

SENATE, No. 2117

STATE OF NEW JERSEY
219th LEGISLATURE

INTRODUCED MARCH 16, 2020

Sponsored by:

Senator MICHAEL J. DOHERTY

District 23 (Hunterdon, Somerset and Warren)

SYNOPSIS

Requires physicians and other prescribers to obtain informed consent from parents or guardians of minors for certain medications with “black box warnings.”

CURRENT VERSION OF TEXT

As introduced.



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

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

24
25 2. Prior to prescribing for an individual under 18 years of age
26 any psychotropic medication, including but not limited to
27 medication for the treatment of Attention Deficit Disorder or
28 Attention Deficit and Hyperactivity Disorder, required by the
29 federal Food and Drug Administration to have a “black box
30 warning” on its labeling, a physician assistant shall inform the
31 individual’s parent or legal guardian about the possible side effects
32 of the medication, and shall obtain informed written consent from
33 the individual’s parent or legal guardian acknowledging receipt of
34 the notification and authorizing issuance of the prescription. In the
35 event written consent cannot be obtained but oral consent is
36 provided, the physician assistant shall make a notation in the
37 patient’s file setting forth the date and circumstances of the
38 informed consent.

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

42
43 3. Prior to prescribing for an individual under 18 years of age
44 any psychotropic medication, including but not limited to
45 medication for the treatment of Attention Deficit Disorder or
46 Attention Deficit and Hyperactivity Disorder, required by the
47 federal Food and Drug Administration to have a “black box
48 warning” on its labeling, an advanced practice nurse shall inform

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

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

12
13 4. The Division of Consumer Affairs in the Department of Law
14 and Public Safety, in consultation with the Department of Health,
15 shall adopt, pursuant to the "Administrative Procedure Act,"
16 P.L.1968 c.410 (C.52:14B-1 et seq.), rules and regulations
17 necessary to implement the provisions of this act.

18
19 5. This act shall take effect 180 days after enactment.
20
21

22 STATEMENT

23
24 This bill requires physicians, physician assistants, advanced
25 practice nurses, and other authorized prescribers to obtain informed
26 written consent from parents or legal guardians of minors prior to
27 prescribing them psychotropic medications that are accompanied by
28 a "black box warning," which consent is to include a written
29 acknowledgement that the parent or guardian received notification
30 about the black box warning. The bill specifies that in cases where
31 written consent cannot be obtained but oral consent is provided, the
32 prescriber must make a notation in the patient's file indicating the
33 date and circumstances of the informed consent.

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

39 A physician, physician assistant, advanced practice nurse, or
40 other authorized prescriber who violates its provisions is subject to
41 disciplinary action by the applicable State professional licensing
42 board.