

§§1,3 -
C.2C:35-11.1 &
2C:35-11.2
§2 - C.45:1-53.1
§4 - Note

P.L. 2019, CHAPTER 339, *approved January 13, 2020*
Assembly, No. 5037 (*Second Reprint*)

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 ²**A** person ²**[to] who** 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 a counterfeit drug ²**or**
23 medical device², ²**[an]** adulterated drug ²**or** medical device², or
24 ²**[a]** 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

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 misbranded drug; or two or more counterfeit medical devices,
2 adulterated medical devices, or misbranded medical devices is
3 guilty of² a crime of the second degree.

4 ²~~[d.] b.~~² In addition to penalties that may be imposed under
5 subsection ²~~[c.] a.~~² of this section ²~~or N.J.S.2C:35-15~~², a violation
6 of this section shall be punishable by a ²~~[civil fine] penalty~~² of not
7 less than ¹~~[one thousand dollars] \$1,000~~¹ and not more than ¹~~[ten~~
8 ~~thousand dollars] \$10,000~~¹ for each violation. ²~~[Fines imposed~~
9 ~~and paid pursuant to this subsection shall be deposited in the~~
10 ~~General Fund.~~

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

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

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

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

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

34 “Counterfeit” means a drug or medical device or the container or
35 labeling of a drug or medical device that, without authorization,
36 bears the trademark, trade name, or other identifying mark, imprint,
37 or device or any likeness thereof of a drug or medical device
38 manufacturer, processor, packer, or distributor other than the person
39 who in fact manufactured, processed, packed, or distributed the
40 medical device and that falsely purports or is represented to be the
41 product of, or to have been packed or distributed by, the drug or
42 medical device manufacturer, processor, packer, or distributor
43 whose trademark, trade name, or other identifying mark, imprint, or
44 device or likeness thereof appears on the drug or medical device or
45 its container or labeling.

46 “Drug” means any medication approved by the federal Food and
47 Drug Administration.

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

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

6 “Medical device” means any device approved by the federal
 7 Food and Drug Administration.

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

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

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

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

1 c. Pursuant to the "Administrative Procedure Act," P.L.1968,
2 c.410 (C.52:14B-1 et seq.), a ²licensing or certifying² board,
3 specified in section 2 of P.L.1978, c.73 (C.45:1-15), ²or other
4 licensing or certifying authority that has jurisdiction over health
5 care professionals pursuant to Title 45 of the Revised Statutes,²
6 may adopt rules and regulations to effectuate the provisions of
7 ¹【this act】 P.L. , c. (C.) (pending before the Legislature as
8 this bill)¹.

9 ²d. As used in this section:

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

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

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

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

45 b. The State Treasurer shall establish and maintain a current
46 list of all persons and entities that are subject to the restrictions set
47 forth in subsection a. of this section based on a conviction of an

1 offense in violation of section 1 of P.L. , c. (C.) (pending
2 before the Legislature as this bill).²

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4 ²~~[3.]~~ 4.² This act shall take effect on the 180th day after the
5 date of enactment.

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10 Enhances penalties related to counterfeit drugs.