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Rhode Island Department of Health issues proposed amendments to *Rules and Regulations for the Licensure and Discipline of Physicians*

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The Rhode Island Department of Health recently released proposed amendments to the *Rules and Regulations for the Licensure and Discipline of Physicians* ("Proposed Regulations"). These changes will be the subject of a hearing on March 31, 2015, at 1:00 p.m. in the Auditorium of the Cannon Building (3 Capitol Hill, Providence, RI). Written comments can also be sent to James.McDonald@health.ri.gov.

There are a number of additions in the Proposed Regulations. Among the additions are provisions for so-called "Visiting Physicians," "Limited Medical Registration" for interns, residents or fellows, the limited registration of "academic faculty," and regulation of the use of lasers in the practice of medicine. There are also a number of potentially significant additions in the definition section of the Proposed Regulations, in particular, the addition of definitions for "Direct physician supervision" and "On-site supervision," and the definition of "Surgery."

A. New Definitions in the Proposed Regulations

One of the additions to the Proposed Regulations is a definition of "Direct Physician Supervision":

> **"Direct physician supervision"** means that the physician is in the physical presence of the patient being treated and is directly observing the use of the modality by a delegate.

Proposed Regulations, page 1. The term "direct physician supervision" is used only once in the regulations (in the new section addressing the use of lasers), in

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relation to the use of electrocautery by Level 1 or Level 2 delegates.[1] This addition provides that "[e]lectrocautery may be used by a Level 1 or Level 2 delegate under direct physician supervision." Proposed Regulations, page 23. While the requirement for "direct physician supervision" in this context is sensible, it would be unfortunate if the Department of Health were to impose requirements of direct supervision in a greater range of contexts. The imposition of direct physician supervision likely would undercut the utility of physician extenders. Thankfully, this outcome appears unlikely because the Proposed Regulations also define "On-site supervision," a term that is used much more frequently, as follows:

> continuous supervision in which the supervising physician is in the same

[1] A Level 1 delegate is defined as:

> an individual who is licensed to practice as an Advanced Practice Registered Nurse (APRN) pursuant to RIGL Chapter 5-34, or as a physician assistant pursuant to RIGL Chapter 5-54, and who is authorized in a written job description or collaborative protocol to use a specific laser/pulsed light device or other energy source, chemical or other modality for non-ablative procedures, as designated in the written job description or collaborative protocol and who has met the educational requirements for a Level 1 Delegate stated in these Regulations.

Proposed Regulations page 2.

A Level 2 delegate is a "person, other than a Level 1 Delegate, who has met the educational requirements for Level 2 Delegates" i.e., 16 hours of training including training in the:

(1) Fundamentals of laser operation;
(2) Bio-effects of laser radiation on the eye and skin;
(3) Significance of specular and diffuse reflections;
(4) Non-beam hazards of lasers;
(5) Non-ionizing radiation hazards;
(6) Laser and laser system classifications; and
(7) Control measures.

Proposed Regulations pages 2, 25.

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> building as the appropriate, properly trained delegate. All treatments and procedures must be performed under the licensed physicians [sic] direction and immediate personal supervision (i.e., the physician is physically present on the premises and immediately available at all times that the non-physician is on duty), and the physician retains full responsibility to patients and the Board for the manner and results of all services rendered.

Proposed Regulations, page 3. On-site supervision is used at least four times in the new provisions relating to the use of lasers. The requirement of on-site supervision has several advantages: it reaffirms the use of delegates/physician extenders, giving physicians the discretion and freedom to focus their attention where it is most necessary, and it represents a reasonable balance between patient safety and efficiency.

One addition to the definitions section in the Proposed Regulations which may be problematic is the definition of surgery:

> **"Surgery"** is performed for the purpose of structurally altering the human body by incision or destruction of tissues and is part of the practice of medicine. Surgery also is the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing, radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities,

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> internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel.

Proposed Regulations, pages 3-4. This definition is incredibly broad, pulling within its ambit treatments and procedures that would not classically be thought of as surgical. For example, reference to "destruction of tissues," "alteration or transportation of live human tissue, which include lasers, ultrasound, ionizing, radiation, scalpels, probes, and needles" and "[i]njection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system" could be read to include radiotherapy and chemotherapy within the definition of surgery, thus creating a significant and potentially problematic ambiguity in the regulations. This ambiguity is further compounded by the parenthetical carve-out indicating that the definition of surgery "does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician." Proposed Regulations, page 4. [2]

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[2] In addition, the definition of surgery, when combined with the new regulations regarding the use of lasers, may run afoul of the decision of the Supreme Court of the United States in North Carolina State Board of Dental Examiners v. Federal Trade Commission, (decided February 25, 2015) (finding that the North Carolina Board of Dental Examiners violated the Sherman Act when it excluded non-dentists from the teeth whitening business in North Carolina. The Supreme Court found that this was an antitrust violation).

The decision in North Carolina State Board of Dental Examiners v. Federal Trade Commission will be the subject of a forthcoming newsletter article.

B. The main additions included in the Proposed Regulations

The Proposed Regulations include a number of additions that appear to have four main purposes:

1. Providing for the practice of medicine by visiting physicians;
2. Providing for limited medical registration to allow interns, residents or fellows to practice without obtaining full licensure in Rhode Island;
3. Providing for limited registration of academic faculty; and
4. The regulation of laser services.

Each will be addressed in turn.

1. Visiting Physicians

A Visiting Physician is a physician who is licensed in a state, other than Rhode Island, who wishes to practice in Rhode Island. Such practice is permitted in a limited number of circumstances:

- If the physician is employed by the Federal Government;
- If the physician is in Rhode Island as a member of an air ambulance team;
- If the physician is being consulted by a physician licensed in Rhode Island or if the physician is providing teaching assistance he or she may practice for a period of not more than seven days;[3]

[3] This provision explicitly precludes the practice of telemedicine absent the supervision of a Rhode Island physician:

The physician, whether or not physically present in Rhode Island, is being

- The physician is present as a volunteer and will only be serving in a non-compensated role with a charitable organization. Said physician may not practice for more than seven days; and
- The physician is present to provide services to a sports team. Said physician must be contracted with the team and cannot provide care for more than seven days.

Proposed Regulations, pages 4-5. The seven day limits imposed by the Proposed Regulations may be extended to thirty days if a physician licensed in Rhode Island requests the extension and shows good cause for the extension. Proposed Regulations, page 5.

2. <u>Limited Medical Registration for interns, residents and fellows</u>

If the Proposed Regulations are accepted, Limited Medical Registration (LMR) will be made available to interns, residents and fellows at approved locations. Proposed Regulations, page 6. The LMR will allow the intern, resident or fellow to practice at the institution designated on the registration. Proposed Regulations, page 6. LMRs will be valid for one year and can be renewed for four consecutive years. Proposed Regulations, page 16.[4] To qualify for an LMR a physician must:

> consulted on a singular occasion by a physician licensed in Rhode Island, or is providing teaching assistance in a medical capacity, for a period not to exceed seven (7) days. **Under no circumstance may a physician who is not present in Rhode Island provide consultation to a patient in Rhode Island who does not have a physician patient relationship with that physician unless that patient is in the physical presence of a physician licensed in Rhode Island.**

Proposed Regulations, page 5 (emphasis added).

[4] There is an exception for physicians who remain in a training program from more than five years.

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- Be over 18;
- Be of good moral character;
- Have graduated from a legally chartered medical school;
- Be appointed as an intern, resident or fellow in a an accredited training program;
- Pay an application fee; and
- Have his/her application signed by the administrator or chief executive officer of the hospital, clinic or other institution where he/she has been appointed as intern, resident or fellow.

Proposed Regulations, pages 11-12.

3. Academic Faculty

The Proposed Regulations also provide for limited registration of "Academic Faculty," a physician "of noteworthy and recognized professional attainment who is clearly an outstanding physician" who has been offered an academic appointment at a Rhode Island medical school. Proposed Regulations, page 10. The registration as academic faculty will allow the physician to practice medicine to the "extent that such practice is incidental to a necessary part of his or her academic appointment." Proposed Regulations, page 10. A physician registered as academic faculty may practice only in hospitals, clinics or other institutions affiliated with the medical school. Proposed Regulations, page 10. Outside of these parameters, academic faculty are not permitted to practice medicine or receive compensation for their practice unless they obtain a full license.

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4. **<u>Regulation of the use of lasers</u>**

The final addition in the Proposed Regulations relates to the use of lasers. In a series of detailed and lengthy provisions, the Department of Health has provided for extensive regulation of the use of lasers. Included within these regulations are provisions regarding: a requirement that physicians register their use of lasers with the Department of Health; the responsibilities that physicians can delegate to physician extenders; the required level of supervision for physician extenders in different circumstances; the need for written protocols; educational requirements; and requirements for quality assurance. These additions can be found from pages 22 through 26 of the Proposed Regulations. Rather than canvassing all of the proposed changes, this section of the bulletin focuses on two of the more important provisions: (1) the provisions relating to delegation; and (2) supervision.

The Proposed Regulations provide that a physician may not delegate the use of lasers/pulsed light devices to anyone where the procedure in question would be deemed to be ablative. Proposed Regulations, page 22. The term ablative is not defined in the regulations. Other, non-ablative, procedures can be delegated to Level 1 and Level 2 delegates in certain circumstances as long as the delegate is properly trained, there are written protocols in place, and the physician provides "on-site supervision." Proposed Regulations, page 23. The physician must always examine the patient, establish a treatment plan, and sign the patient's chart prior to any non-ablative treatment by a delegate.

Pursuant to the Proposed Regulations, supervision of a delegate by a physician "shall be deemed adequate" if the physician:

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1. Ensures that the patient has been adequately informed about the procedure (including an outline of reasonably foreseeable side-effects or risks) and has given consent;
2. Is responsible for the formulation or approval of written protocols and is responsible for patient specific deviations from the protocol;[5]
3. Reviews and signs the written protocol annually;
4. Evaluates the skill of the delegate at least quarterly, including documentation of the delegate's ability to operate the devices safely and respond to complications appropriately.

Proposed Regulations, pages 23-24.

The proposed regulations relating to laser treatment are relatively detailed and will require significant effort on the part of physicians.

Overall, the Proposed Regulations contain a number of extensive and significant additions. These potential additions are worthy of careful consideration.

[5] Written protocols must include:

- A statement identifying the individual physician authorized to utilize the specified device and responsible for the delegation of the performance of the specified procedure;
- A statement of the activities, decision criteria, and plan the delegate shall follow when performing delegated procedures;
- Selection criteria to screen patients for the appropriateness of non-ablative treatments;
- Identification of devices and settings to be used for patients who meet selection criteria;
- Methods by which the specified device is to be operated;
- A description of appropriate care and follow-up for common complications, serious injury, or emergencies as a result of the non-ablative treatment; and
- Documentation of decisions made and a plan for communication or feedback to the authorizing physician concerning specific decisions made.

Proposed Regulations, page 24.

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