity" means as defined in 42 U.S.C. § 256b(a)(4).

(5) "Pharmacy benefits manager" means as defined in § 3302A of this title.

(6) "Purchaser" means as defined in § 3351A of this title.

(b) A pharmacy benefits manager or purchaser may not discriminate, either directly or indirectly, against a covered entity or the covered entity's contracted pharmacy on the basis of its participation in the 340B program, including by doing any of the following:

(1) Providing a reimbursement rate for a 340B drug that is less than the national average drug acquisition cost rate for that drug as determined by the United States Centers for Medicare and Medicaid Services, measured at the time the drug is administered or dispensed, or if no such rate is available at that time, a reimbursement rate that is less than the wholesale acquisition cost of the drug, as contemplated under § 3372A of this title.

(2) Imposing a term or condition that differs from terms or conditions imposed on an entity that is not a covered entity or the covered entity's contracted pharmacy, including any of the following:

a. Imposing a fee, chargeback, clawback, or other adjustment to the covered entity or the covered entity's contracted pharmacy that is not imposed on or exceeds the amount imposed on an entity that is not a covered entity or the covered entity's contracted pharmacy.

b. Restricting or requiring participation in a pharmacy network.

c. Requiring more frequent auditing or a broader scope of audit for inventory management systems using generally accepted accounting principles, unless such audit is required under state or federal law.

d. Requiring a covered entity or the covered entity's contracted pharmacy to reverse, resubmit, identify, modify, or clarify a claim after the initial adjudication, unless these actions are the normal course of pharmacy business and not related to the 340B program or required under applicable state or federal law.

e. Requiring accreditation or recertification inconsistent with, more stringent than, or in addition to state or federal law.

<u>f. Discriminating against a 340B entity or the entity's contracted pharmacy in a manner that prevents or</u> interferes with an individual's choice to receive a prescription drug from a 340B covered entity or the covered entity's contracted pharmacy, including the administration of the drug.

g. Imposing any provision determined by the Insurance Commissioner to interfere with the ability of a covered entity or the covered entity's contracted pharmacy to maximize the value of discounts provided under the 340B program.

(c) A violation of subsection (b) of this section by any person constitutes an unfair practice in the insurance business under Chapter 23 of this title.

(d) Any contract that is entered into, amended, extended, or renewed after [the effective date of this Act] that includes a provision that violates subsection (b) of this section is against public policy and is void and unenforceable.

Section 3. If a provision of this Act or the application of this Act to a person or circumstance is held invalid, the provisions of this Act are severable if the invalidity does not affect the other provisions of this Act that can be given effect without the invalid provision or application of this Act.

Section 4. Nothing in Section 1 or Section 2 of this Act is to be construed or applied to be less restrictive than any federal law as to any person or entity regulated by this Act. Nothing in Section 1 or Section 2 of this Act is to be construed or applied to be in conflict with any of the following:

(a) Applicable federal law and related regulation.

(b) Other laws of this State if the State law is compatible with applicable federal law.

Approved September 19, 2024