

ASSEMBLY, No. 378

STATE OF NEW JERSEY

213th LEGISLATURE

PRE-FILED FOR INTRODUCTION IN THE 2008 SESSION

Sponsored by:

Assemblyman PATRICK J. DIEGNAN, JR.

District 18 (Middlesex)

Assemblywoman NILSA CRUZ-PEREZ

District 5 (Camden and Gloucester)

Assemblyman MICHAEL J. DOHERTY

District 23 (Warren and Hunterdon)

Co-Sponsored by:

Assemblywomen Stender and Karrow

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



(Sponsorship Updated As Of: 2/29/2008)

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:

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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 informed
15 consent from the individual's parent or legal guardian for the
16 notification.

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

20

21 2. Prior to prescribing for an individual under 18 years of age
22 any psychotropic medication, including but not limited to
23 medication for the treatment of Attention Deficit Disorder or
24 Attention Deficit and Hyperactivity Disorder, required by the
25 federal Food and Drug Administration to have a "black box
26 warning" on its labeling, an advanced practice nurse shall inform
27 the individual's parent or legal guardian about the possible side
28 effects of the medication and shall obtain informed consent from
29 the individual's parent or legal guardian for the notification.

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

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

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

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STATEMENT

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45 This bill would require physicians, advanced practice nurses, and
46 other authorized prescribers to obtain informed consent from
47 parents or legal guardians of minors prior to prescribing them

1 psychotropic medications that are accompanied by a “black box
2 warning.”

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

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