



Protecting Patient Safety & Ensuring Quality Care: State Regulation of Medical Spa Facilities

Frequently Asked Questions

The global market for medical aesthetic procedures is growing and is forecast to reach approximately \$4 billion in 2017. According to the American Society of Plastic Surgeons (ASPS), 11.6 million minimally invasive procedures were performed in 2010. The top five minimally-invasive procedures include the use of botulinum toxins (5.4 million); soft tissue fillers (1.8 million); chemical peels (1.1 million); laser hair removal (938,000); and microdermabrasion (825,000).

As the demand for services expands, so does the need for appropriate oversight. The American Academy of Dermatology Association (AADA) has developed a position statement and model statute to aid members, state dermatology societies, state medical societies, state medical boards, and policymakers in regulating medical spa facilities and protecting patient safety.

Why are regulations needed?

Medical spas are facilities that offer a range of services, including medical and surgical procedures, for the purpose of improving an individual's well-being and/or appearance. Most existing state laws do not explicitly recognize medical aesthetic services as the practice of medicine and surgery.

In these settings, medical aesthetic services are provided by physicians, as well as non-physicians. These providers often have limited or no formal training or education in aesthetic medicine and may be operating with limited or no supervision by a licensed and qualified physician. As such, patient safety and quality of care can be jeopardized.

What are the key elements of these regulations?

Standards of practice for the performance of medical aesthetic services in a medical spa facility are crucial to protect patient safety and ensure quality care. These standards include training and education requirements of both physicians and non-physicians performing services, written treatment plans and procedure protocols, and reporting of adverse events, in addition to facility licensure, inspection and state enforcement.

Is this an attempt to restrict the performance of medical aesthetic services?

No. Patient safety concerns necessitate appropriate regulation of medical spa facilities by establishing laws to govern the performance of medical aesthetic services in these facilities. Media reports from around the country continue to highlight adverse events, ranging from burns to patient death, as a result of a medical aesthetic services performed in non-traditional settings, such as medical spas, with limited to no supervision or formal training of the provider.

How will this affect existing state laws?

It is crucial to update existing state laws, if applicable, to account for a rise in demand for medical aesthetic services. In addition, many states do not explicitly recognize these types of procedures as the practice of medicine and surgery – which is paramount to protecting patient safety. The AADA’s model statute is intended to provide a full picture of necessary regulations to provide oversight of the medical spa industry and enact important patient safeguards. The model statute can be adapted to account for existing state laws – e.g., certification for laser hair removal practitioners.

Do any states currently regulate medical spa facilities?

Currently, only a few states address the performance of medical aesthetic services or medical spa facilities. Maryland has the most comprehensive regulations in place regarding the performance, delegation and supervision of medical aesthetic services (COMAR 10.32.09). Iowa currently has regulations addressing the role of the medical spa director (Iowa Code Chapter 13 and Chapter 23), while Colorado also has regulations governing the delegation and performance of medical aesthetic services (12-36-106(3)(I), C.R.S.). No state law or regulations currently address all components of the AADA’s model statute. Many states have laws governing the use of lasers and the corporate practice of medicine.

For more information, please contact the American Academy of Dermatology Association at 202-842-3555 or email Kathryn Chandra, Assistant Director of State Policy, at kchandra@aad.org.



Position Statement
on
Medical Spa Standards of Practice
(Approved by the Board of Directors: May 7, 2011)

This position statement establishes standards of practice for the performance, delegation, assignment, and supervision of medical and surgical procedures performed by a physician or non-physician under a physician's direction at a medical spa facility.

Medical spas are facilities that offer a range of services, including medical and surgical procedures, for the purpose of improving an individual's well-being and/or appearance. The distinguishing feature of medical spas is that medicine and surgery are practiced in a non-traditional setting.

Procedures by any means, methods, devices, or instruments that can alter or cause biologic change or damage the skin and subcutaneous tissue constitute the practice of medicine and surgery. These include but are not limited to the use of: scalpels; all lasers 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.

Any procedure that constitutes the practice of medicine, including but not limited to any procedure using a Food and Drug Administration (FDA)-cleared or regulated device that can alter or cause biologic change or damage, should be performed only by an appropriately-trained physician or appropriately-trained non-physician personnel under the direct, on-site supervision of an appropriately-trained physician in accordance with applicable local, state, or federal laws and regulations.

The optimal quality of medical aesthetic care is delivered when a qualified and licensed physician provides direct, on-site supervision to all qualified and licensed non-physician personnel. On-site supervision means a supervising physician that is both present at the site and is able to respond immediately, in-person, during a delegated or assigned medical aesthetic procedure. Each medical spa facility should maintain up-to-date written procedures regarding appropriate delegation and supervision protocols for all medical aesthetic procedures performed within the facility.

A medical director of a medical spa facility should be clearly identified by licensure, medical specialty, training and education, as the medical director in all marketing materials and Internet Web sites related to the medical spa facility. If marketing materials mention a physician's board-certification, the certifying board and specific specialty should be stated, e.g., Diplomate of the American Board of Medical Specialties (ABMS) in Dermatology. Furthermore, the medical director shall ensure that marketing and advertising materials of a medical spa facility do not include false, misleading, or deceptive representations.

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A medical director shall be ultimately responsible for all acts personally delegated or delegated by an assigned supervising physician to non-physician personnel in a medical spa facility. A medical director or supervising physician is responsible for performing an initial assessment of each patient in a medical spa facility, preparing a written treatment plan, obtaining informed consent from all patients including disclosure of personnel performing the procedure(s), creating and maintaining patient medical records in accordance with local, state and federal laws and regulations, and reviewing all patient charts. Any adverse events that occur as a result of the performance of a medical aesthetic service must be reported immediately to the facility's medical director and supervising physician.

Any physician or non-physician personnel who provide medical aesthetic care must be qualified to: 1) perform such services by virtue of having received appropriate theoretical and clinical instruction and training in each service to be performed including safety, clinical application, pre- and post-procedural care; and 2) handle any resultant emergencies or sequelae. 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 facility. Continuing medical education of all licensed medical professionals should be mandatory and repeated with reasonable frequency to help ensure maximal proficiency. This documented training and education must be readily available to the public and must include instruction in the use of all FDA-cleared or regulated products or devices used or provided by the medical spa facility.

Medical spa facilities should be licensed and inspected on a regular basis to ensure compliance with all applicable federal and state laws. Medical spa facilities must be able to prove they have the necessary personnel, equipment and protocols to safely perform all offered procedures and handle any emergencies or sequelae that may arise. Any incident within the medical spa facility that results in a patient death, transport of the patient to the hospital, or a significant complication or adverse event requiring additional medical treatment, shall be reported to the appropriate state agency, the FDA if cleared or regulated devices were involved, or both. Medical spa facilities, medical directors, and all non-physician personnel shall maintain appropriate liability insurance or communicate lack of insurance in advance to all patients.

Patient health and safety is paramount and should not be compromised in the interest of financial gain. Therefore, owners and employees of medical spa facilities who are not licensed to practice medicine shall not exercise control over an employed physician's medical judgment or engage in decisions related to patient care and/or the performance of medical aesthetic services.

This Position Statement is intended to offer guiding principles regarding the practice of medicine and surgery in medical spa facilities. This Position Statement is not intended to establish a legal standard of care.



American Academy of Dermatology Association

Model Legislation/Regulation on Medical Spa Standards of Practice

.01 Scope (Notes^{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 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 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 (Note³) 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.

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.

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.

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) 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

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.

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.

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.

.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 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)*.

State medical board regulation of minimally invasive cosmetic procedures

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Background: There is little information regarding commonalities, differences, and trends in the regulation of minimally invasive cosmetic procedures (MICP) across different state medical boards in the United States.

Objective: We sought to assess current state medical board regulations regarding MICP, so as to better understand current and emerging trends in rules regarding delegation, and management of patient complaints.

Methods: We conducted structured interviews with officials at US allopathic medical boards, supplemented with information from board World Wide Web sites.

Results: A total of 31 (62%) boards participated. Most (20 boards; 63% of total respondents) reported that all MICP can be delegated at the physician's discretion and responsibility to at least one category of nonphysician; 7 states were expecting changes in delegation rules; and 4 states had very specific delegation requirements. Approximately equal numbers of boards required some general supervision of nonphysicians (14, 45%), or required some type of on-site supervision (13, 42%); a small number explicitly permitted off-site supervision (4, 13%). There was variation in the number of physician assistants one physician could supervise. Most boards (15 states) required some type of mandatory reporting, but not necessarily of incidents involving MICP. Very few (4) required reporting of both office- and nonoffice-based MICP incidents. Western states had liberal delegation and supervision requirements; these requirements were more stringent in Southern states.

Limitations: Not all boards participated in this study.

Conclusion: There is substantial variation in board regulation of MICP. Many boards are promulgating new rules. Medical boards also have limited ability to regulate nonphysicians. (J Am Acad Dermatol 10.1016/j.jaad.2011.01.009.)

Key words: botulinum toxins; dermatology; formal; lasers; physician assistants; social control.

In the United States, regulation of medical treatment by nonphysician medical personnel resides principally at the level of allopathic state medical boards. The rising numbers of mid-level providers, such as physician assistants (PAs) and nurse practitioners, have increased the urgency of

the need for clear rules to define their scope of practice.¹⁻³

In the context of so-called minimally invasive cosmetic procedures (MICP), the issues are particularly opaque. MICP as defined include but are not limited to cutaneous laser (excluding full-face

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ablative resurfacing, but including fractional non-ablative and ablative resurfacing) and light procedures, radiofrequency and ultrasound procedures, injectable prepackaged soft-tissue augmentation materials, botulinum toxin injection, and superficial to mid-depth chemical peels. Because many of these treatments are not considered medically necessary and are not reimbursed by insurers and other third-party payers, state medical boards may be the sole oversight organization ensuring appropriate delegation and regulation.

Our purpose is to focus on state (allopathic) medical boards and: (1) describe some of the commonalities in current state laws and regulations that govern MICP; (2) highlight the vast areas of ambiguity and of difference across states; and (3) characterize some of the regional and national regulatory trends that are likely to motivate short- and medium-term changes in rules. To achieve our objectives, we examine present and pending state medical board rules pertaining to MICP.

METHODS

There were two data sources: (1) telephone interviews with officials at state medical boards; and (2) state medical board World Wide Web sites.

Telephone interviews

Interviews were during a period of 6 weeks from June 17 to July 29, 2008. Efforts were made to reach an official most able to comment on MICP regulation at each of the 50 state medical boards. If initial attempts were not successful because of staff unavailability, repeated attempts were made until contact was made or the 6-week period expired, whichever came first. If, despite repeated efforts, an appropriate person could not be reached via telephone, an e-mail or fax was sent requesting the necessary information. The telephone interviews were semistructured. Each state official was asked the same questions pertaining to delegation and supervision of MICP. Officials were asked whether a physician could delegate any MICP to a nonphysician, which nonphysicians could receive delegation,

which MICP could be delegated, and what type of physician supervision was required. Questions relating to patient complaints were also included. Finally, there was also an opportunity at the end of the interview for each state officer to share his or her thoughts regarding future trends in MICP regulation in his or her state.

CAPSULE SUMMARY

- There is wide variation across state medical boards regarding the rules for delegation and supervision of minimally invasive cosmetic procedures, such as cutaneous laser, and injectable neurotoxins and fillers. Differences include on-site versus off-site supervision; the types and numbers of nonphysician providers who can be supervised; the requirements for reporting adverse events; and the degree to which there are specific rules about cosmetic procedure regulation.
- Rules are in flux, with a large minority of states considering, planning, or currently implementing changes.
- State medical boards can only regulate physicians. They cannot directly regulate various types of nonphysician providers who provide cosmetic procedures.

State medical board World Wide Web sites

Relevant information about MICP regulation and delegation (ie, statutes, rules, regulations, policies, guidelines, and board opinions) was abstracted from each state medical board's World Wide Web site. Interview responses were taken to supersede other sources of information on pending rules and legislation. Complete results are displayed in [Table I](#).

RESULTS

Of the 50 state medical boards contacted, 31 (62%) were interviewed by telephone for a duration of 6 minutes to 36 minutes each (median of 21 minutes). Staff at 19 state boards did not complete interviews. The

reason was either persistent unavailability of the appropriate person or a decision by the board to decline to participate in the interview process.

Officers at most state boards that participated (20 boards and 63% of total respondents) reported that all MICP can be delegated at the physician's discretion and responsibility to at least one category of nonphysician professional, and that their state does not anticipate any changes to rules and regulations regarding this at the time of the survey. Seven state boards were expecting changes in rules, regulations, or governing legislation regarding which procedures may be delegatable. Specifically, changes to liberalize delegation to nonphysician providers (eg, making delegatable to nonphysicians a broader array of procedures, including some laser resurfacing and laser hair removal procedures, and additional injection procedures) had been approved but not yet implemented, were pending approval, or were likely to be promulgated soon. The remaining small subset of participant state medical boards (4) reported

Table I. Summary of medical board delegation rules (by state)

State	Participated in survey	MICP that can be delegated	Nonphysicians authorized to receive delegation	Required supervision of nonphysicians receiving delegation	Limits on No. of nonphysicians receiving delegation	Reporting requirements for adverse patient outcomes
Alabama	Y	2	2	2	6	1
Alaska	N	-	-	-	-	-
Arizona	N	-	-	-	-	-
Arkansas	N	-	-	-	-	-
California	Y	4	2	3	3	1
Colorado	N	-	-	-	-	-
Connecticut	Y	1	2	2	5	3
Delaware	N	-	-	-	-	-
Florida	Y	2	2	2	6	1
Georgia	Y	4	4	1	6	1
Hawaii	Y	1	2	1	6	3
Idaho	Y	1	2	3	2	4
Illinois	Y	4	4	2	6	1
Indiana	Y	3	1	1	1	3
Iowa	Y	3	3	1	6	2
Kansas	N	-	-	-	-	-
Kentucky	N	-	-	-	-	-
Louisiana	Y	1	1	2	1	2
Maine	Y	1	1	2	6	5
Maryland	Y	1	2	1	6	2
Massachusetts	Y	4	4	1	1	3
Michigan	Y	4	1	1	3	1
Minnesota	Y	3	1	1	6	4
Mississippi	Y	1	1	2	6	1
Missouri	N	-	-	-	-	-
Montana	N	-	-	-	-	-
Nebraska	Y	1	2	1	6	1
Nevada	N	-	-	-	-	-
New Hampshire	N	-	-	-	-	-
New Jersey	Y	2	2	3	6	1
New Mexico	N	-	-	-	-	-
New York	Y	1	2	1	6	3
North Carolina	N	-	-	-	-	-

Continued

Table I. Cont'd

State	Participated in survey	MICP that can be delegated	Nonphysicians authorized to receive delegation	Required supervision of nonphysicians receiving delegation	Limits on No. of nonphysicians receiving delegation	Reporting requirements for adverse patient outcomes
North Dakota	N	-	-	-	-	-
Ohio	Y	2	2	2	1	2
Oklahoma	Y	1	1	2	3	4
Oregon	Y	1	3	2	6	4
Pennsylvania	N	-	-	-	-	-
Rhode Island	Y	1	1	1	6	1
South Carolina	N	-	-	-	-	-
South Dakota	N	-	-	-	-	-
Tennessee	Y	1	1	2	6	1
Texas	Y	1	1	1	4	1
Utah	N	-	-	-	-	-
Vermont	N	-	-	-	-	-
Virginia	Y	3	1	1	6	6
Washington	Y	4	4	2	5	3
West Virginia	Y	4	4	2	4	1
Wisconsin	Y	3	1	1	6	1
Wyoming	Y	3	1	3	3	1
Key	Y = yes N = no	1 = All MICP can be delegated, to at least one nonphysician profession, at physician's discretion and responsibility; state does not anticipate any changes to rules and regulations regarding this at this time 2 = Very specific rules or regulations regarding delegation 3 = Not specifically addressed in state rules or regulations; at	1 = Anyone licensed or unlicensed that is qualified, appropriately trained, and properly supervised; at physician's discretion and physician is ultimately responsible 2 = Very specific rules or regulations regarding delegation 3 = Not specifically addressed in state rules or regulations; at physician's discretion and ultimately physician	1 = General or broad supervision OR not specifically addressed or defined; at physician's discretion 2 = Require some sort of on-site (on premises) supervision 3 = Supervision does not need to be on-site; can be off-site where physician does not have to be present in same building as delegated individual	1 = Can supervise up to 2 PAs at a time 2 = Can supervise up to 3 PAs at a time 3 = Can supervise >3 PAs at a time 4 = Have very specific supervision limits 5 = Either have no clear limits OR rules regarding limitation are in process of being drafted and not effective yet	1 = Require mandatory reporting under certain criteria but not necessarily or specifically of adverse events relating to MICP 2 = No 3 = Unsure 4 = Both office-based and nonoffice-based reporting required 5 = Only Nonoffice-based required to report

Continued

Table I. Cont'd

State	Participated in survey	MICP that can be delegated	Nonphysicians authorized to receive delegation	Required supervision of nonphysicians receiving delegation	Limits on No. of nonphysicians receiving delegation	Reporting requirements for adverse patient outcomes
		physician's discretion and ultimately physician is responsible for delegated procedure	is responsible for delegated procedure	when procedure is being performed	6 = Not specified/unclear OR did not answer	6 = Did not answer or could not be reached
		4 = Have passed rules/regulations that are not effective as of yet OR in process of regulating via currently proposed rules/regulations OR definitely expect to regulate this in near future	4 = Have passed rules/regulations that are not effective as of yet OR in process of regulating via currently proposed rules/regulations OR definitely expect to regulate this in near future			

MICP, Minimally invasive cosmetic procedure; PA, physician assistant.

having very specific rules or regulations pertaining to the types of procedures able to be delegated.

Regarding which classes of nonphysicians could receive delegation, approximately half of participating state medical boards (15 boards or 48%) had liberal rules that allowed any licensed or unlicensed practitioner who was qualified, appropriately trained, and properly supervised to receive delegation. Delegation was at the physician's discretion and with the physician ultimately responsible for the procedure performed. Interestingly, the next largest group of participating boards (11 states) reported very specific and restrictive rules regarding the ability to receive delegation. The remaining boards (5) were expecting pending changes regarding the types of medical personnel who could receive physician delegation.

Regarding the type of supervision required of nonphysicians receiving delegation, approximately half of the participating boards (14 boards or 45%) reported general or broad supervision that was often not specifically defined, and was left to the physician's discretion. An almost equal number of participating boards (13 boards or 42%) required some method of on-site supervision. A small number of boards (4) specifically allowed off-site physician supervision of nonphysician providers.

Regarding the number of PAs that a given physician may supervise at a time, the states were divided. Some states permitted supervision of two PAs per physician (4 states), some up to 3 PAs (one state), and some more than 3 PAs (4 states). An overwhelming majority of the states (18 states), however, did not clearly specify the number of PAs that a physician may supervise. At the other extreme, a minority of the participant states (two states) provided very specific supervision limits that exceeded the level of detail of the other states.

Most state medical boards (15 states) required some type of mandatory reporting, but not necessarily of adverse patient incidents involving MICP. In fact, very few states (4) required reporting of both office- and nonoffice-based MICP.

Geographic trends

Based on the responses received, there appeared to be geographic differences among state medical boards regarding MICP regulation. Stricter requirements tended to be seen in Southern states. Specifically, all of the participating Southern states (11 participating of 16 total) had specific guidelines pertaining to delegation to and supervision of nonphysicians, with all having rules as to who could accept delegation and the type of supervision required in each case. All except one of these states

already had or were in process of altering regulations to clarify which MICP may be delegated. Finally, a majority of the Southern states required some sort of mandatory reporting of adverse patient incidents, but not necessarily or specifically those relating to MICP.

Participating Western states (6 participating of 13 total) tended to require less regulation of nonphysician provision of MICP. For instance, most of these states permitted off-site physician supervision of delegated nonphysicians performing MICP. In addition, several of these states had minimal to no regulations regarding the method of physician supervision of delegated MICP. However, most of these states did restrict the types of nonphysicians who were able to receive delegation.

DISCUSSION

This study revealed significant differences among state medical boards regarding regulation of nonphysician provision of MICP. These differences include: (1) on-site versus off-site supervision; (2) the types of nonphysician personnel who can receive delegation; and (3) the number of nonphysician personnel within various categories who may be supervised by a single allopathic physician. In addition, many states do require mandatory reporting of some adverse events, but not necessarily such events when they occur during MICP. Geographic differences included relatively more stringent requirements for MICP regulation in Southern states compared with Western states. Overall, there appear to be ongoing efforts in many states to add and refine regulations pertaining to delegation to nonphysicians and performance of MICP.

The strengths of this study include extraction of current regulatory information from multiple sources, including interviews with state medical board officers, and administrative rules promulgated by specific medical boards, relevant state legislation, and prior legal opinions. The interviews also permitted acquisition of information about pending or expected changes in administrative rules. We believe directly contacting officials at state boards was more helpful than relying on written materials because many of the relevant rules and administrative

regulations were in flux or were based on precedent rather than firm policy.

Limitations of this study include the inability to interview officers at each state medical board. Multiple attempts were made, but some boards did not make personnel available for this purpose. Although we can only speculate as to the reasons for this, it may have been that at certain allopathic state medical boards official uncertainty about the application of current rules and regulations to cosmetic procedures may have made boards reluctant to go on the record to explain their procedures. Similarly, to the extent that imminent rule changes were afoot or that boards were aware of the politically fraught environment (eg, the differing views of doctor groups, nursing groups, PAs, corporate entities) surrounding the regulation of MICP, some boards may have preferred to actively withhold engaging us.

In addition, this study had restricted scope in assessing the methods for reporting complaints and adverse events associated with MICP. Although state medical boards were queried regarding the numbers and types of MICP-specific complaints they received, complaints about nonphysician performance of such procedures might have been underdetected to the extent that other venues for reporting, such as state cosmetology or electrology boards, may have received these complaints.

Overall, there is substantial variation in the degree to which different state medical boards regulate cosmetic procedures, in particular so-called minimally invasive procedures. There is an increasing realization that minor cosmetic procedures pose a potential threat to patient safety if not performed in an appropriate manner, and more boards are attempting to promulgate specific administrative rules within a complex political, regulatory, and economic environment.

REFERENCES

1. Resneck JS Jr, Kimball AB. Who else is providing care in dermatology practices? Trends in the use of nonphysician caregivers. *J Am Acad Dermatol* 2008;58:211-6.
2. Nestor MS. The use of mid-level providers in dermatology: a liability risk? *Semin Cutan Med Surg* 2005;24:148-51.
3. White SM, Geronemus R. Should non-physicians perform cosmetic procedures? *Dermatol Surg* 2002;28:856-9.