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.

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

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

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

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

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

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

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

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

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

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

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

STATEMENT

This bill requires physicians, physician assistants, advanced practice nurses, and other authorized prescribers to obtain informed electronic or written consent prior to prescribing them psychotropic medications that are accompanied by a "black box warning," which consent is to include an electronic or a written acknowledgement that the patient or the patient's guardian received notification about the black box warning. The bill specifies that in cases where electronic or written consent cannot be obtained but oral consent is provided, 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.

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