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December 10, 2018

Secretary Marylou Sudders
Executive Office of Health and Human Services
One Ashburton Place, Room 1109
Boston, MA 02108

Dear Secretary Sudders,

Pursuant to St. 2018, c. 208, § 100, the Harm Reduction Commission is investigating the feasibility of opening a supervised injection site in Massachusetts. Attached you will find a list of BORIM policies, procedures, statutes and regulations that would need to be amended in order to allow a physician to participate in a harm reduction site.

I am also attaching 2013 legislation from Vermont, *An Act Relating to Patient Choice and Control at End of Life*. It appears, rather than amending existing statutes or regulations, Vermont created immunity for physicians who provide aid to patients wishing to choose medical aid-in-dying. The immunity is for civil liability, criminal liability and disciplinary actions. An option may be to include language in legislation offering immunity for physicians participating in harm reduction sites.

Please feel free to contact me if you would like more information on any of the Board's authorities.

Sincerely,

George Zachos,
Executive Director

BOARD OF REGISTRATION IN MEDICINE POLICIES, PROCEDURES AND REGULATORY CHANGES NECESSARY TO ALLOW PHYSICIANS TO WORK IN A HARM REDUCTION SITE

Below are the major statutory and regulatory changes that would be necessary for BORIM licensees to work or volunteer in a medically-supervised injection site.

1. Good Moral Character is a requirement for licensure as a physician.

M.G.L. c. 112, § 2: *"Each applicant who shall furnish the board with satisfactory proof that he is eighteen years of age or over and of good moral character..."*

One of the Board's basic statutory requirements for licensure is to possess "good moral character." Any violation of state law or federal law (below) would call into question a physician's character and ethics.

There are many adjudicatory cases supporting discipline when the good moral character requirement is not met or ceases to be met, e.g., Levy v. Board of Registration in Medicine, 378 Mass. 519 (1979). "Any conduct, although not specified, which by common opinion and fair judgment is determined to be unprofessional or dishonorable may constitute grounds for revocation;" and Raymond v. Board of Registration in Medicine, 387 Mass. 708 (1982), "Lack of good moral character and conduct that undermines public confidence in the integrity of the medical profession are grounds for discipline."

2. State drug laws and other criminal laws would need to be amended.

A medically-supervised injection site would violate M.G.L. c. 94C, § 35, being knowingly present where heroin is kept.

M.G.L. c. 94C, § 35: *"Any person who is knowingly present at a place where heroin is kept or deposited in violation of the provisions of this chapter, or any person who is in the company of a person, knowing that said person is in possession of heroin in violation of the provisions of this chapter, shall be punished by imprisonment for not more than one year or by a fine of not more than one thousand dollars, or both; provided, however, that the provisions of the third paragraph of section thirty-four relative to probation sealing of the records and repeated violations shall apply to him."*

Please note: there is a safe haven exception for the patient under G.L. c. 94C, § 34A, which states: *"A person who experiences a drug-related overdose and is in need of medical assistance and, in good faith, seeks such medical assistance, or is the subject of such a good faith request for medical assistance, shall not be charged or prosecuted for possession of a controlled substance under said sections 34 or 35 if the evidence for the charge of possession of a controlled substance was gained as a result of the overdose and the need for medical assistance."*

This safe haven does not apply to the physician, who would still be subject to civil and criminal liability and professional discipline.

3. Violating any state criminal laws would subject the physician to discipline.

The below statute and regulation would not be an issue if participation in a harm reduction site did not violate state law or federal law:

M.G.L. c. 112, § 5, eighth paragraph, (g): *"has been convicted of a criminal offense which reasonably calls into question his ability to practice medicine"*

243 CMR 1.03(5)(a)(7): *Conviction of a crime.*

4. If federal laws are violated, the physician would be subject to liability and discipline.

Federal laws will be implicated. Heroin is a Schedule 1 drug under the federal Controlled Substance Act and therefore has been deemed illegal and to have no legitimate medical purpose. Specifically the CSA states: *"All drugs listed in Schedule I have no currently accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use... Some examples of substances listed in Schedule I are: heroin; lysergic acid diethylamide (LSD); marijuana (cannabis); peyote; methaqualone; and methylenedimethoxymethamphetamine ("ecstasy")."*

21 U.S.C. § 856 also bars the maintenance of drug-involved premises: *"knowingly open or maintain...any place, whether permanently or temporarily...for purpose of using any controlled substance."* While this law was written to address "crack houses" the language also seems to fit safe injection sites and therefore, a conviction under this statute would be a violation of this statute and regulations.

5. Unless there is an exception for physicians volunteering at a harm reduction site, a Massachusetts physician must carry malpractice insurance in order to practice medicine.

M.G.L. c. 112, § 2: *"The board is authorized to promulgate regulations requiring physicians to obtain professional malpractice liability insurance or a suitable bond or other indemnity against liability for professional malpractice in such amounts as may be determined by the board."*

243 CMR 2.07(16): A physician must carry mandatory professional malpractice insurance.

6. Physician participation in a harm reduction site may be seen as violating the standard of care and grounds for discipline.

A physician-patient relationship may develop in a situation where the physician is required to intervene and the standard of care becomes an issue.

MGL c. 112, § 5, eighth paragraph, (c): *"is guilty of conduct which places into question the physician's competence to practice medicine, including but not limited to gross misconduct in the practice of medicine or of practicing medicine fraudulently, or beyond its authorized scope, or with gross incompetence, or with gross negligence on a particular occasion or negligence on repeated occasions"*

243 CMR 1.03(5)(a)(3): *"Conduct which places into question the physician's competence to practice medicine, including but not limited to gross misconduct in the practice of medicine, or practicing medicine fraudulently, or beyond its authorized scope, or with gross incompetence, or with gross negligence on a particular occasion or negligence on repeated occasions"*.

243 CMR 1.03(5)(a)18: *Misconduct in the practice of medicine is a ground for discipline.*

243 CMR 1.03(5)(a)(17): *Malpractice within the meaning of 112/61*

7. BORIM's enabling act states that violation of any state law or regulation regarding the practice of medicine is grounds for discipline.

The below would not be an issue if volunteering at a harm reduction site did not violate state or federal law, and the physician was providing the appropriate level of care.

MGL c. 112, § 5, eighth paragraph, (b): *"is guilty of an offense against any provision of the laws of the commonwealth relating to the practice of medicine, or any rule or regulation adopted thereunder"*

MGL c. 112, § 5, eighth paragraph, (h): *"is guilty of violating any rule or regulation of the board, governing the practice of medicine."*

243 CMR 1.03(5)(a)(2): *"Commitment of an offense against any provision of the laws of the Commonwealth relating to the practice of medicine, or any rule or regulation adopted thereunder."*

243 CMR 2.07(5): Violation of M.G.L. c. 94C (the state drug laws) violates the Board's regulations.

243 CMR 1.03(5)(a)(11): Violation of any rule or regulation of the Board.

8. The Board policy "Prescribing Practices Policy and Guidelines," (2015) would be amended to address licensees who work or volunteer in a harm reduction site.

No. 39. An act relating to patient choice and control at end of life.

(S.77)

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 18 V.S.A. chapter 113 is added to read:

CHAPTER 113. PATIENT CHOICE AT END OF LIFE

§ 5281. DEFINITIONS

(a) As used in this chapter:

(1) "Bona fide physician-patient relationship" means a treating or consulting relationship in the course of which a physician has completed a full assessment of the patient's medical history and current medical condition, including a personal physical examination.

(2) "Capable" means that a patient has the ability to make and communicate health care decisions to a physician, including communication through persons familiar with the patient's manner of communicating if those persons are available.

(3) "Health care facility" shall have the same meaning as in section 9432 of this title.

(4) "Health care provider" means a person, partnership, corporation, facility, or institution, licensed or certified or authorized by law to administer health care or dispense medication in the ordinary course of business or practice of a profession.

(5) "Impaired judgment" means that a person does not sufficiently understand or appreciate the relevant facts necessary to make an informed decision.

(6) "Interested person" means:

(A) the patient's physician;

(B) a person who knows that he or she is a relative of the patient by blood, civil marriage, civil union, or adoption;

(C) a person who knows that he or she would be entitled upon the patient's death to any portion of the estate or assets of the patient under any will or trust, by operation of law, or by contract; or

(D) an owner, operator, or employee of a health care facility, nursing home, or residential care facility where the patient is receiving medical treatment or is a resident.

(7) "Palliative care" shall have the same definition as in section 2 of this title.

(8) "Patient" means a person who is 18 years of age or older, a resident of Vermont, and under the care of a physician.

(9) "Physician" means an individual licensed to practice medicine under 26 V.S.A. chapter 23 or 33.

(10) "Terminal condition" means an incurable and irreversible disease which would, within reasonable medical judgment, result in death within six months.

§ 5282. RIGHT TO INFORMATION

The rights of a patient under section 1871 of this title to be informed of all available options related to terminal care and under 12 V.S.A. § 1909(d) to

receive answers to any specific question about the foreseeable risks and benefits of medication without the physician's withholding any requested information exist regardless of the purpose of the inquiry or the nature of the information. A physician who engages in discussions with a patient related to such risks and benefits in the circumstances described in this chapter shall not be construed to be assisting in or contributing to a patient's independent decision to self-administer a lethal dose of medication, and such discussions shall not be used to establish civil or criminal liability or professional disciplinary action.

§ 5283. REQUIREMENTS FOR PRESCRIPTION AND

DOCUMENTATION; IMMUNITY

(a) A physician shall not be subject to any civil or criminal liability or professional disciplinary action if the physician prescribes to a patient with a terminal condition medication to be self-administered for the purpose of hastening the patient's death and the physician affirms by documenting in the patient's medical record that all of the following occurred:

(1) The patient made an oral request to the physician in the physician's physical presence for medication to be self-administered for the purpose of hastening the patient's death.

(2) No fewer than 15 days after the first oral request, the patient made a second oral request to the physician in the physician's physical presence for

medication to be self-administered for the purpose of hastening the patient's death.

(3) At the time of the second oral request, the physician offered the patient an opportunity to rescind the request.

(4) The patient made a written request for medication to be self-administered for the purpose of hastening the patient's death that was signed by the patient in the presence of two or more witnesses who were not interested persons, who were at least 18 years of age, and who signed and affirmed that the patient appeared to understand the nature of the document and to be free from duress or undue influence at the time the request was signed.

(5) The physician determined that the patient:

(A) was suffering a terminal condition, based on the physician's physical examination of the patient and review of the patient's relevant medical records;

(B) was capable;

(C) was making an informed decision;

(D) had made a voluntary request for medication to hasten his or her death; and

(E) was a Vermont resident.

(6) The physician informed the patient in person, both verbally and in writing, of all the following:

(A) the patient's medical diagnosis;

(B) the patient's prognosis, including an acknowledgement that the physician's prediction of the patient's life expectancy was an estimate based on the physician's best medical judgment and was not a guarantee of the actual time remaining in the patient's life, and that the patient could live longer than the time predicted;

(C) the range of treatment options appropriate for the patient and the patient's diagnosis;

(D) if the patient was not enrolled in hospice care, all feasible end-of-life services, including palliative care, comfort care, hospice care, and pain control;

(E) the range of possible results, including potential risks associated with taking the medication to be prescribed; and

(F) the probable result of taking the medication to be prescribed.

(7) The physician referred the patient to a second physician for medical confirmation of the diagnosis, prognosis, and a determination that the patient was capable, was acting voluntarily, and had made an informed decision.

(8) The physician either verified that the patient did not have impaired judgment or referred the patient for an evaluation by a psychiatrist, psychologist, or clinical social worker licensed in Vermont for confirmation that the patient was capable and did not have impaired judgment.

(9) If applicable, the physician consulted with the patient's primary care physician with the patient's consent.

(10) The physician informed the patient that the patient may rescind the request at any time and in any manner and offered the patient an opportunity to rescind after the patient's second oral request.

(11) The physician ensured that all required steps were carried out in accordance with this section and confirmed, immediately prior to writing the prescription for medication, that the patient was making an informed decision.

(12) The physician wrote the prescription no fewer than 48 hours after the last to occur of the following events:

(A) the patient's written request for medication to hasten his or her death;

(B) the patient's second oral request; or

(C) the physician's offering the patient an opportunity to rescind the request.

(13) The physician either:

(A) dispensed the medication directly, provided that at the time the physician dispensed the medication, he or she was licensed to dispense medication in Vermont, had a current Drug Enforcement Administration certificate, and complied with any applicable administrative rules; or

(B) with the patient's written consent:

(i) contacted a pharmacist and informed the pharmacist of the prescription; and

(ii) delivered the written prescription personally or by mail or facsimile to the pharmacist, who dispensed the medication to the patient, the physician, or an expressly identified agent of the patient.

(14) The physician recorded and filed the following in the patient's medical record:

(A) the date, time, and wording of all oral requests of the patient for medication to hasten his or her death;

(B) all written requests by the patient for medication to hasten his or her death;

(C) the physician's diagnosis, prognosis, and basis for the determination that the patient was capable, was acting voluntarily, and had made an informed decision;

(D) the second physician's diagnosis, prognosis, and verification that the patient was capable, was acting voluntarily, and had made an informed decision;

(E) the physician's attestation that the patient was enrolled in hospice care at the time of the patient's oral and written requests for medication to hasten his or her death or that the physician informed the patient of all feasible end-of-life services;

(F) the physician's verification that the patient either did not have impaired judgment or that the physician referred the patient for an evaluation and the person conducting the evaluation has determined that the patient did not have impaired judgment;

(G) a report of the outcome and determinations made during any evaluation which the patient may have received;

(H) the date, time, and wording of the physician's offer to the patient to rescind the request for medication at the time of the patient's second oral request; and

(I) a note by the physician indicating that all requirements under this section were satisfied and describing all of the steps taken to carry out the request, including a notation of the medication prescribed.

(15) After writing the prescription, the physician promptly filed a report with the Department of Health documenting completion of all of the requirements under this section.

(b) This section shall not be construed to limit civil or criminal liability for gross negligence, recklessness, or intentional misconduct.

§ 5284. NO DUTY TO AID

A patient with a terminal condition who self-administers a lethal dose of medication shall not be considered to be a person exposed to grave physical harm under 12 V.S.A. § 519, and no person shall be subject to civil or criminal liability solely for being present when a patient with a terminal condition

self-administers a lethal dose of medication or for not acting to prevent the patient from self-administering a lethal dose of medication.

§ 5285. LIMITATIONS ON ACTIONS

(a) A physician, nurse, pharmacist, or other person shall not be under any duty, by law or contract, to participate in the provision of a lethal dose of medication to a patient.

(b) A health care facility or health care provider shall not subject a physician, nurse, pharmacist, or other person to discipline, suspension, loss of license, loss of privileges, or other penalty for actions taken in good faith reliance on the provisions of this chapter or refusals to act under this chapter.

(c) Except as otherwise provided in this section and sections 5283, 5289, and 5290 of this title, nothing in this chapter shall be construed to limit liability for civil damages resulting from negligent conduct or intentional misconduct by any person.

§ 5286. HEALTH CARE FACILITY EXCEPTION

A health care facility may prohibit a physician from writing a prescription for a dose of medication intended to be lethal for a patient who is a resident in its facility and intends to use the medication on the facility's premises, provided the facility has notified the physician in writing of its policy with regard to the prescriptions. Notwithstanding subsection 5285(b) of this title, any physician who violates a policy established by a health care facility under

this section may be subject to sanctions otherwise allowable under law or contract.

§ 5287. INSURANCE POLICIES; PROHIBITIONS

(a) A person and his or her beneficiaries shall not be denied benefits under a life insurance policy, as defined in 8 V.S.A. § 3301, for actions taken in accordance with this chapter.

(b) The sale, procurement, or issue of any medical malpractice insurance policy or the rate charged for the policy shall not be conditioned upon or affected by whether the physician is willing or unwilling to participate in the provisions of this chapter.

§ 5288. NO EFFECT ON PALLIATIVE SEDATION

This chapter shall not limit or otherwise affect the provision, administration, or receipt of palliative sedation consistent with accepted medical standards.

§ 5289. PROTECTION OF PATIENT CHOICE AT END OF LIFE

A physician with a bona fide physician-patient relationship with a patient with a terminal condition shall not be considered to have engaged in unprofessional conduct under 26 V.S.A. § 1354 or 26 V.S.A. § 1842 if:

(1) the physician determines that the patient is capable and does not have impaired judgment;

(2) the physician informs the patient of all feasible end-of-life services, including palliative care, comfort care, hospice care, and pain control;

(3) the physician prescribes a dose of medication that may be lethal to the patient;

(4) the physician advises the patient of all foreseeable risks related to the prescription; and

(5) the patient makes an independent decision to self-administer a lethal dose of the medication.

§ 5290. IMMUNITY FOR PHYSICIANS

A physician shall be immune from any civil or criminal liability or professional disciplinary action for actions performed in good faith compliance with the provisions of this chapter.

§ 5291. SAFE DISPOSAL OF UNUSED MEDICATIONS

The Department of Health shall adopt rules providing for the safe disposal of unused medications prescribed under this chapter.

§ 5292. STATUTORY CONSTRUCTION

Nothing in this chapter shall be construed to authorize a physician or any other person to end a patient's life by lethal injection, mercy killing, or active euthanasia. Action taken in accordance with this chapter shall not be construed for any purpose to constitute suicide, assisted suicide, mercy killing, or homicide under the law. This section shall not be construed to conflict with section 1553 of the Patient Protection and Affordable Care Act, Pub.L. No. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Pub.L. No. 111-152.

Sec. 2. REPEAL

18 V.S.A. § 5283 (immunity for prescription and documentation) is repealed on July 1, 2016.

Sec. 3. EFFECTIVE DATES

(a) Sec. 1 (18 V.S.A. chapter 113) of this act shall take effect on passage, except that 18 V.S.A. §§ 5289 (protection of patient choice at end of life) and 5290 (immunity for physicians) shall take effect on July 1, 2016.

(b) The remaining sections of this act shall take effect on passage.

Date the Governor signed the bill: May 20, 2013