SPONSOR: Rep. Harris & Sen. S. McBride
Reps. Dorsey Walker, K. Johnson, Minor-Brown, Morrison, Neal, Romer, Wilson-Anton, Baumbach, Lambert; Sen. Poore

HOUSE OF REPRESENTATIVES
152nd GENERAL ASSEMBLY

HOUSE BILL NO. 383

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 1. Amend Subchapter V, Chapter 25, Title 24 of the Delaware Code by making deletions as shown by strike through and insertions as shown by underline as follows:

§ 2540A. Prohibition of discrimination against 340B drug distribution by manufacturers and wholesalers.

(a) As used in this section:

(1) "340B drug" means a drug that meets all of the following criteria:

a. The drug is a covered outpatient drug under 42 U.S.C. § 256b.

b. The drug has been subject to an offer for reduced prices by a manufacturer under 42 U.S.C. § 256b(a)(1).

c. The drug is purchased by a covered entity or would have been purchased by a covered entity but for the restriction or limitation under paragraph (b)(1) of this section.

(2) "Covered entity" means as defined in 42 U.S.C. § 256b(a)(4) and also includes a pharmacy contracted with a covered entity.

(3) "Manufacturer" means as defined in § 2502 of this title and also includes manufacturers of biological products.

(4) "Package" means as defined in 21 U.S.C. § 360eee.

(5) "Repackager" means as defined in 21 U.S.C. § 360eee.

(6) "Third-party logistics provider" means as defined in 21 U.S.C. § 360eee.

(7) "Wholesale distributor" means as defined in 21 U.S.C. § 360eee.

(b) A manufacturer, repackager, third-party logistics provider, wholesale distributor, or an agent or affiliate of such manufacturer, repackager, third-party logistics provider, or wholesale distributor, may not, either directly or indirectly, do any of the following:

(1) Deny, restrict, prohibit, discriminate against, or otherwise limit the acquisition of the 340B drug by, or delivery of the 340B drug to, a covered entity, unless receipt of the 340B drug by the covered entity is prohibited by the United States Department of Health and Human Services.

(2) Require a covered entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug to a covered entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

(c) The Department of Justice may promulgate regulations to implement the provisions of this section.

(d) The commission of any act prohibited by subsection (b) of this section is an unlawful practice under § 2513 of Title 6. Each package of 340B drugs determined to be subject to a prohibited act under subsection (b) of this section constitutes a separate violation. In lieu of the $10,000 civil penalty that may be assessed under § 2522(b) of Title 6, a civil penalty may be assessed in the amount of $50,000 per violation. The other remedies available under Chapter 25 of Title 6 and Subchapter II of Chapter 25 of Title 29 apply to violations of this chapter.

(e) The Board is authorized to take disciplinary action against a licensee based on the outcome of any investigation or proceeding brought by the Department of Justice.

(f) Limited distribution of a drug required under 21 U.S.C. § 355-1 is not a violation of this section.

Section 2. Amend Subchapter V, 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) As used in 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 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) and also includes a pharmacy contracted with a covered entity.

(5) “Health carrier” means as defined in § 7601 of this title, and also includes Medicare and Medicaid plans in accordance with applicable state and federal law.

(6) “Pharmacy benefits manager” means as defined in § 3302A of this title.

(b) A pharmacy benefits manager or health carrier may not discriminate, either directly or indirectly, against a covered entity 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 defined in 42 U.S.C. § 1395w-3a(c)(6)(B).

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

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

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 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.

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

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

(c) A violation of paragraph (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 paragraph (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.

SYNOPSIS

Section 1 of this Act prohibits discrimination against 340B drug distribution by manufacturers, repackagers, third-party logistics providers, and wholesalers. Violations are deemed an unlawful practice enforceable by the Consumer Protection Unit of the Department of Justice. The Department of Justice has authority to promulgate regulations under this section. The Board of Pharmacy may take disciplinary action against licensees based on the outcome of investigations or proceedings brought by the Department of Justice.

Section 2 of this Act prohibits discrimination by pharmacy benefits managers against 340B covered entities. Violations are deemed unfair practices in the insurance business. Contracts purporting to include provisions in violation of this Act are deemed void and unenforceable.

Section 3 of this Act contains severability language in the event that any provision or the application of the Act to a person or circumstance is deemed to be invalid.

Section 4 of this Act contains non-preemption language to ensure that the Act can be read and interpreted to not conflict with other State or federal law.