HOUSE DOCKET, NO. 3176 FILED ON: 1/16/2015

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:
Shaunna L. O'Connell	*3rd Bristol*
Nancy Sylvester	*13 Pinckney Street Taunton, MA 02780*
David F. DeCoste	*5th Plymouth*
Paul McMurtry	*11th Norfolk*

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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:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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