

HOUSE No. 3265

The Commonwealth of Massachusetts

PRESENTED BY:

Shaunna L. O'Connell

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to psychotropic drugs.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Shaunna L. O'Connell</i>	<i>3rd Bristol</i>	<i>1/16/2015</i>
<i>Nancy Sylvester</i>	<i>13 Pinckney Street Taunton, MA 02780</i>	<i>1/16/2015</i>
<i>David F. DeCoste</i>	<i>5th Plymouth</i>	<i>3/18/2015</i>
<i>Paul McMurtry</i>	<i>11th Norfolk</i>	<i>3/23/2015</i>
<i>Marybeth Williams</i>	<i>The National Consumer Voice for Quality Long-Term Care 1001 Connecticut Avenue, NW, Suite 425 Washington, DC 20036</i>	<i>6/15/2015</i>
<i>Arlene Germain</i>	<i>Massachusetts Advocates for Nursing Home Reform 38 Banks Terrace Swampscott, MA 01907</i>	<i>6/15/2015</i>
<i>Toby S. Edelman</i>	<i>Center for Medicare Advocacy, Inc. 1025 Connecticut Avenue, NW, Suite 709 Washington, DC 20036</i>	<i>6/15/2015</i>
<i>Richard J. Mollot</i>	<i>Long Term Care Community Coalition One Penn Plaza, Suite 6252 New York, NY 10119</i>	<i>6/15/2015</i>
<i>Patricia L. McGinnis</i>	<i>California Advocates for Nursing</i>	<i>6/15/2015</i>

*Home Reform 650 Harrison Street,
2nd Floor San Francisco, CA 94107*

HOUSE No. 3265

By Mrs. O’Connell of Taunton, a petition (accompanied by bill, House, No. 3265) of Shaunna L. O’Connell and others for legislation to further regulate the prescribing of psychotropic medications. Mental Health and Substance Abuse.

The Commonwealth of Massachusetts

In the One Hundred and Eighty-Ninth General Court
(2015-2016)

An Act relative to psychotropic drugs.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 Chapter 111 of the General Laws, as appearing in the 2012 Official Edition, is hereby
2 amended by inserting after section 72BB the following section:—

3

4 Section 72CC. (a) For the purposes of this section, the following terms shall have the
5 following meanings:--

6 “Facility”, a facility for the delivery of health services and includes: a hospital, state
7 mental hospital, facility for long-term care, or rehabilitation facility.

8

9 “Incapacitated person”, an individual who for reasons other than advanced age or
10 minority, has a clinically diagnosed condition that results in an inability to receive and evaluate
11 information or make or communicate decisions to such an extent that the individual lacks the

12 ability to meet essential requirements for physical health, safety, or self-care, even with
13 appropriate technological assistance.

14

15 “Legal representative”, for any patient adjudged incompetent under the laws of the
16 commonwealth, the person duly appointed by a court of competent jurisdiction to act on the
17 patient’s behalf, and, for any patient who has not been adjudged incompetent by a state court,
18 any legal-surrogate designated in accordance with state law.

19

20 “Psychoactive medication”, any medication used for managing behavior, sleep disorders,
21 stabilizing mood, or treating psychiatric disorders and contains a boxed warning for off-label
22 use.

23

24 (b) A physician, an advanced practice nurse prescriber certified under 244 CMR 4.00, or
25 a physician assistant licensed under 263 CMR 3.05, who prescribes a psychoactive medication to
26 a patient, shall notify the facility if the prescribed medication has a boxed warning under 21 CFR
27 201.57.

28

29 (c) Except as provided in subsection (i) or subsection (j), before administering a
30 psychoactive medication to a patient, a facility shall obtain written informed consent from the
31 patient or, if the patient is incapacitated, a legal representative of the patient, on a form provided

32 by the department under subsection (e) or on a form that contains the same information as the
33 form under subsection (e).

34

35 (d) Within 48 hours of increasing the dosage of a psychoactive medication, a facility
36 shall obtain written informed consent from the patient or, if the patient is incapacitated, a legal
37 representative of the patient.

38

39 (e) The department shall make available on its web site drug-specific forms for obtaining
40 informed consent for the administration of psychoactive medication that contain all of the
41 following:

42

43 (1) A space for a description of the benefits or risks, if any, of the proposed treatment.

44 (2) A space for a description of the way the psychoactive medication shall be
45 administered, including but not limited to, how long and how often the drug shall be used, and
46 how and by whom side effects shall be monitored.

47

48 (3) A description, using the most recently issued information from the Food and Drug
49 Administration, of the side effects or risks of side effects of the medication and any warnings
50 about the medication. The description shall include, but not limited to, boxed warnings, potential
51 drug interactions and information relative to FDA approval.

52 (4) A space for a description of any alternative treatments, including but not limited to,
53 behavior interventions and medications.

54

55 (5) A space for a description of treatment modes and medications that have been
56 previously administered.

57

58 (6) A space for indicating the period for which the informed consent is effective, which
59 shall be no longer than 3 months from the time the consent is given.

60

61 (7) A statement that the patient or a legal representative of the patient may withdraw
62 informed consent, in writing, at any time.

63

64 (8) A statement that patient or a legal representative of the patient has the right to accept
65 or refuse the psychoactive medication at any time.

66

67 (9) A space for a description of the possible consequences or benefits, if any, of not
68 receiving the medication and a statement that the withdrawal or refusal of treatment shall not
69 relieve a facility of its duty to provide reasonable treatment to the patient.

70

71 (10) A declaration that the patient or the legal representative of the patient has been
72 provided with specific, complete, and accurate information, and sufficient time to study the
73 information or to seek additional information concerning the medication.

74

75 (11) A space for the signature of the patient or the legal representative of the patient.

76

77 (f) The facility shall give the patient, or a legal representative of the patient, a copy of the
78 completed informed consent form. The original shall be included in the patient file.

79

80 (g) Unless consent is withdrawn sooner, written informed consent obtained under this
81 subsection is valid for the period specified on the informed consent form but not for longer than
82 3 months from the date the patient, or a legal representative of the patient, signed the form.

83

84 (h) A patient, or a legal representative of the patient, has the right to revoke consent for
85 any reason, at any time.

86

87 (i) A facility is not required to obtain written informed consent before administering a
88 psychoactive medication to a patient under subsection (c) if all of the following apply:

89

90 (1) There is an emergency in which a patient is at imminent and serious risk of physical
91 or emotional harm or the patient puts others at imminent and serious risk of physical harm, and
92 in which time or distance precludes obtaining written informed consent before administering
93 psychoactive medication.

94

95 (2) A physician has determined that the patient or others will be harmed if the
96 psychoactive medication is not administered before written informed consent is obtained.

97 (j) If subsection (i) applies, the facility shall obtain oral consent from the patient or, if the
98 patient is incapacitated, a legal representative of the patient, before administering the
99 psychoactive medication, except as provided in subsection (k). The oral consent and
100 documentation as to why the drug was prescribed, signed by the patient or legal representative of
101 the patient, shall be entered in the patient's medical record. The oral consent shall be valid for a
102 maximum period of 2 days, after which time the facility may not continue to administer the
103 psychoactive medication unless it has obtained written informed consent under subsection (c).

104

105 (k) If subsection (i) applies, the patient is incapacitated, and the facility has made a good
106 faith effort to obtain oral consent, under subsection (j), of a legal representative of the patient but
107 has been unable to contact such a person, the facility may administer the psychoactive
108 medication to the patient for up to 48 hours before obtaining consent under subsection (c) or
109 subsection (i).

110

111 (l) Rogers Guardianships shall be exempted from any requirement of this law which is in
112 conflict with Rogers Guardianship regulations and protocols.

113

114 (m) The department of public health shall adopt regulations to implement this section on
115 or before April 1, 2016.