

SENATE, No. 3558

STATE OF NEW JERSEY
219th LEGISLATURE

INTRODUCED MARCH 15, 2021

Sponsored by:

Senator PATRICK J. DIEGNAN, JR.

District 18 (Middlesex)

SYNOPSIS

Requires physicians and other prescribers to obtain electronic or written consent for certain medications with “black box warnings.”

CURRENT VERSION OF TEXT

As introduced.



1 AN ACT concerning the prescribing of certain medications and
2 supplementing Title 45 of the Revised Statutes.

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

6

7 1. Prior to prescribing an individual any psychotropic
8 medication, including but not limited to medication for the
9 treatment of Attention Deficit Disorder or Attention Deficit and
10 Hyperactivity Disorder, required by the federal Food and Drug
11 Administration to have a “black box warning” on its labeling, a
12 physician or other authorized prescriber shall inform the individual
13 or the individual’s legal guardian about the possible side effects of
14 the medication and shall obtain informed electronic or written
15 consent from the individual or the individual’s legal guardian
16 acknowledging receipt of the notification and authorizing issuance
17 of the prescription. In the event electronic or written consent
18 cannot be obtained but oral consent is provided, the physician or
19 other authorized prescriber shall make a notation in the patient’s
20 file setting forth the date and circumstances of the informed
21 consent.

22 A physician or other authorized prescriber who prescribes a
23 medication in violation of this act shall be subject to disciplinary
24 action by the State Board of Medical Examiners.

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26 2. Prior to prescribing an individual any psychotropic
27 medication, including but not limited to medication for the
28 treatment of Attention Deficit Disorder or Attention Deficit and
29 Hyperactivity Disorder, required by the federal Food and Drug
30 Administration to have a “black box warning” on its labeling, a
31 physician assistant shall inform the individual or the individual’s
32 legal guardian about the possible side effects of the medication, and
33 shall obtain informed electronic or written consent from the
34 individual or the individual’s legal guardian acknowledging receipt
35 of the notification and authorizing issuance of the prescription. In
36 the event electronic or written consent cannot be obtained but oral
37 consent is provided, the physician assistant shall make a notation in
38 the patient’s file setting forth the date and circumstances of the
39 informed consent.

40 A physician assistant who prescribes a medication in violation of
41 this act shall be subject to disciplinary action by the State Board of
42 Medical Examiners.

43

44 3. Prior to prescribing an individual any psychotropic
45 medication, including but not limited to medication for the
46 treatment of Attention Deficit Disorder or Attention Deficit and
47 Hyperactivity Disorder, required by the federal Food and Drug
48 Administration to have a “black box warning” on its labeling, an

1 advanced practice nurse shall inform the individual or the
2 individual's legal guardian about the possible side effects of the
3 medication and shall obtain informed electronic or written consent
4 from the individual or the individual's legal guardian
5 acknowledging receipt of the notification and authorizing issuance
6 of the prescription. In the event electronic or written consent
7 cannot be obtained but oral consent is provided, the advanced
8 practice nurse shall make a notation in the patient's file setting forth
9 the date and circumstances of the informed consent.

10 An advanced practice nurse who prescribes a medication in
11 violation of this act shall be subject to disciplinary action by the
12 New Jersey Board of Nursing.

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14 4. The Division of Consumer Affairs in the Department of Law
15 and Public Safety, in consultation with the Department of Health,
16 shall adopt, pursuant to the "Administrative Procedure Act,"
17 P.L.1968 c.410 (C.52:14B-1 et seq.), rules and regulations
18 necessary to implement the provisions of this act.

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20 5. This act shall take effect 180 days after enactment.

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STATEMENT

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25 This bill requires physicians, physician assistants, advanced
26 practice nurses, and other authorized prescribers to obtain informed
27 electronic or written consent prior to prescribing them psychotropic
28 medications that are accompanied by a "black box warning," which
29 consent is to include an electronic or a written acknowledgement
30 that the patient or the patient's guardian received notification about
31 the black box warning. The bill specifies that in cases where
32 electronic or written consent cannot be obtained but oral consent is
33 provided, the prescriber must make a notation in the patient's file
34 indicating the date and circumstances of the informed consent.

35 The United States Food and Drug Administration (FDA) requires
36 pharmaceutical companies to place a "black box warning" on a drug
37 label if medical studies indicate that the drug carries a significant
38 risk of serious or life-threatening adverse effects. A "black box
39 warning" is the strongest warning that the FDA requires.

40 A physician, physician assistant, advanced practice nurse, or
41 other authorized prescriber who violates the requirements
42 established under the bill is subject to disciplinary action by the
43 applicable State professional licensing board.