

Appropriate Business and Clinical Management of Medical Spas

Summary: Medical spas offer a variety of cosmetic treatments, including medical procedures. Because these procedures can pose certain safety risks for patients, the delivery of this care should involve proper physician oversight and supervision. Thus, the American Society of Plastic Surgeons (ASPS) has developed a *practice reference* to (1) inform the appropriate business and clinical management of medical spas and (2) provide state policymakers with benchmarks for policies that protect patient safety.

BACKGROUND

Medical spas, sometimes referred to as “medi-spas” or “med spas,” combine some medical procedures normally performed in a doctor’s office with the experience of a day spa. They offer non-invasive treatments, including cosmetic procedures, with a focus on looking younger and healthier.

Medical spas are often led by physician directors, many with plastic surgery or dermatology backgrounds. However, some are operated by physicians from other specialties or even non-physicians, such as nurse practitioners or other mid-level providers, raising safety concerns.¹⁻⁴ Requirements for medical spa ownership and supervision, and medical practice management more broadly, vary by state.⁵

RATIONALE

Medical spas are of interest to ASPS because they offer not only cosmetic *non-medical* procedures but also cosmetic *medical* procedures⁶—which stimulate, alter, or destroy living tissue. Treatments considered medical include procedures such as hair transplants, cosmetic soft tissue fillers, cosmetic injections, and numerous energy-based treatments.

Cosmetic medical procedures pose certain safety risks. They require practitioners to have adequate training to perform them effectively and, most critical, manage any complications that may arise. Thus, any facilities offering these services should adhere to appropriate business and clinical management principles to provide patients with the highest quality care.

This document does not explicitly address liability issues, but the suggested approaches are meant to protect patient safety and, in turn, could support risk management.

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► REFERENCE *for Surgeons*

ASPS has developed a practice reference for the optimal business and clinical management of a medical spa in order to help ensure that structural elements are in place to optimize safety and quality. **Members should consider how they may abide by these principles in the context of their state’s statutes and regulations that directly or indirectly govern supervision in medical spas.**

For example, many states have policies that reflect the “corporate practice of medicine doctrine,” which prohibits corporations from practicing medicine.⁷ These policies often bar non-physicians from owning medical practices or employing physicians. In addition, states may have statutes or regulations with requirements for virtual supervision or telemedicine consults that could apply to medical spas. Another aspect of state law that should be considered is the differing levels of independence granted by states to certain mid-level practitioners.

Role of the Medical Director

ASPS has identified several considerations specific to the qualifications and responsibilities of the medical director in a medical spa. The Society believes optimal state regulations would follow these considerations. In a neutral context, where existing state laws are not a consideration, the medical director should—

Qualifications

- Be a physician licensed to practice medicine in the state where the facility operates.

- Have the proper education, training, experience, and competence to safely administer, delegate, and supervise each cosmetic medical procedure at the medical spa. This includes completion of an Accreditation Council for Graduate Medical Education (ACGME)-accredited residency in a medical specialty that provides complete training in the procedures performed at the medical spa.

Responsibilities

- Accept responsibility for the safety of all patients treated at the medical spa.
- Establish a means for obtaining the appropriate informed consent from each patient prior to treatment.
- Develop and sign written protocols for any cosmetic medical procedure that may be performed at the medical spa.
- Ensure that all physicians or non-physician practitioners are trained and qualified to perform the procedures with which they are tasked—including certification for the use of specific equipment—and assess their clinical performance.
 - Procedures using a Food and Drug Administration (FDA)-cleared or FDA-regulated device should be performed only by an appropriately trained physician or by appropriately trained non-physician personnel under the direct supervision of an appropriately trained physician.
 - FDA-regulated drugs should be prescribed only by an appropriately trained physician or by appropriately trained non-physician personnel under the direct supervision of an appropriately trained physician.
- Ensure that licensed medical professionals, such as nurse practitioners, physician assistants, registered nurses, licensed vocational nurses, and licensed practical nurses, comply with their professional scope of practice and act in accordance with their respective state licensing boards.
- Confirm that the medical spa is equipped with all necessary equipment, supplies, and processes to address medical complications and emergencies that may arise during treatment.
- Understand and abide by all applicable local and state statutes and regulations.

Role of the Supervising or Delegating Physician

The supervising or delegating physician at a medical spa may be the medical director or any physician at the facility who delegates tasks or procedures to non-

physicians. In the absence of an identified medical director, the supervising or delegating physician assumes the additional responsibilities of a medical director.

ASPS has also identified considerations specific to the qualifications and responsibilities of the supervising or delegating physician in a medical spa. The Society believes optimal state regulations would follow these considerations. In a neutral context, where existing state laws are not a consideration, the supervising or delegating physician should—

Qualifications

- Have the proper education, training, experience, and competence to safely administer, delegate, and supervise each cosmetic medical procedure at the medical spa. This includes completion of an ACGME-accredited residency in a medical specialty that provides complete training in the procedures they are performing, supervising, or delegating at the medical spa.

Responsibilities

- Accept responsibility for the safety of all patients whose treatment they supervise.
- Ensure that appropriate informed consent is obtained from each patient prior to treatment.
- Provide necessary supervision, according to state-specific requirements and the physician's professional judgement, over each cosmetic medical procedure performed under the physician's supervision at the medical spa.
- Ensure that all practitioners under the physician's supervision are trained and qualified to perform the procedures with which they are tasked—including certification for the use of specific equipment, such as FDA-cleared or FDA-regulated devices.
- Delegate only those medical procedures that are in the physician's area of expertise and within the statutory or regulatory scope of the profession of the non-physician practitioner performing the procedures.
- When delegating procedures to a non-physician practitioner, maintain ultimate responsibility for the patient's care. This may include conducting an initial evaluation for each new patient to establish the appropriate diagnosis and treatment plan.
- When supervising or delegating minimally invasive cosmetic medical procedures by non-physicians, remain within 50 miles or 1 hour of travel time from the facility and remain immediately available for consultation during the procedure.

- Understand and abide by all applicable local and state statutes and regulations.

► REFERENCE

FOR POLICYMAKERS

States have an opportunity to implement policies that ensure appropriate clinical supervision and optimal practice in medical spas. States should consider the following principles⁸ when developing policies aimed at improving patient safety for these entities:

- Codify a definition of “surgery” and a definition of “cosmetic medical procedure.” 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.
- Specify that any procedure that constitutes the practice of medicine, including any procedure using an FDA-cleared or FDA-regulated device that can alter or cause biologic change or damage, should be performed only by an appropriately trained physician or by appropriately trained non-physician personnel under the direct supervision of an appropriately trained physician.
- Mandate that medical spa facilities be licensed and inspected on a regular basis to ensure compliance with all applicable federal and state statutes and regulations.
- Provide requirements to ensure transparency and truthful advertising:
 - A medical director of a medical spa facility should be clearly identified as the medical director in all marketing materials and websites related to the medical spa facility, and all such communications should also list the medical director’s licensure, ACGME/American Osteopathic Association (AOA)-trained medical specialty, and American Board of Medical Specialties (ABMS)/AOA board certification.
 - If marketing materials mention a physician’s board certification, the certifying board and specific specialty should also be stated (e.g., Diplomate of the ABMS in Dermatology). States should implement restrictions on the use of non-ABMS or AOA boards in advertising, as

many have insufficient standards for securing diplomate status.

- The medical director must ensure that marketing and advertising materials of a medical spa facility do not include false, misleading, or deceptive representations.
- Non-physicians must wear identification that displays their provider type and licensing.
- Set standards for the qualifications of personnel performing procedures or managing the medical spa:
 - Any physician or non-physician personnel who provides a cosmetic medical procedure must be qualified to (1) perform such procedures by virtue of having received appropriate theoretical and clinical instruction and training in each service to be performed—including safety, clinical application, and pre- and post-procedural care—and (2) handle any resultant emergencies or sequelae.
 - Any licensed physician or non-physician employed by a medical spa, including a medical director, must have received appropriate documented training and education in the safe and effective performance of all cosmetic medical procedures performed in the facility.
- Require that deaths and significant complications be reported to the state for investigation:
 - 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 of more than 24 hours, or a significant complication or adverse event requiring additional medical treatment must be reported to the state within a time frame that aligns with the state’s guidelines for adverse event reporting. Such reports should be investigated by the appropriate state entity.
 - Any adverse events involving the use of FDA-cleared or FDA-regulated devices must be reported to the FDA in accordance with federal statutes and regulations.
- Specify that the state’s board of medical examiners must establish and maintain an online registry for medical spas and a continuous process for monitoring and inspecting facilities for compliance.

This document was approved for distribution by the ASPS Medical Spa Task Force on September 15, 2023; the ASPS Healthcare Delivery Committee on October 4, 2023; and the ASPS Board of Directors on December 8, 2023.

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