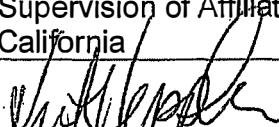




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MEMORANDUM

DATE	April 20, 2011
TO	Members, Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals; Medical Board of California
FROM	 Kurt Heppler, Senior Staff Counsel Division of Legal Affairs
SUBJECT	Definitions; Medical Spa and Medi-Spa

Members, at a recent meeting of the Medical Board of California's (Board) Advisory Committee on Physician Responsibility in the Supervision of Affiliated Health Care Professionals (Committee), an inquiry was made regarding the definition of a 'medical spa' or a 'medi-spa' and if other licensing jurisdictions had adopted or enacted such definitions.

To address this inquiry, Board staff placed a query on the Federation of State Medical Board's Internet site. The following are the results of that query.

1. Limited Responses. Only eight states (Arkansas, Iowa, Oklahoma, Maine, Mississippi, New Mexico, Virginia, and West Virginia) responded to the Board's inquiry.
2. Statutes and Regulations. Of the eight responses, West Virginia amended its definition of surgery to include the use of lasers, ionizing radiation, and pulsed light and radiofrequency devices on humans. Iowa has adopted the attached regulation relating to medical spas, and Oklahoma has adopted guidelines on the same issue (attached). The rest of the responding states have not tackled this task.

Staff hopes the information is useful to the Committee.

Attachments

IOWA ADMINISTRATIVE RULE

653—13.8(148,272C)

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

474 FILED IAB 9/22/10

MEDICINE BOARD[653](cont'd)

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.

IAB 9/22/10 FILED 475

MEDICINE BOARD[653](cont'd)

ITEM 2. Adopt the following new subrules 23.1(43) and 23.1(44):

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)“1,” written verification of the education and training of all nonphysician persons who perform medical aesthetic services at a medical spa.

[Filed 8/25/10, effective 10/27/10]

Oklahoma State Board of Medical Licensure and Supervision

Policy and Guidelines for Medical Spas & Aesthetic Procedures

Definitions (Oklahoma Law & Rules)

Practice of Medicine

Every person shall be regarded as practicing allopathic medicine within the meaning and provisions of this act, who shall append to his or her name the letters "M.D.", "Physician" or any other title, letters or designation which represent that such person is a physician, or who shall for a fee or any form of compensation diagnose and/or treat disease, injury or deformity of persons in this state by any allopathic legend drugs, surgery, manual, or mechanical treatment unless otherwise authorized by law.

Doctor/Patient Relationship

Means a person has a medical complaint/issue, which has been addressed by the doctor and there is a correlation between the complaint/issue and the treatment/procedure performed or drug given/prescribed/dispensed.

Surgery

The ablation or alteration of any human tissue by any means including but not limited to the use of sharp surgery, heat, cold, abrasion, laser, chemicals, injection/placement of substances subcutaneous, or the use of FDA approved devices *that can only be initially purchased by physicians* is the practice of medicine as defined in Title 59 O.S. Section 492. Lasers are instruments of surgery. No matter what type of laser is being utilized, a physician involved in the process should following these guidelines.

GUIDELINES

The practice of medicine and surgery as defined above is grounded upon the **doctor/patient relationship** which at a minimum requires a **face-to-face evaluation of the patient** by the physician or a physician assistant under a physician's supervision, prior to the determined treatment or procedure, development of a patient chart, providing patient informed consent and the process for the patient's follow up care.

There are several important guidelines to follow when supervising other practitioners.

- If the physician is utilizing unlicensed, trained assistants under their control and supervision, the physician must be on-site (premise) before, during and after the medical treatment or procedure.
- If the physician is utilizing an Oklahoma licensed physician assistant (PA), the physician can delegate any of the defined medical services to that licensed PA under general supervision, which does not require the physician to necessarily be on-site.

- If the physician is utilizing an Oklahoma licensed nurse, [RN, LPN, APN (advance practice nurse) or APN with prescriptive authority] and **IF** they are functioning within the scope of their practice act, then the physician may delegate any of the defined medical services to that licensed nurse under general supervision, which may not require the physician to be on-site. It is imperative that the physician contact the Oklahoma Board of Nursing (405-962-1800) to find out the nurse's scope of practice and level of physician supervision required.
- If the physician is utilizing any other Oklahoma recognized practitioner such as a certified micropigmentologist or licensed aesthetist, the physician must contact the Oklahoma Department of Health (405-271-6576) or the Board of Cosmetology (405-521-2441) respectively and find out the scope of their practice act and level of medical supervision required.
- In no instance may a physician allow one of the aforementioned practitioners to further delegate the medical service to another practitioner.
- Physicians who are medical directors for one or multiple medical spa and aesthetic facilities are subject to these guidelines.

When in doubt of a specific medical procedure/treatment and the corresponding level of supervision, the physician should contact the Oklahoma Board of Medical Licensure and Supervision or appropriate regulatory agency before potentially placing their medical license in jeopardy.

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Approved 11/7/08