.01 Scope (Notes\textsuperscript{1,2})

A. This (Act/regulation) establishes standards of practice for the performance, delegation, assignment, and supervision of medical and surgical procedures performed by a medical director or under a supervising physician's direction at a medical spa facility.

B. This (Act/regulation) is not intended to apply to licensed medical facilities, clinics or practices that provide medical aesthetic services as part of or incident to their other medical services.

C. This (Act/regulation) does not govern the practice of cosmetology, electrology, or other professions, which may take place alone or in a medical spa facility, as defined in (state statutes) and regulated by other respective licensing boards.

.02 Definitions

“Medical Aesthetic Services” means the treatment of the skin, hair, nails and mucous membranes for the purpose of altering one’s appearance, by any means, methods, devices, or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue. Medical aesthetic services constitute the practice of medicine and surgery and include but are not limited to the use of: scalpels; all lasers (Note\textsuperscript{3}) and light sources, microwave energy, electrical impulses, and all other energy emitting devices; thermal destruction; chemical application; particle sanding; and other foreign or natural substances by injection or insertion.

“Medical Director” means a licensed physician who directs a medical spa facility, as described by this Act/regulation or a licensed physician who serves as the medical advisor for a medical spa facility.

\textsuperscript{1} This model statute is intended regulate medical aesthetic services performed outside a medical facility (e.g., the office of a licensed medical provider working pursuant to their scope of practice) and provide oversight of the medical spa industry.

\textsuperscript{2} This model statute shall apply to medical spa facilities meaning “any entity, however organized, in which the practice of medicine and surgery occurs for the purpose of improving an individual’s appearance.” This does not include the practice of medicine and surgery which occurs in a licensed physician’s office, a health care clinic, ambulatory surgery center, or hospital, regardless if the medicine and surgery performed is for the purpose of improving an individual’s appearance.

\textsuperscript{3} The definition of medical aesthetic services is not intended restrict the use of laser modalities used by licensed health care providers for the purpose of treating a health condition pursuant to the licensee’s scope of practice (e.g., the use of infra-red phototherapy as applied by arrays of super luminous diodes and low-level lasers by chiropractors or physical therapists).
“Medical Spa Facility” means any entity, however organized, in which the practice of medicine and surgery occurs for the purpose of improving an individual’s appearance.

"Non-Physician" means an individual who is not a licensed physician in (state) and who meets the requirements of this Act/regulation.

"On-site Supervision" means oversight exercised by a supervising physician who is both present at the site and able to respond immediately, in-person during a delegated or assigned medical aesthetic service.

“Supervising Physician” means an individual licensed and in good standing in accordance with (state statute), who is responsible for overseeing services provided by a non-physician.

.03 Practice of Medicine

The performance of medical aesthetic services is the practice of medicine and surgery. A medical aesthetic service shall be performed only by a qualified licensed or certified non-physician if the service has been delegated by a medical director or supervising physician who is responsible for on-site supervision of the services performed.

.04 Medical Director & Supervising Physician Qualifications

A. A medical director and all other supervising physicians shall obtain a license to practice medicine in (state) before a medical director or supervising physician may perform, delegate, assign, or supervise medical aesthetic services in a medical spa facility.

B. Education.

1. A medical director and all supervising physicians who perform, assign, supervise, or delegate the performance of medical aesthetic services by a qualified and licensed non-physician must first be trained, as defined by (state entity), in the indications for, and performance of, medical aesthetic services, including use of medical devices or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue.

2. Training programs provided by a manufacturer or vendor of a medical devices or supplies may not be a medical director’s or supervising physician’s only education in the medical aesthetic service or the operation medical devices to be used.
3. ACCME or AOA-approved continuing education, or completion of an ACGME or AOA-accredited postgraduate program, which includes training in the medical aesthetic service to be performed, satisfies this requirement.

.05 Delegation of Medical Aesthetic Services

A. A medical aesthetic service may be delegated by a medical director or supervising physician to a qualified and licensed non-physician who has obtained the highest level of training, as described herein, and who meets all the requirements of (this Act/regulation).

B. A medical director or supervising physician may not permit a non-physician to perform delegated medical aesthetic services unless the individual has received:
   1. Training as described in (this Act/regulation);
   2. Any additional requirements prescribed by that individual's licensing board; and
   3. The non-physician's services are supervised on-site by the medical director or a supervising physician.

.06 Physician Responsibilities

A. A medical director shall:
   1) Perform all responsibilities of a supervising physician unless the medical director assigns supervision of medical aesthetic services to a licensed and qualified physician in his/her absence from a medical spa facility;
   2) Be clearly identified, including board certification (if applicable), as the medical director in all marketing materials and Internet Web sites, and all other forms of communication, related to the medical spa facility;
   3) Ensure that all marketing materials of a medical spa facility do not include false, misleading, or deceptive representations regarding the training, qualifications, licensure, and board certification (if applicable) of all medical spa facility personnel and the nature or quality of services provided by the facility or its staff;
   4) Retain ultimate responsibility for all acts personally delegated or delegated by an assigned supervising physician to a non-physician in a medical spa facility;
   5) Develop and maintain written office protocols for each service performed in the medical spa facility;
6) Establish protocols to be followed if a patient requires emergency services. This should include procedures for emergency transport such as maintaining in a readily accessible manner and location, the name and telephone numbers of the ambulance service if one is to be utilized and the hospital to which the patient is to be transported, and the functions to be undertaken until the transfer of the patient is completed;

7) Establish procedures to be followed in the event that a medical aesthetic service needs to be terminated because of an equipment malfunction or other complication; and

8) Complete the education and training requirements set forth in this Act/regulation.

B. A supervising physician shall:

1) Personally perform an initial assessment of each patient;

2) Prepare a written treatment plan for each patient, including diagnosis and planned course of treatment, personnel performing the service(s) and specification of the device and device settings to be used;

3) Obtain informed consent of the patient to be treated by a physician or non-physician;

4) Provide on-site supervision whenever a non-physician is performing a delegated medical aesthetic service;

5) Create and maintain medical records in a manner consistent with accepted medical practice and in compliance with federal and (state statutes);

6) Review and sign all patient charts within seven business days following performance of a medical aesthetic service; and

7) Complete the education and training requirements set forth in this Act/regulation.

.07 Non-Physician's Responsibilities

A. Non-physicians must comply with all provisions of this Act/regulation.
B. A non-physician may not use an aesthetic medical device or perform a medical aesthetic service unless the individual has received:
   1) The training described in *(this Act/regulation)*;
   2) Any additional training or certification required by that non-physician's licensing board; and
   3) Receives on-site supervision from the medical director or supervising physician for all services provided at the medical spa facility.

C. A non-physician shall:
   1) Review and follow written protocols for each delegated medical aesthetic service;
   2) Verify that the medical director or supervising physician has assessed the patient and given written treatment instructions for services to be performed;
   3) Review the medical aesthetic services to be performed with the patient to ensure that the patient:
      a) Is aware that the treatment will be provided by a non-physician;
      b) Understands that the patient may, upon request, receive treatment by a physician instead of a non-physician; and
      c) Has given consent in writing to treatment by a non-physician.
   4) Notify the medical director and supervising physician about any adverse events or complications before the patient leaves the medical spa facility;
   5) Document all relevant details of the medical aesthetic service in the patient's chart, including any adverse events and complications; and
   6) Satisfy any requirements imposed by the licensing board of the non-physician.

.08 Qualifications, Training & Education

A. Any licensed physician or non-physician employed by a medical spa facility, including a medical director, must have received appropriate documented
training and education in the safe and effective performance of all medical aesthetic services performed in the medical spa facility.

B. The medical director shall be responsible for assuring that any individual to whom the medical director or supervising physician delegates or assigns the performance of a medical aesthetic service is properly trained. Training shall include both theoretical instruction and clinical instruction pursuant to this (Act/regulation).

C. Theoretical instruction shall include:
   1) Aesthetic and medical indications and contraindications for each service;
   2) Identification of realistic and expected outcomes of each service;
   3) Selection, maintenance, and utilization of products and equipment;
   4) Appropriate technique for each service, including infection control and safety precautions;
   5) Pharmacological intervention specific to each service;
   6) Identification of complications and adverse reactions for each service;
   7) Emergency procedures to be used in the event of:
      a) Complications;
      b) Adverse reactions;
      c) Equipment malfunction; or
      d) Any other interruption of a service; and
   8) Appropriate documentation of the procedure in each patient's chart.

D. Clinical instruction shall include:
   1) Observation by a medical director or supervising physician of performance of the service and use of any medical product or device; and
   2) Performing the service and using the medical product or device under the direct, personal supervision of a medical director or supervising physician who is present and observing the service a sufficient number of times to assure that the non-physician is competent to perform the service.
E. Training and education of all licensed physicians and non-physicians in the medical spa, including the medical director, shall be documented and readily available for review. Proficiency in the performance of all medical aesthetic services and use of any medical products or devices provided in a medical spa facility shall be assessed and documented on a regular basis by the medical director.

F. The credentials, education and training received, and proficiency evaluations of all medical spa facility personnel shall be readily presented and available in writing to all patients.

.09 Adverse Events

A. Any incident within the medical spa facility that results in a patient death, transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, or a significant complication or adverse event requiring additional medical treatment, shall be reported to the (state entity) within seven days, in writing and on such forms as shall be required by (state entity). Such reports shall be investigated by (state entity). Any adverse events involving the use of US Food and Drug Administration (FDA)-cleared or regulated devices shall be reported to the FDA in accordance with federal laws and regulations.

.10 Facility Licensure (Note⁴)

A. No individual, partnership, association, or corporation shall establish, conduct, operate or maintain in this state a medical spa facility, without having a license issued by (state entity).

B. An applicant shall submit an application on a form to be prepared by (state entity), showing that the applicant is of reputable and responsible character and able to comply with the standards for a medical spa facility and with rules and regulations lawfully promulgated under (this Act/regulation). The application shall contain the following information:

1) The name or names of the applicant or applicants;

2) The name of the medical spa facility to be operated;

3) The location of the medical spa facility;

⁴ This section was developed by reviewing licensure and enforcement requirements/language of varied state health care facility, ambulatory surgical center, and tanning facility regulations.
4) The name and physician license number of the medical spa director;

5) The name and physician license number of all supervising physicians;

6) A list of all medical devices used within the medical spa facility;

7) A list of all services to be performed within the medical spa facility;

8) A copy of all written office protocols for all services performed in the medical spa facility, as per the requirements of (this Act/regulation); and

9) A license fee as determined by (state entity).

C. An owner of a medical spa facility shall submit an application and obtain a separate license for each medical spa facility to be operated.

D. (State entity) shall promulgate additional licensure requirements that define appropriate health and safety standards necessary to protect the health and welfare of patients in a medical spa facility. Specific elements to be addressed include, but are not limited to:

1) Facility and building standards;

2) Sanitation;

3) Hazardous waste disposal; and

4) Emergency preparedness.

E. (State entity) shall maintain current information on all licensed medical spa facilities. The information shall include:

1) Name, location and mailing address of the medical spa facility;

2) Description of the medical spa facility;

3) Date of last inspection;

4) Reported adverse events;

5) Penalties;

6) Suspensions; and

7) Other disciplinary actions.
F. If (state entity) determines that a license for any medical spa facility will not be granted, it shall so notify the applicant.

G. If (state entity) finds that the applicant complies with this part and the rules and regulations promulgated under this part, then the (state entity) shall approve the issuance of a license, and thereupon a license shall be issued by (state entity) licensing the applicant to operate the medical spa facility for a period of one year (Note5).

H. Each medical spa facility license shall expire one year (Note6) following the issue date and shall become invalid on that date unless renewed. A licensee shall renew its license in accordance with the rules established by (this Act/regulation). A license shall be renewed from year to year and shall not be assignable or transferable, shall be issued only for the premises named in the application, shall be posted in a conspicuous place in the facility and on any online or print marketing or communication materials of the facility.

11 Inspection

A. The (state entity) shall conduct random inspections of every licensed medical spa facility within the first six months of operation using an inspection report form approved by (state entity). Such inspections shall be repeated within a period of no less than two years and no more than four years, or in response to the filing of a complaint with (state entity).

B. For each inspection:
   1) A representative of (state entity) shall provide proper identification.
   2) The owner of a medical spa facility shall permit access to all parts of the facility and all pertinent employee records and facility protocols required for inspection.
   3) An inspection report shall identify in a narrative form any violations of (this Act/regulation) and shall be cross-referenced to the section of (the Act/regulation) being violated.
   4) Results of the inspection shall be made available to the public upon request.

12 Penalties

A. Any person who violates any provision of (this Act/regulation) or who shall refuse to comply with a lawful order or directive of (state entity), shall be liable for

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5 The AADA wrote this model statute and used a period of one year as the term for licensure of medical spa facilities. Each state may determine there is a longer time period which would be appropriate for licensure of these facilities in comparison to other such permits (e.g., beauty salons).

6 See previous Note.
monetary penalties of \((amount\ determined\ by\ state\ entity)\) and not to exceed \((amount\ determined\ by\ state\ entity)\), and all other applicable law and/or injunctive action as provided by law, or both.

B. The \((state\ entity)\) may revoke, suspend or deny renewal of a license(s) to operate a medical spa facility for failure to comply with any provision of \((this\ Act/\ regulation)\).

C. The \((state\ entity)\) may revoke, suspend, or take other disciplinary action against the medical license of any medical director or supervising physicians found to be in violation of the requirements of \((this\ Act/\ regulation)\).