CHAPTER 339

AN ACT concerning counterfeit drugs, and supplementing Title 2C of the New Jersey Statutes and Title 45 of the Revised Statutes.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

C.2C:35-11.1 Counterfeit drugs, medical devices; degree of crime; definitions.

- 1. a. A person who knowingly creates, distributes, dispenses. administers, installs, implants, possesses, or has under the person's control with intent to distribute a counterfeit drug or medical device, adulterated drug or medical device, or misbranded drug or medical device:
- (1) in an amount of four or fewer dosage units; one container or labeling of a counterfeit drug, adulterated drug, or misbranded drug is guilty of a crime of the fourth degree;
- (2) in an amount of at least five but fewer than 100 dosage units; at least two but fewer than five containers or labelings of a counterfeit drug, adulterated drug, or misbranded drug; or one counterfeit medical device, adulterated medical device, or misbranded medical device is guilty of a crime of the third degree; and
- (3) in an amount of 100 or more dosage units; five or more containers or labelings of a counterfeit drug, adulterated drug, or misbranded drug; or two or more counterfeit medical devices, adulterated medical devices, or misbranded medical devices is guilty of a crime of the second degree.
- b. In addition to penalties that may be imposed under subsection a. of this section or N.J.S.2C:35-15, a violation of this section shall be punishable by a penalty of not less than \$1,000 and not more than \$10,000 for each violation
 - c. Notwithstanding the definitions set forth in N.J.S.2C:35-2, as used in this section:
 - "Adulterated" means a drug or medical device that is adulterated pursuant to R.S.24:5-10.
 - "Container" means vial, bottle, can, jar, tube, package, or any other receptacle.

"Counterfeit" means a drug or medical device or the container or labeling of a drug or medical device that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof of a drug or medical device manufacturer, processor, packer, or distributor other than the person who in fact manufactured, processed, packed, or distributed the medical device and that falsely purports or is represented to be the product of, or to have been packed or distributed by, the drug or medical device manufacturer, processor, packer, or distributor whose trademark, trade name, or other identifying mark, imprint, or device or likeness thereof appears on the drug or medical device or its container or labeling.

"Drug" means any medication approved by the federal Food and Drug Administration.

"Label" means a display of written, printed, or graphic matter upon the immediate container of any drug.

"Labeling" means all labels and other written, printed or graphic matter (1) upon a drug or any of its containers or wrappers, or (2) accompanying such drug or container.

"Medical device" means any device approved by the federal Food and Drug Administration.

"Misbranded" means a drug or medical device with respect to which the label is: false or misleading in any particular; does not bear the name and address of the manufacturer, packer, or distributor and does not have an accurate statement of the quantities of the active ingredients; or does not show an accurate monograph for legend drugs; or is misbranded based upon other considerations as provided in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s.301 et seq.

C.45:1-53.1 Violations, notice to licensing board; license revocation; definitions.

- 2. a. Any pharmacist or other health care professional who is charged with an offense in violation of section 1 of P.L.2019, c.339 (C.2C:35-11.1) shall promptly notify the applicable licensing board of the pending charge. Failure to provide the prompt notice required by this subsection shall be deemed grounds for disciplinary action by the applicable licensing board.
- b. Upon conviction of an offense in violation of section 1 of P.L.2019, c.339 (C.2C:35-11.1)), the CDS registration of the pharmacist or other health care professional shall be revoked for a period of not less than five years and that professional's certification or license shall be revoked by the applicable licensing board based solely upon the fact of the conviction, for a period of time to be determined by that board.
- c. Pursuant to the "Administrative Procedure Act," P.L.1968, c.410 (C.52:14B-1 et seq.), a licensing or certifying board, specified in section 2 of P.L.1978, c.73 (C.45:1-15), or other licensing or certifying authority that has jurisdiction over health care professionals pursuant to Title 45 of the Revised Statutes, may adopt rules and regulations to effectuate the provisions of P.L.2019, c.339 (C.2C:35-11.1 et al.).

d. As used in this section:

"CDS registration" means registration with the Division of Consumer Affairs to manufacture, distribute, dispense, or conduct research with controlled dangerous substances issued pursuant to section 11 of P.L.1970, c.226 (C.24:21-11).

"Health care professional" means a professional licensed pursuant to Title 45 of the Revised Statutes to provide a health care service to a patient including, but not limited to: a licensed physician, advanced practice nurse, nurse, pharmacist, psychologist, psychiatrist, psychoanalyst, clinical social worker, physician assistant, professional counselor, dentist, orthotist, prosthetist, respiratory therapist, speech pathologist, audiologist, optometrist, veterinarian, or any other health care professional acting within the scope of a valid license or certification issued pursuant to Title 45 of the Revised Statutes.

"Pharmacist" means a pharmacist licensed pursuant to P.L.2003, c.280 (C.45:14-40 et seq.).

C.2C:35-11.2 Restrictions upon conviction.

- 3. a. Any person convicted of an offense in violation of section 1 of P.L.2019, c.339 (C.2C:35-11.1) shall be ineligible, either directly or indirectly, to submit a bid, enter into any contract, or conduct business with any board, agency, authority, department, commission, public corporation, or other body of this State, of this and one or more other states, or of any political subdivision of this State, for a period of not more than 10 years from the date of conviction for a crime of the second degree, five years from the date of conviction for a crime of the fourth degree. It is the purpose of this subsection to prohibit any individual convicted of an offense in violation of section 1 of P.L.2019, c.339 (C.2C:35-11.1) and any business, including any corporation, partnership, association or proprietorship in which the individual is a principal, or with respect to which the individual owns, directly or indirectly, or controls five percent or more of the stock or other equity interest of the business, from conducting business with public entities in this State.
- b. The State Treasurer shall establish and maintain a current list of all persons and entities that are subject to the restrictions set forth in subsection a. of this section based on a conviction of an offense in violation of section 1 of P.L.2019, c.339 (C.2C:35-11.1).

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4. This act shall take effect on the 180th day after the date of enactment.

Approved January 13, 2020.