SENATE DOCKET, NO. 1650 FILED ON: 1/16/2015

SENATE . . . . . No. 1041

The Commonwealth of Massachusetts

PRESENTED BY:

John F. Keenan

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 high volume and high risk prescriptions.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
John F. Keenan	*Norfolk and Plymouth*
Josh S. Cutler	*6th Plymouth*
Tackey Chan	*2nd Norfolk*
Carolyn C. Dykema	*8th Middlesex*
James M. Cantwell	*4th Plymouth*
Jason M. Lewis	*Fifth Middlesex*
Barbara L'Italien	*Second Essex and Middlesex*
Joan B. Lovely	*Second Essex*
Randy Hunt	*5th Barnstable*

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By Mr. Keenan, a petition (accompanied by bill, Senate, No. 1041) of John F. Keenan, Josh S. Cutler, Tackey Chan, Carolyn C. Dykema and other members of the General Court for legislation relative to high volume and high risk prescriptions. Mental Health and Substance Abuse.

The Commonwealth of Massachusetts

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

An Act relative to high volume and high risk prescriptions.

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

SECTION 1. Section 1 of Chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting the following new definitions:-

"Extended-release long-acting opioid" or "in an extended release form" shall mean a drug that is subject to the United States Food and Drug Administration's Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioid Analgesics.

"Non-abuse deterrent opioid" or "in a non-abuse deterrent form" shall mean an opioid drug product that is approved for medical use but that does not meet the requirements for listing as a drug with abuse-deterrent properties pursuant to section 13 of chapter 17.

SECTION 2. Section 7 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting after subsection (a) the following new subsection:

-“(a ½) The department shall, by regulation, establish a specialty designation to registrations issued pursuant to subsection (a), which shall give authorization to a practitioner to issue a prescription for extended-release long-acting opioid drugs in a non-abuse deterrent form that pose a heightened level of public health risk, as identified pursuant to section 13 of chapter 17. This designation may be issued only to a practitioner licensed pursuant to chapter 112 who is actively practicing in Massachusetts and who has completed appropriate continuing medical education credits in pain management and in substance abuse prevention pursuant to standards for such training which shall be established by the practitioner’s corresponding board of registration.”

SECTION 3. Section 18 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by striking, in the first sentence of section (d ½), the words “A prescription” and inserting in place thereof the following:

-“Except as further restricted by subsection (f), a prescription”

SECTION 4. Said section 18 is hereby further amended by inserting after subsection (e) the following new subsection:-

(f) A prescription for a narcotic substance that poses a heightened level of public health risk, as identified pursuant to section 13 of chapter 17, shall be issued only by a practitioner who has received a specialty designation under subsection (a ½) of section 7 and who is currently enrolled in and compliant with all the requirements of the prescription monitoring program; provided that in no case shall such a prescription be issued in an emergency department setting. A registered pharmacist filling a prescription under this subsection shall determine, in accordance with professional standards and personal judgment, that such prescription is authentic

and valid, and shall verify the prescription by telephonic or other means. A pharmacist shall not fill a prescription for which a verification cannot be obtained. A pharmacist shall not be liable for refusing to fill a prescription for which a verification cannot be obtained, provided that documented good faith efforts were made to determine the authenticity and validity of such prescription.

SECTION 5. Chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting the following new section:-

Section 18A. Requirements for the issuance of prescriptions for opioids in high volume.

(a) For a narcotic substance contained in schedule II or schedule III, that has not been identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health, a prescription issued by a practitioner in an emergency department shall not exceed a five day supply.

(b) For a narcotic substance contained in schedule II or schedule III, that has not been identified pursuant to section 13 of chapter 17 as posing a heightened risk to the public health, an initial prescription shall be limited to a fifteen day supply; provided that the term “initial prescription” shall be defined in regulation by the department. A subsequent prescription issued within sixty days of the date of issuance of the initial prescription shall not exceed an additional fifteen day supply, and no combination of initial and subsequent prescriptions issued within a sixty day period may exceed a total of a thirty day supply except pursuant to the conditions established in subsection (c).

(c) A practitioner intending to issue a subsequent prescription to a patient such that the total prescribed quantity will exceed a thirty day supply within a sixty day window shall: (i)

evaluate the patient's current condition, risk factors, history of substance abuse if any, and current medications; (ii) make a determination that other pain management treatments are or would be inadequate for the patient; (iii) utilize the prescription monitoring program prior to the issuance of the prescription; and (iv) enter into a pain management treatment agreement with the patient that appropriately addresses the risk factors for abuse or misuse of the prescribed substance, according to guidelines for such agreements published by the department, and document said agreement in the patient's interoperable electronic health record.

(d) For an opioid drug identified, pursuant to section 13 of chapter 17, as posing a heightened level of risk to the public health, a practitioner, prior to issuing an initial prescription, shall: (i) evaluate the patient's current condition, risk factors, history of substance abuse if any, and current medications; (ii) make a determination that other pain management treatments, including drugs presenting a lower risk for abuse or misuse, are or would be inadequate for the patient; (iii) utilize the prescription monitoring program prior to the issuance of the prescription; and (iv) enter into a pain management treatment agreement with the patient that appropriately addresses the risk factors for abuse or misuse of the prescribed substance, according to guidelines for such agreements published by the department, and document said agreement in the patient's interoperable electronic health record.

SECTION 6. Section 22 of chapter 94C of the General Laws, as appearing in the 2012 Official Edition, is hereby amended by inserting the following new subsection:

"(c) A practitioner who dispenses, by issuing a written prescription, an extended-release and long-acting opioid drug in a non-abuse deterrent form that has been identified, pursuant to section 13 of chapter 17, as posing a heightened level of risk to the public health, shall, in

addition to the requirements of subsection (a), and in a manner determined in regulation by the department, prepare appropriate documentation of the medical need for said product and a statement of the practitioner's professional judgment that other treatments or products are not suitable for the patient. Said documentation shall be placed in the patient's medical file.

SECTION 7. Section 24A of Chapter 94C, as amended by Chapter 38 of the Acts of 2013 and Chapter 258 of the Acts of 2014, is hereby further amended in subsection (c) by inserting after the words "schedule II or III" the following words:-

", and shall further include requiring participants who are duly authorized to prescribe high risk drugs, pursuant to subsection (a ½) of section 7, to utilize the prescription monitoring program prior to each issuance of such a prescription."

SECTION 8. Said section 24A is hereby further amended by inserting the following new subsection:

(m) On at least a bi-annual basis, and utilizing the monitoring program established by this section, the department shall conduct a random audit of prescriptions for drugs identified pursuant to section 13 of chapter 17 as posing a heightened level of risk to the public health, to determine whether such prescriptions have been issued in compliance with the requirements of subsection (g) of section 18. Any potential violations discovered through said audit process shall be reported to the corresponding board of registration.