

ASSEMBLY, No. 399

STATE OF NEW JERSEY 214th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2010 SESSION

Sponsored by:

Assemblyman PATRICK J. DIEGNAN, JR.

District 18 (Middlesex)

Co-Sponsored by:

Assemblywomen Stender, Evans, Assemblyman Egan, Assemblywoman Greenstein and Assemblyman DiMaio

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

Introduced Pending Technical Review by Legislative Counsel



1 AN ACT concerning the prescribing of certain medications to
2 minors and 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:

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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 written
15 informed consent from the individual's parent or legal guardian for
16 the notification. In the event written consent cannot be obtained,
17 the physician or other authorized prescriber shall make a notation in
18 the patient's file setting forth the date and circumstances of the
19 informed consent.

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

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

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

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40 3. The Division of Consumer Affairs in the Department of Law
41 and Public Safety, in consultation with the Department of Health
42 and Senior Services, shall adopt, pursuant to the "Administrative
43 Procedure Act," P.L.1968 c.410 (C.52:14B-1 et seq.), rules and
44 regulations necessary to implement the provisions of this act.

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46 4. This act shall take effect 180 days after enactment.

STATEMENT

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This bill requires physicians, advanced practice nurses, and other authorized prescribers to obtain informed written consent from parents or legal guardians of minors prior to prescribing them psychotropic medications that are accompanied by a “black box warning.” The bill specifies that in cases where written consent cannot be obtained, the prescriber must make a notation in the patient’s file indicating the date and circumstances of the informed consent.

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

Under the bill, a physician, advanced practice nurse, or other authorized prescriber who violates its provisions is subject to disciplinary action by the applicable State professional licensing board.