

ASSEMBLY, No. 3954

STATE OF NEW JERSEY 219th LEGISLATURE

INTRODUCED APRIL 9, 2020

Sponsored by:

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District 11 (Monmouth)

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Co-Sponsored by:

Assemblywoman Jasey, Assemblyman Rooney, Assemblywoman McKnight, Assemblyman Tully and Assemblywoman Swain

SYNOPSIS

Provides enhanced penalty for distribution of counterfeit drugs and medical devices during declared states of emergency.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 4/13/2020)

1 AN ACT concerning counterfeit drugs and medical devices and
2 amending P.L.2019, c.339.

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

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7 1. Section 1 of P.L.2019, c.339 (C.2C:35-11.1) is amended to
8 read as follows:

9 1. a. A person who knowingly creates, distributes, dispenses,
10 administers, installs, implants, possesses, or has under the person's
11 control with intent to distribute a counterfeit drug or medical
12 device, adulterated drug or medical device, or misbranded drug or
13 medical device:

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

17 (2) in an amount of at least five but fewer than 100 dosage
18 units; at least two but fewer than five containers or labelings of a
19 counterfeit drug, adulterated drug, or misbranded drug; or one
20 counterfeit medical device, adulterated medical device, or
21 misbranded medical device is guilty of a crime of the third degree;

22 **[and]**

23 (3) in an amount of 100 or more dosage units; five or more
24 containers or labelings of a counterfeit drug, adulterated drug, or
25 misbranded drug; or two or more counterfeit medical devices,
26 adulterated medical devices, or misbranded medical devices is
27 guilty of a crime of the second degree ; and

28 (4) in any amount of dosage units; any number of containers or
29 labelings of a counterfeit drug, adulterated drug, or misbranded
30 drug; or any number of counterfeit medical devices, adulterated
31 medical devices, or misbranded medical devices, is guilty of a
32 crime of the second degree if the act occurs during a declared state
33 of emergency;

34 b. In addition to penalties that may be imposed under
35 subsection a. of this section or N.J.S.2C:35-15, a violation of this
36 section shall be punishable by a penalty of not less than \$1,000 and
37 not more than \$10,000 for each violation. For the purposes of
38 paragraph (4) of subsection a. and subsection d. of this section, the
39 penalty shall be imposed for each dosage unit, container, or labeling
40 of a counterfeit, adulterated, or misbranded drug, or each
41 counterfeit, adulterated, or misbranded medical device involved in
42 the commission of the crime.

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

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.

1 "Adulterated" means a drug or medical device that is adulterated
2 pursuant to R.S.24:5-10.

3 "Agent" means an authorized person who acts on behalf of or at
4 the direction of another person or entity.

5 "Broker" means any person engaged in the business of soliciting
6 or negotiating the sale, resale, exchange, or shipment of drugs or
7 medical devices.

8 "Container" means vial, bottle, can, jar, tube, package, or any
9 other receptacle.

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

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

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

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

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

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

39 d. A person, including but not limited to an agent or a broker,
40 who derives a pecuniary benefit from a violation of paragraph (4) of
41 subsection a. of this section is guilty of a crime of the second
42 degree.

43 (cf: P.L.2019, c.339, s.1)

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45 2. This act shall take effect immediately.

STATEMENT

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This bill enhances penalties related to the distribution of counterfeit, adulterated, or misbranded drugs or medical devices during a declared state of emergency.

Under current law, a person who knowingly creates, distributes, dispenses, administers, installs, implants, possesses, or has under the person's control with intent to distribute a counterfeit, adulterated, or misbranded drug or medical device commits a crime. The degree of the crime can be second, third, or fourth degree, depending on the number of: (1) dosage units of drugs; (2) containers or labelings of drugs; or (3) the number of medical devices involved in the commission of the crime.

Under the provisions of this bill, during a declared state of emergency, an offense would be a second degree crime, irrespective of the number of units or items involved. The bill also specifies that during a declared state of emergency, any person, including an agent or a broker, who derives a pecuniary benefit from a violation of the provisions of this bill would be guilty of a crime of the second degree. The bill defines an "agent" as an authorized person who acts on behalf of or at the direction of another person or entity; and a "broker" as any person engaged in the business of soliciting or negotiating the sale, resale, exchange, or shipment of drugs or medical devices. A crime of the second degree is punishable by a term of imprisonment of five to 10 years, a fine of up to \$150,000, or both.

Additionally, current law provides a penalty of not less than \$1,000 and not more than \$10,000 for each violation. The provisions of the bill specify that the penalty will be assessed for each dosage unit, container, or labeling of a counterfeit, adulterated, or misbranded drug or each counterfeit, adulterated, or misbranded medical device involved in the commission of the crime during a declared state of emergency. These penalty monies are deposited into the "Drug Enforcement and Demand Reduction Fund," established pursuant to subsection c. of N.J.S.2C:35-15.