

STATE OF NEW YORK

6462

2021-2022 Regular Sessions

IN SENATE

April 29, 2021

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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1 (ii) Atypical antipsychotic drugs: aripiprazole, lumapeterone, clozar-
2 il, iloperidone, ziprasidone, paliperidone, lurasidone, brexipiprazole,
3 risperidone, asenapine, quetiapine, cariprazine, or olanzapine; and

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

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

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

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

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

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

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

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

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