

MEDICINE BOARD[653]

Notice of Intended Action

**Proposing rule making related to standards of practice for medical directors for medical spas
and providing an opportunity for public comment**

The Board of Medicine hereby proposes to amend Chapter 13, “Standards of Practice and Principles of Medical Ethics,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 147.76.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapters 148 and 272C.

Purpose and Summary

This rule making amends rule 653—13.8(148,272C), which establishes the minimum requirements for a physician who serves as a medical director at a medical spa.

Fiscal Impact

This rule making will likely increase the pool of potential providers at medical spas and increase access to medical aesthetic services provided at medical spas. It will likely have a positive fiscal impact, which is difficult to measure at this time.

Jobs Impact

This rule making will likely increase the pool of potential providers at medical spas and increase access to medical aesthetic services provided at medical spas. It will likely have a positive jobs impact, which is difficult to measure at this time.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 653—Chapter 3.

Public Comment

Any interested person may submit written or oral comments concerning this proposed rule making. Written or oral comments in response to this rule making must be received by the Board no later than 4:30 p.m. on November 20, 2018. Comments should be directed to:

Kent Nebel
Iowa Board of Medicine
400 S.W. 8th Street, Suite C
Des Moines, Iowa 50309
Phone: 515.281.7088
Fax: 515.242.5908
Email: kent.nebel@iowa.gov

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 20, 2018
10 a.m.

Board Office, Suite C
400 S.W. 8th Street
Des Moines, Iowa

Persons who wish to make oral comments at the public hearing may be asked to state their names for the record and to confine their remarks to the subject of this proposed rule making.

Any persons who intend to attend the public hearing and have special requirements, such as those related to hearing or mobility impairments, should contact the Board and advise of specific needs.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Amend rule 653—13.8(148,272C) as follows:

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 or qualified laser technicians. 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 or qualified laser technicians.

“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; collagen induction therapy (microneedling); fat-freezing treatment (cool sculpting); 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~~ at 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 performed by~~ performed by qualified licensed or certified nonphysician persons or qualified laser technicians at a medical spa. The medical director is ultimately responsible

for all medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians at a medical spa.

“*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 laser technician*” means any person, licensed or unlicensed, who has successfully completed a minimum of 120 hours of training, including a minimum of 40 hours of didactic study and 80 hours of clinical training, in the safe and effective use of lasers in the performance of medical aesthetic services at an accredited laser training program. For the purposes of this rule, a qualified laser technician may only use lasers in the performance of delegated medical aesthetic services under the supervision of a qualified supervising physician at a medical spa. An unlicensed qualified laser technician may not perform any other medical aesthetic services defined in this rule.

“*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 health- or skin care-related licensing board in Iowa and is qualified to perform delegated medical aesthetic services under the supervision of a qualified supervising physician at a medical spa.

“*Supervision*” means the oversight of qualified licensed or certified nonphysician persons or qualified laser technicians 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 or qualified laser technicians if the service has been delegated by ~~the~~ a medical director who is responsible for supervision of the services performed at a medical spa in Iowa. ~~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 or qualified laser technicians;
- 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 websites 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 or qualified laser technicians, 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 or qualified laser technicians is responsible for providing appropriate supervision. The medical director shall:

- a. Ensure that all licensed or certified nonphysician persons or qualified laser technicians are qualified and competent to safely perform each delegated 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 or qualified laser technicians 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 or qualified laser technicians each week and review at least 10 percent of patient charts for medical aesthetic services performed by qualified licensed or certified nonphysician persons or qualified laser technicians;

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

f. Be available, in person or electronically, at all times, to consult with qualified licensed or certified nonphysician persons or qualified laser technicians who perform delegated 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 or qualified laser technicians who perform delegated medical aesthetic services;

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

i. Ensure that all qualified licensed or certified nonphysician persons or qualified laser technicians maintain accurate and timely medical records for the delegated 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 or qualified laser technicians 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 qualified licensed or certified nonphysician persons or qualified laser technicians are visibly displayed at each medical spa where they perform medical aesthetic services 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 or qualified laser technicians who perform delegated medical aesthetic services at a medical spa, within 14 days of a request by the board.

13.8(6) *Continuing medical education.* All medical directors, qualified licensed or certified nonphysician persons and qualified laser technicians who practice at a medical spa in Iowa shall complete a minimum of 20 hours of continuing medical education in the safe and effective performance of medical aesthetic services each year.

~~13.8(6)~~ **13.8(7)** *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)~~ **13.8(8)** *Physician assistants.* Nothing in ~~these rules~~ this rule shall be interpreted to contradict or supersede the rules established in 645—Chapters 326 and 327.