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To: Massachusetts licensed physicians, physician assistants, nurses, pharmacists, pharmacies, hospitals, and clinics

From: Robert Goldstein, MD, PhD, Commissioner, Department of Public Health

Date: January 3, 2024

Subject: Reminder to Licensees Regarding Licensure Obligations and Providing Standard of Care

The Department of Public Health takes patients' rights and the provision of high quality, evidence-based, safe care by all providers very seriously. **This includes providing patients accurate and complete information for informed decision-making, accurate portrayal and advertising of clinical services, and licensees practicing within their scope of practice and their license.** The Department issues this memorandum to outline and remind licensees of their obligations under state law and as a condition of licensure.

Clinic Licensure Requirements

Massachusetts law requires that clinics be licensed by the Department of Public Health (DPH). (See [M.G.L. c. 111, § 51](#).) A clinic is any entity, however organized, whether conducted for profit or not for profit, that is advertised, announced, established, or maintained for the purpose of providing ambulatory medical, surgical, dental, physical rehabilitation, or mental health services. However, the law provides an exception from licensure requirements under this section for any entity that is wholly owned and controlled by one or more of its medical practitioners and does not use the word "clinic," "institute" or "dispensary" in its name. (See [M.G.L. c. 111, § 52](#) for the definition of "clinic.") Thus, any entity that provides ambulatory medical services is subject to clinic licensure if it is not wholly owned and controlled by one or more of its practitioners.

Ambulatory medical services are services providing diagnosis or treatment of a health condition and include procedures such as diagnosing pregnancies, performing ultrasounds and other clinical procedures. **Any entity that offers ambulatory medical services, including said procedures, is subject to clinic licensure and must meet the requirements of 105 CMR 140.000, unless otherwise exempt.**

Additionally, any clinic providing medical services must meet the requirements of 105 CMR 140.000, including specific requirements related to staffing¹.

Failure to adhere to the staffing requirements of 105 CMR 140.000 could not only jeopardize a clinic license through administrative action including licensure suspension or revocation², but may also result in the referral of licensed providers deemed out of compliance to the appropriate licensing board.

Entities and individuals may be referred to the Attorney General's Office by DPH for prosecution of deceptive practices by holding the entity out as a clinic, or performing unlicensed medical services.

Massachusetts Controlled Substances Registration (MCSR) Requirements

All practitioners and entities must comply with controlled substance requirements in M.G.L. c. 94C, as implemented by 105 CMR 700.000, regardless of whether the entity is licensed as a clinic or owned and operated by one or more practitioners. A MCSR is required for any practitioner or entity to purchase, store, or dispense any controlled substance, which includes any prescription medication in Massachusetts.

Licensed Healthcare Professionals

The Board of Registration in Medicine (BORIM) and the Boards of Registration within the Bureau of Health Professions Licensure (BHPL) at the Department of Public Health regulate and oversee individual healthcare practitioners, including physicians, nurses, and physician assistants.

All healthcare practitioners in Massachusetts are subject to professional discipline for the failure to comply with recognized standards of practice and for engaging in conduct that is dishonest or deceitful.

1. Licensed healthcare professionals must comply with recognized standards of practice.

Nurses are required to comply with recognized standards of nursing practice and to act within the scope of practice for nurses.³

Board of Registration in Nursing (BORN) regulations require that a nurse shall perform nursing techniques and procedures, including but not limited to providing ultrasounds, only after appropriate education and demonstrated clinical competency.⁴ In other words, a nurse is prohibited from using any technique or procedure if they have not received appropriate education

¹ 105 CMR 140.310 through 105 CMR140.334

² 105 CMR 140.130 through 105 CMR 140.134

³ 244 CMR 7.03(1)(i); 244 CMR 9.03(5); 244 CMR 9.03(47); 244 CMR 7.03(1)(h); 244 CMR 9.03(10).

⁴ 244 CMR 9.03(11) & (12)

and demonstrated clinical competency. Nurses are responsible and accountable for their nursing actions, judgments, and competencies.⁵

Physicians and Advanced Practice Registered Nurses (APRN) who practice in violation of good and accepted health care practice may be disciplined for conduct which places into question their competence to practice.⁶ For example, there is strong evidence that medication abortion reversal is unproven, unethical, and unsafe to provide to patients⁷; such that a physician or APRN who offers or provides this treatment could be found to be practicing inconsistently with accepted practice and subject to discipline.

Similarly, physician assistants (PAs) must act within the scope of practice for PAs, 263 CMR 5.09(4), and may only assume duties and responsibilities within their scope of practice and for which they have acquired and maintained necessary knowledge, skills, and abilities.⁸

Failure to comply with recognized standards of practice is grounds for professional discipline, up to and including license revocation.

2. Licensed healthcare professionals, including physicians, nurses, and physician assistants, may not engage in deceitful conduct or any conduct that poses a risk to public health, safety, or welfare.

Physicians may not practice medicine deceitfully or engage in conduct which has the capacity to deceive or defraud.⁹ They also may not advertise in a manner that is false, deceptive, or misleading, or that has the effect of intimidating or exerting undue pressure.¹⁰ Nor may they engage in conduct that undermines public confidence in the integrity of the medical profession, even where the physician may not have engaged in wrongdoing or deceit.¹¹

These principles have been specifically applied to advertising and communications concerning the qualifications and licensure of an unlicensed individual providing services in the same location as the physician. For example, advertising or communications that suggest interpretation of ultrasound results is being performed by a licensed and qualified provider, when the person interpreting the results is not licensed or qualified would constitute false, deceptive, and misleading practice. Additionally, licensed individuals practicing in the setting where any such service is provided undermines the public confidence. Conduct or advertising which is objectively

⁵ 244 CMR 9.03(9).

⁶ For physicians see 243 CMR 1.03(5)(a); for APRNs, the standards of care to which nurses in advanced practice shall be held, shall be those standards which protect consumers, and provide them with safe and comprehensive care, and shall be standards comparable to other professionals, including physicians, providing the same services. MGL c. 112 §80B.

⁷ See American College of Obstetricians and Gynecologists advocacy stance regarding medication abortion “reversals”: [Medication Abortion "Reversal" Is Not Supported by Science | ACOG](#)

⁸ 263 CMR 5.09(5).

⁹ 243 CMR 1.03(5)(a)10

¹⁰ 243 CMR 2.07(11)(a).

¹¹ *Welter v. Board of Registration in Medicine*, 490 Mass 718, 725, 196 N.E.3d 312, 320 (2022), cert. denied sub nom. *Welter v. Massachusetts Bd. of Registration in Med.*, 143 S. Ct. 2561 (2023).

deceptive, even if technically accurate, is prohibited and may be the basis for discipline, irrespective of whether the physician had an intent to deceive or whether anyone was subjectively deceived¹².

BORN regulations also prohibit a nurse from engaging in any fraudulent conduct, and any conduct likely to have an adverse effect on health, safety, or welfare of the public.¹³ Any conduct that undermines public confidence in the integrity of the profession is grounds for discipline of a nursing or physician assistant license.¹⁴

The BORN and Board of Registration of Physician Assistants (BORPA) regulations further prohibit nurses and PAs from exercising undue influence on a patient, including the promotion or sale of services, goods, appliances, or drugs, in such a manner as to exploit the patient for financial gain of the nurse or a third party.

A nurse or physician assistant may not engage in any behavior that is likely to have an adverse effect on the health, safety, or welfare of the public.^{15 16}

A nurse or physician assistant shall not knowingly falsify, or attempt to falsify, any documentation or information related to any aspect of their practice or delivery of medical services.¹⁷

Finally, the regulations explicitly prohibit nurses and PAs from engaging in false, deceptive, or misleading advertising or any other fraudulent practice.¹⁸

Based on the foregoing, any conduct or communication by a physician, nurse, or PA that is misleading or inaccurate would be a violation of regulations governing practice of the profession and may be grounds for discipline which could include but may not be limited to reprimand, probation, suspension, or revocation of the individual's license to practice.

All services performed by a physician assistant must be supervised by a licensed physician and the services must be: (1) within the competence of the PA, as determined by the supervising physician; and (2) within the scope of services for which the supervising physician can provide adequate supervision.¹⁹ Moreover, the supervising physician must provide supervision adequate to ensure the PA practices medicine in accordance with accepted standards of medical practice.²⁰

¹² *Welter, supra*, at 490 Mass. 726-728.

¹³ 244 CMR 9.03 (32), 244 CMR 7.03(1)(w); 244 CMR 9.03(47).

¹⁴ 244 CMR 7.03(1)(x); 263 CMR 6.02(2)(x).

¹⁵ 244 CMR 9.03(47); 263 CMR 6.03(2)(w).

^{16 16} See American College of Obstetricians and Gynecologists advocacy stance regarding medication abortion "reversals": [Medication Abortion "Reversal" Is Not Supported by Science | ACOG](#)

¹⁷ 244 CMR 9.03(31); 263 CMR 5.09(8).

¹⁸ 244 CMR 9.03(32); 263 CMR 5.09(21) & (22).

¹⁹ 263 CMR 5.03.

²⁰ 263 CMR 5.04.

3. Licensed healthcare professionals, including physicians, nurses, and physician assistants, are required to comply with the law.

Failure of physicians, nurses, and PAs to comply with all laws, regulations, advisory rulings, and policies of their respective licensing board are subject to discipline.²¹

Similarly, nurses and PAs may not aid another person in performing any act prohibited by laws or regulation²².

4. Advanced Practice Registered Nurses

Nurses authorized to practice in the advanced role must adhere to their scope of practice. 244 CMR 4.06; 244 CMR 9.04 (1). APRNs must also fully disclose, when proposing any diagnostic or therapeutic intervention which is beyond the scope of generic nursing practice, to the patient or to the patient's representative the risks and benefits of, and alternatives to, such intervention and shall document such disclosure in the patient's record. 244 CMR 9.04 (5).

APRNs who provide abortion services must comply with [Advisory Ruling 21-02 Certified Nurse Midwives and Certified Nurse Practitioners as Providers of Abortions for Pregnancies of Less than 24 Weeks](#).

5. Responsibility concerning activities of unlicensed individuals.

BORIM addresses physician responsibility for activities of unlicensed individuals in several ways. First, physicians may not knowingly permit, aid, or abet an unlicensed person to perform activities requiring a license.²³ In addition, physicians may not delegate medical services to an individual who is not licensed to perform those services in Massachusetts.²⁴ Medical services requiring licensure are services which fall within the definition of the practice of medicine, which may only be performed by licensed physicians, and other licensed health care professionals to the extent that the services also fall within the scope of practice of the license held.²⁵ Such services include diagnosis, treatment, use of instruments or other devices, or the prescribing, administering, dispensing, or distributing of drugs for the relief of diseases or adverse physical or mental conditions.²⁶ It also includes conduct by an individual that encourages reliance by others on the individual's knowledge or skill in the maintenance of human health. Id. For example, BORIM has imposed discipline on a physician who authored ultrasound reports on the basis of sonographer impressions in lieu of personally reviewing images.

²¹ 243 CMR 1.03(5)(a)2. and 11; 244 CMR 7.03(1)(a), (b), (e); 263 CMR 6.03(2)(a), (b), (e).

²² 244 CMR 9.03(7); 263 CMR 5.09(24).

²³ 243 CMR 1.03(5)(a)6

²⁴ 243 CMR 2.07(4).

²⁵ See 243 CMR 2.01(4)

²⁶ 243 CMR 2.01(4)

Additionally, 244 CMR 3.00 sets forth the responsibilities and functions of nurses and states requirements for delegation of nursing activities to unlicensed persons.

Conclusion

The Department expects the attention and cooperation of all licensees in providing accurate patient education, delivering safe and quality patient care, and adhering to professional standards under state licensure and the rights of all Massachusetts patients.