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New rules define expectations for skin spas, medical directors

DES MOINES – The Iowa Board of Medicine has increased the protection for consumers who use medical spas for treatment of skin conditions, Botox injections and tattoo removal.

New administrative rules, which became effective October 27, require medical spas that offer medical aesthetic services to use a licensed physician to perform or oversee these services. The physician can delegate these services, but they must be performed by a qualified licensed or certified non-physician professional, and then only under the physician's supervision.

The rules, adopted by the Board last summer, establish practice standards for physicians who assume the role of, or hold themselves out as, medical director or medical advisor for a medical spa. The Board developed the rules in response to consumer complaints of inappropriate treatment at spas, and reports about spas that were marketed as having a physician on staff, but the physician was never present.

Siroos Shirazi, M.D., chairman of the Board of Medicine, said the new rules establish accountability for the physician who serves as a medical director, who can now face disciplinary action, including license suspension or revocation and a civil penalty of up to \$10,000, for improper delegation and supervision.

“The medical director is responsible for implementing policies and procedures to ensure quality patient care and for the delegation and supervision of medical aesthetic services to qualified licensed or certified non-physician personnel at the spas,” Shirazi said.

He noted the rules are not intended to apply to physicians who serve as medical directors of licensed medical facilities, clinics or practices that provide medical aesthetic services as part of or incident to their other medical services.

The new rules, which culminate nearly two years of work by the Board and in collaboration with the Iowa Board of Cosmetology Arts and Sciences, apply to all medical spas in Iowa and do not include an exception for any existing medical spa.

The new rules are in Iowa Administrative Code 653 Chapters 13 (Standards of Practice and Principles of Medical Ethics) and Chapter 23 (Grounds for Discipline). The following is text of the new rules:

653—13.8(148,272C) Standards of practice—medical directors at medical spas—delegation and supervision of medical aesthetic services performed by qualified licensed or certified nonphysician persons. This rule establishes standards of practice for a physician or surgeon or osteopathic physician or surgeon who serves as a medical director at a medical spa.

13.8(1) Definitions. As used in this rule:

“*Alter*” means to change the cellular structure of living tissue.

“*Capable of*” means any means, method, device or instrument which, if used as intended or otherwise to its greatest strength, has the potential to alter or damage living tissue below the superficial epidermal cells.

“*Damage*” means to cause a harmful change in the cellular structure of living tissue.

“*Delegate*” means to entrust or transfer the performance of a medical aesthetic service to qualified licensed or certified nonphysician persons.

“*Medical aesthetic service*” means the diagnosis, treatment, or correction of human conditions, ailments, diseases, injuries, or infirmities of the skin, hair, nails and mucous membranes by any means, methods, devices, or instruments including the use of a biological or synthetic material, chemical application, mechanical device, or displaced energy form of any kind if it alters or damages or is capable of altering or damaging living tissue below the superficial epidermal cells, with the exception of hair removal. Medical aesthetic service includes, but is not limited to, the following services: ablative laser therapy; vaporizing laser therapy; nonsuperficial light device therapy; injectables; tissue alteration services; nonsuperficial light-emitting diode therapy; nonsuperficial intense pulse light therapy; nonsuperficial radiofrequency therapy; nonsuperficial ultrasonic therapy; nonsuperficial exfoliation; nonsuperficial microdermabrasion; nonsuperficial dermaplane exfoliation; nonsuperficial lymphatic drainage; Botox injections; collagen injections; and tattoo removal.

“*Medical director*” means a physician who assumes the role of, or holds oneself out as, medical director or a physician who serves as a medical advisor for a medical spa. The medical director is responsible for implementing policies and procedures to ensure quality patient care and for the delegation and supervision of medical aesthetic services to qualified licensed or certified nonphysician persons.

“*Medical spa*” means any entity, however organized, which is advertised, announced, established, or maintained for the purpose of providing medical aesthetic services. Medical spa shall not include a dermatology practice which is wholly owned and controlled by one or more Iowa-licensed physicians if at least one of the owners is actively practicing at each location.

“*Nonsuperficial*” means that the therapy alters or damages or is capable of altering or damaging living tissue below the superficial epidermal cells.

“Qualified licensed or certified nonphysician person” means any person who is not licensed to practice medicine and surgery or osteopathic medicine and surgery but who is licensed or certified by another licensing board in Iowa and qualified to perform medical aesthetic services under the supervision of a qualified physician.

“Supervision” means the oversight of qualified licensed or certified nonphysician persons who perform medical aesthetic services delegated by a medical director.

13.8(2) Practice of medicine. The performance of medical aesthetic services is the practice of medicine. A medical aesthetic service shall only be performed by qualified licensed or certified nonphysician persons if the service has been delegated by the medical director who is responsible for supervision of the services performed. A medical director shall not delegate medical aesthetic services to nonphysician persons who are not appropriately licensed or certified in Iowa.

13.8(3) Medical director. A physician who serves as medical director at a medical spa shall:

- a. Hold an active unrestricted Iowa medical license to supervise each delegated medical aesthetic service;
- b. Possess the appropriate education, training, experience and competence to safely supervise each delegated medical aesthetic service;
- c. Retain responsibility for the supervision of each medical aesthetic service performed by qualified licensed or certified nonphysician persons;
- d. Ensure that advertising activities do not include false, misleading, or deceptive representations; and
- e. Be clearly identified as the medical director in all advertising activities, Internet Web sites and signage related to the medical spa.

13.8(4) Delegated medical aesthetic service. When a medical director delegates a medical aesthetic service to qualified licensed or certified nonphysician persons, the service shall be:

- a. Within the medical director’s scope of practice and medical competence to supervise;
- b. Of the type that a reasonable and prudent physician would conclude is within the scope of sound medical judgment to delegate; and
- c. A routine and technical service, the performance of which does not require the skill of a licensed physician.

13.8(5) Supervision. A medical director who delegates performance of a medical aesthetic service to qualified licensed or certified nonphysician persons is responsible for providing appropriate supervision. The medical director shall:

- a. Ensure that all licensed or certified nonphysician persons are qualified and competent to safely perform each medical aesthetic service by personally assessing the person’s education, training, experience and ability;
- b. Ensure that a qualified licensed or certified nonphysician person does not perform any medical

aesthetic services which are beyond the scope of that person's license or certification unless the person is supervised by a qualified supervising physician;

c. Ensure that all qualified licensed or certified nonphysician persons receive direct, in-person, on-site supervision from the medical director or other qualified licensed physician at least four hours each week and that the regular supervision is documented;

d. Provide on-site review of medical aesthetic services performed by qualified licensed or certified nonphysician persons each week and review at least 10 percent of patient charts for medical aesthetic services performed by qualified licensed or certified nonphysician persons;

e. Be physically located, at all times, within 60 miles of the location where qualified licensed or certified nonphysician persons perform medical aesthetic services;

f. Be available, in person or electronically, at all times, to consult with qualified licensed or certified nonphysician persons who perform medical aesthetic services, particularly in case of injury or an emergency;

g. Assess the legitimacy and safety of all equipment or other technologies being used by qualified licensed or certified nonphysician persons who perform medical aesthetic services;

h. Develop and implement protocols for responding to emergencies or other injuries suffered by persons receiving medical aesthetic services performed by qualified licensed or certified nonphysician persons;

i. Ensure that all qualified licensed or certified nonphysician persons maintain accurate and timely medical records for the medical aesthetic services they perform;

j. Ensure that each patient provides appropriate informed consent for medical aesthetic services performed by the medical director or other qualified licensed physician and all qualified licensed or certified nonphysician persons and that such informed consent is timely documented in the patient's medical record;

k. Ensure that the identity and licensure and certification of the medical director, other qualified licensed physicians and all licensed or certified nonphysician persons are visibly displayed at each medical spa and provided in writing to each patient receiving medical aesthetic services at a medical spa; and

l. Ensure that the board receives written verification of the education and training of all qualified licensed or certified nonphysician persons who perform medical aesthetic services at a medical spa, within 14 days of a request by the board.

13.8(6) Exceptions. This rule is not intended to apply to physicians who serve as medical directors of licensed medical facilities, clinics or practices that provide medical aesthetic services as part of or incident to their other medical services.

13.8(7) Physician assistants. Nothing in these rules shall be interpreted to contradict or supersede the rules established in 645—Chapters 326 and 327.

653 –23.1 (148, 272X) Grounds for discipline – Improper delegation and supervision with regard to rule 653—13.8 (148, 272C)

23.1(43) Violation of the standards of practice for medical directors who delegate and supervise medical aesthetic services performed by nonphysician persons at a medical spa as set out at rule 653—13.8(148,272C).

23.1(44) Failure to provide the board, within 14 days of a request by the board as set out at 653—paragraph 13.8(5) “l,” written verification of the education and training of all nonphysician persons who perform medical aesthetic services at a medical spa.

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