STATE OF NEW YORK

4380

2025-2026 Regular Sessions

IN SENATE

February 4, 2025

Introduced by Sen. COMRIE -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to limiting the off label use of antipsychotic drugs with black box warnings on elderly patients with dementia; and to amend the education law, in relation to professional medical misconduct

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. The public health law is amended by adding a new section 280-d to read as follows:

§ 280-d. Use of antipsychotic drugs on elderly patients with dementia. 1. As used in this section:

(a) "off label" means a medical practice in which a physician prescribes a drug for a different medical purpose than the one for which such drug is approved for;

(b) "black box warning" means a warning issued by the federal Food and Drug Administration and placed on the package insert of a prescription drug that may be fatal or cause server side effects;

(c) "chemical restraint" means when an antipsychotic drug that provides no medical benefit to a patient with dementia and is used to sedate such patient, control such patient's behavior or restrict such patient's movement;

(d) "antipsychotic drug" means any typical or atypical antipsychotic drug that is intended to be used on patients with mental illness that require a black box warning and shall include but not be limited to the following:

(i) Typical antipsychotic drugs: haloperidol, loxapine, thioridazine, molindone, thiothixene, fluphenazine, trifluoperazine, chlorpromazine, perphenazine, or promozide; or

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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(ii) Atypical antipsychotic drugs: aripiprazole, lumapeterone, clozaril, iloperidone, ziprasidone, paliperidone, lurasidone, brexipiprazole, risperidone, asenapine, quetiapine, cariprazine, or olanzapine; and

(e) "patient" means an elderly individual with dementia who is:

(i) a resident of a residential health care facility as defined in article twenty-eight of this chapter or an adult care facility certified under section four hundred sixty-one-b of the social services law; or

(ii) in the care of a hospital as defined in article twenty-eight of this chapter, a facility as defined in article twenty of this chapter or any other health care facility who care for individuals with dementia.

2. No antipsychotic drug that contains a black box warning shall be used for an off label purpose on a patient known to have dementia or to chemically restrain a patient known to have dementia. An order for an antipsychotic drug may only be issued in an emergency situation and by a health care professional who specializes in dementia or is specifically trained in the treatment of dementia patients if such a patient is agitated and where it is reasonably necessary to protect the life, health or safety of the patient or another person. Where an order is made under this subdivision, the health care professional shall immediately record the use of the antipsychotic drug, the reason for the use, and the dosage, in the patient's medical record; and shall promptly notify the patient or the patient's lawful representative who would have had the authority to consent that such drug with a black box warning was used and any family member required to be notified under this section and record such notifications in the patient's medical record.

3. This section does not increase the lawful scope of practice of any health care professional and does not diminish or impair any requirement for or regulation of consent to health care treatment. A health care professional who fails to comply with the provisions of this section may be found guilty of professional misconduct pursuant to article one hundred thirty-one-a of the education law.

4. The commissioner may make rules or regulations to implement the provisions of this section.

§ 2. Section 6530 of the education law is amended by adding a new subdivision 51 to read as follows:

51. Failing to comply with the provisions of section two hundred eighty-d of the public health law.

§ 3. This act shall take effect on the thirtieth day after it shall have become a law. Effective immediately, the addition, amendment and/or repeal of any rule or regulation necessary for the implementation of this act on its effective date are authorized to be made and completed on or before such effective date.