

SENATE, No. 1138

STATE OF NEW JERSEY
219th LEGISLATURE

INTRODUCED JANUARY 30, 2020

Sponsored by:

Senator JOSEPH F. VITALE

District 19 (Middlesex)

SYNOPSIS

Requires DOH to make list of drugs with “black box” warnings accessible through its website.

CURRENT VERSION OF TEXT

As introduced.



1 AN ACT concerning the provision of certain prescription drug
2 information to the public and supplementing Title 26 of the
3 Revised Statutes.

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

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8 1. The Legislature finds and declares that:

9 a. A “black box” warning is a type of warning that appears on
10 prescription drugs that may cause serious adverse effects, so named
11 for the black border that usually surrounds the text of the warning;

12 b. The federal Food and Drug Administration, or FDA, requires
13 pharmaceutical companies to place a “black box” warning on a drug
14 label if medical studies indicate that the drug carries a significant
15 risk of serious or life-threatening adverse effects;

16 c. A “black box” warning is the most serious warning that the
17 FDA requires to be placed on the label of a prescription medication;

18 d. Advertisements that serve to remind health care
19 professionals of the availability of a prescription drug product,
20 known as “reminder ads,” are not allowed for products that carry a
21 “black box” warning on their label;

22 e. In many cases, patients are unaware that they have been
23 prescribed a medication that carries a “black box” warning because
24 the warning is not clearly or conveniently displayed in a manner
25 that is easily identifiable by the patient;

26 f. Physicians and consumers often have to negotiate their way
27 through a variety of websites in order to obtain accurate and current
28 information on “black box” warnings; and

29 g. The public interest clearly requires that both prescribers and
30 members of the general public have convenient and timely access to
31 up-to-date information, which is contained in a centralized location,
32 about which drugs are required by the FDA to carry a “black box”
33 warning on their label.

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35 2. The Department of Health shall post on its website a list of
36 all drugs that are required by the FDA to carry a “black box”
37 warning on their label. If the FDA makes this information available
38 to the public on its own website on or after the effective date of this
39 act, the department website may provide a hypertext link to that
40 information as an alternative to posting the list of those drugs.

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42 3. This act shall take effect immediately.

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45 STATEMENT

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47 This bill requires the Department of Health (DOH) to post on its
48 website a list of all drugs that are required by the federal Food and

1 Drug Administration (FDA) to carry a “black box” warning on their
2 label.

3 The bill provides that if the FDA makes this information
4 available to the public on its own website on or after the effective
5 date of the bill, the DOH website may provide a hypertext link to
6 that information as an alternative to posting the list of those drugs.

7 A “black box” warning, which the FDA requires a
8 pharmaceutical company to place on a drug label if medical studies
9 indicate that the drug carries a significant risk of serious or life-
10 threatening adverse effects, is the most serious warning that the
11 FDA requires to be placed on the label of a prescription medication.