

[Second Reprint]

ASSEMBLY, No. 5037

STATE OF NEW JERSEY
218th LEGISLATURE

INTRODUCED FEBRUARY 14, 2019

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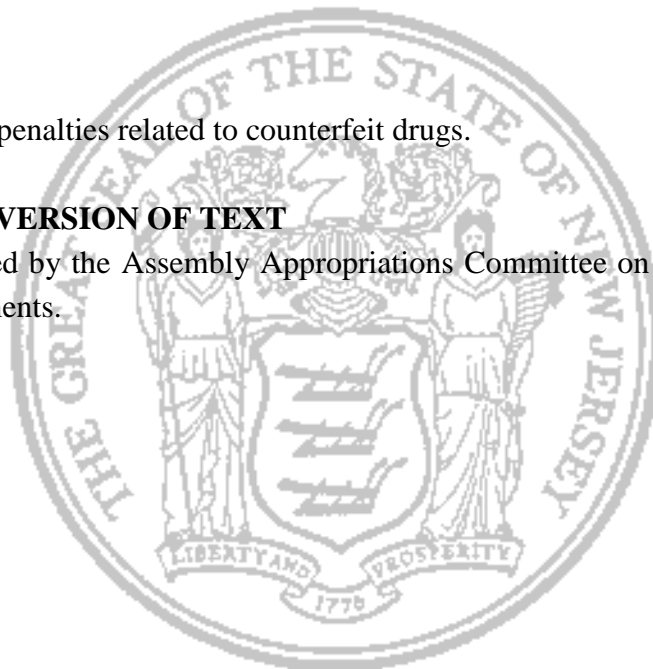
**Assemblymen Webber, Holley, Armato, Mazzeo, Senators Lagana,
A.R.Bucco and Ruiz**

SYNOPSIS

Enhances penalties related to counterfeit drugs.

CURRENT VERSION OF TEXT

As reported by the Assembly Appropriations Committee on June 18, 2019,
with amendments.



(Sponsorship Updated As Of: 12/17/2019)

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

3

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

6

7 1. a. ²[As used in this section, "counterfeit drug" means a drug
8 or the container or labeling of a drug, that, without authorization,
9 bears the trademark, trade name, or other identifying mark, imprint,
10 or device or any likeness thereof of a drug manufacturer, processor,
11 packer, or distributor other than the person who in fact
12 manufactured, processed, packed, or distributed the drug and that
13 falsely purports or is represented to be the product of, or to have
14 been packed or distributed by, the drug manufacturer, processor,
15 packer, or distributor whose trademark, trade name, or other
16 identifying mark, imprint, or device or likeness thereof appears on
17 the drug or its container or labeling.

18 b. Notwithstanding any provision of law to the contrary, it is
19 unlawful for any ²A² person ²[to] who² knowingly ²[possess, sell,
20 dispense, give, receive, or administer a] creates, distributes,
21 dispenses administers, installs, implants, possesses, or has under the
22 person's control with intent to distribute a² counterfeit drug ²or
23 medical device², ²[an]² adulterated drug ²or medical device², or
24 ²[a]² misbranded drug ²[.

25 c. A violation of this section shall be ²[] or medical device:

26 (1) in an amount of four or fewer dosage units; one container or
27 labeling of a counterfeit drug, adulterated drug, or misbranded drug
28 is guilty of a crime of the fourth degree;

29 (2) in an amount of at least five but fewer than 100 dosage units;
30 at least two but fewer than five containers or labelings of a
31 counterfeit drug, adulterated drug, or misbranded drug; or one
32 counterfeit medical device, adulterated medical device, or
33 misbranded medical device is guilty of a crime of the third degree;
34 and

35 (3) in an amount of 100 or more dosage units; five or more
36 containers or labelings of a counterfeit drug, adulterated drug, or
37 misbranded drug; or two or more counterfeit medical devices,
38 adulterated medical devices, or misbranded medical devices is
39 guilty of² a crime of the second degree.

40 ²[d.] b.² In addition to penalties that may be imposed under
41 subsection ²[c.] a.² of this section ²or N.J.S.2C:35-15², a violation
42 of this section shall be punishable by a ²[civil fine] penalty² of not
43 less than ¹[one thousand dollars] \$1,000¹ and not more than ¹[ten
44 thousand dollars] \$10,000¹ for each violation. ²[Fines imposed

EXPLANATION – Matter enclosed in bold-faced brackets **[thus]** in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Assembly ALP committee amendments adopted March 7, 2019.

²Assembly AAP committee amendments adopted June 18, 2019.

1 and paid pursuant to this subsection shall be deposited in the
2 General Fund.

3 e. Any person convicted of an offense under this section shall
4 be ineligible, either directly or indirectly, to submit a bid, enter into
5 any contract, or ¹[to] conduct ¹[any] business with any board,
6 agency, authority, department, commission, public corporation, or
7 other body of this State, of this or one or more other states, or of
8 one or more political subdivisions of this State. It is the purpose of
9 this subsection to ¹[bar] prohibit¹ any individual convicted ¹[of
10 any of the above enumerated offenses] pursuant to this section¹ and
11 any business, including any corporation, partnership, association or
12 proprietorship in which ¹[such] the¹ individual is a principal, or
13 with respect to which ¹[such] the¹ individual owns, directly or
14 indirectly, or controls five percent or more of the stock or other
15 equity interest of ¹[such] the¹ business, from conducting business
16 with public entities in this State.

17 f. The Department of Law and Public Safety shall publish on
18 its Internet website a list of individuals convicted pursuant to this
19 section.]

20 c. Notwithstanding the definitions set forth in N.J.S.2C:35-2,
21 as used in this section:

22 “Adulterated” means a drug or medical device that is adulterated
23 pursuant to R.S.24:5-10.

24 “Container” means vial, bottle, can, jar, tube, package, or any
25 other receptacle.

26 “Counterfeit” means a drug or medical device or the container or
27 labeling of a drug or medical device that, without authorization,
28 bears the trademark, trade name, or other identifying mark, imprint,
29 or device or any likeness thereof of a drug or medical device
30 manufacturer, processor, packer, or distributor other than the person
31 who in fact manufactured, processed, packed, or distributed the
32 medical device and that falsely purports or is represented to be the
33 product of, or to have been packed or distributed by, the drug or
34 medical device manufacturer, processor, packer, or distributor
35 whose trademark, trade name, or other identifying mark, imprint, or
36 device or likeness thereof appears on the drug or medical device or
37 its container or labeling.

38 “Drug” means any medication approved by the federal Food and
39 Drug Administration.

40 “Label” means a display of written, printed, or graphic matter
41 upon the immediate container of any drug.

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

45 “Medical device” means any device approved by the federal
46 Food and Drug Administration.

1 “Misbranded” means a drug or medical device with respect to
2 which the label is: false or misleading in any particular; does not
3 bear the name and address of the manufacturer, packer, or
4 distributor and does not have an accurate statement of the quantities
5 of the active ingredients; or does not show an accurate monograph
6 for legend drugs; or is misbranded based upon other considerations
7 as provided in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.
8 s.301 et seq.²

9
10 2. a. ²[An individual who received ¹[his or her] a¹
11 professional certification or license pursuant to Title 45 of the
12 Revised Statutes shall have that] Any pharmacist or other health
13 care professional who is charged with an offense in violation of
14 section 1 of P.L. , c. (C.) (pending before the Legislature
15 as this bill) shall promptly notify the applicable licensing board of
16 the pending charge. Failure to provide the prompt notice required
17 by this subsection shall be deemed grounds for disciplinary action
18 by the applicable licensing board.

19 b. Upon conviction of an offense in violation of section 1 of
20 P.L. , c. (C.) (pending before the Legislature as this bill),
21 the CDS registration of the pharmacist or other health care
22 professional shall be revoked for a period of not less than five years
23 and that professional's² certification or license ²shall be² revoked
24 by the ²[corresponding] applicable licensing² board²], specified in
25 section 2 of P.L.1978, c.73 (C.45:1-15), following a] based solely
26 upon the fact of the² conviction ²[pursuant to section 1 of ¹[this
27 act] P.L. , c. (C.) (pending before the Legislature as this
28 bill)¹]² , for a period of time to be determined by that board.

29 ²[b. The State Board of Pharmacy, in consultation with the
30 Department of Law and Public Safety, shall publish on its Internet
31 website a list of individuals licensed by the board who have been
32 convicted pursuant to section 1 of ¹[this act] P.L. , c. (C.)
33 (pending before the Legislature as this bill)¹, and adopt regulations,
34 pursuant to the "Administrative Procedure Act," P.L.1968, c.410
35 (C.52:14B-1 et seq.), listing the individuals licensed by the board
36 who have been convicted pursuant to section 1 of ¹[this act]
37 P.L. , c. (C.) (pending before the Legislature as this
38 bill)¹.]²

39 c. Pursuant to the "Administrative Procedure Act," P.L.1968,
40 c.410 (C.52:14B-1 et seq.), a ²licensing or certifying² board,
41 specified in section 2 of P.L.1978, c.73 (C.45:1-15), ²or other
42 licensing or certifying authority that has jurisdiction over health
43 care professionals pursuant to Title 45 of the Revised Statutes,²
44 may adopt rules and regulations to effectuate the provisions of
45 ¹[this act] P.L. , c. (C.) (pending before the Legislature as
46 this bill)¹.

1 ²d. As used in this section:

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

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

16 “Pharmacist” means a pharmacist licensed pursuant to P.L.2003,
17 c.280 (C.45:14-40 et seq.).²

18
19 ²3. a. Any person convicted of an offense in violation of section
20 1 of P.L. , c. (C.) (pending before the Legislature as this bill)
21 shall be ineligible, either directly or indirectly, to submit a bid,
22 enter into any contract, or conduct business with any board, agency,
23 authority, department, commission, public corporation, or other
24 body of this State, of this and one or more other states, or of any
25 political subdivision of this State, for a period of not more than 10
26 years from the date of conviction for a crime of the second degree,
27 five years from the date of conviction for a crime of the third
28 degree, and two years from the date of conviction for a crime of the
29 fourth degree. It is the purpose of this subsection to prohibit any
30 individual convicted of an offense in violation of section 1 of
31 P.L. , c. (C.) (pending before the Legislature as this bill) and
32 any business, including any corporation, partnership, association or
33 proprietorship in which the individual is a principal, or with respect
34 to which the individual owns, directly or indirectly, or controls five
35 percent or more of the stock or other equity interest of the business,
36 from conducting business with public entities in this State.

37 b. The State Treasurer shall establish and maintain a current
38 list of all persons and entities that are subject to the restrictions set
39 forth in subsection a. of this section based on a conviction of an
40 offense in violation of section 1 of P.L. , c. (C.) (pending
41 before the Legislature as this bill).²

42
43 ²[3.] ^{4.}² This act shall take effect on the 180th day after the
44 date of enactment.