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

HOUSE OF REPRESENTATIVES
152nd GENERAL ASSEMBLY

HOUSE SUBSTITUTE NO. 1
FOR
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) "Pricing unit" means the smallest dispensable amount of a prescription drug that could be dispensed.

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

(7) "Wholesale distributor" means as defined § 2502 of this title and also includes wholesale distributors of biological products.

(b) A manufacturer, third-party logistics provider, wholesale distributor, or an agent or affiliate of such manufacturer, 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 prohibitions contained in subsection (b) of this section do not apply to the acquisition of a 340B drug by, or delivery of a 340B drug to, a covered entity that qualifies as a covered entity under 42 U.S.C. §§ 256b(a)(4)(L) through 256b(a)(4)(O).

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

(e) 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.

(f) The Board is authorized to take any disciplinary action available under this chapter against a permit holder or individual licensee for a violation of this section. The Board may also refer any complaint it receives about a permit holder or licensee to the Department of Justice for investigation of potential violations.

(g) Limited distribution of a drug required under 21 U.S.C. §§ 355-1, 841, 842, or 843 is not a violation of this section.

(h) By January 1 of each year, every covered entity subject to the provisions of subsection (b) of this section must submit an annual report to the Delaware Board of Pharmacy, the Speaker of the House, the Senate President Pro Tempore, the Office of the Governor, and the members of the House Health Committee, the Senate Health Committee, and the Joint Finance Committee. and publish on the website of the covered entity an annual report containing the following:

(1) A description of how the covered entity uses its savings from participation in the 340B program to benefit the community through programs and services funded in whole or in part by savings from the 340B program.

(2) The estimated annual savings from the 340B program to the covered entity, and the annual estimated expenditures by the covered entity on community benefit activities.

(3) A description of the covered entity's internal review and oversight of the 340B program, which must comply with the federal Department of Health and Human Services, Health Resources and Services Administration program rules and guidance.

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) 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) "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 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, 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

This substitute for House Bill 383 does the following:

Like House Bill 383, Section 1 of this Act prohibits discrimination against 340B drug distribution by manufacturers, third-party logistics providers, and wholesale distributors. 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 to implement the provisions of this Act. This Section differs from House Bill 383 by removing repackagers from the list of entities prohibited from engaging in 340B drug discrimination, authorizing the Board of Pharmacy to promulgate regulations and take disciplinary action against both licensees and holders of permits issued by the Board, and requiring covered entities, manufacturers, third-party-logistics providers, and wholesale distributors to publish annual reports on their websites and provide copies of the reports to the Board of Pharmacy, Speaker of the House, Senate

President Pro Tempore, Office of the Governor, and members of the House and Senate Health Committees and Joint Finance Committee.

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. This Section differs from House Bill 383 by making technical changes to correct internal references and changing references to "health carriers" to reference "purchasers" instead.

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.