



Healthcare

INBRIEF®

A Risk Management Bulletin for Allied Healthcare Facilities | 2024 Issue 2

Medical Spas and Medical Aesthetics: Ten Strategies to Reduce Risk

Medical spas (referred to as “medispas” hereafter) and medical aesthetic firms represent a fast-growing and lucrative sector of the holistic health market. (See “Market Fast Facts” to the right.) These enterprises – most of which are owned by traditional healthcare providers – generally offer patients/clients a wide range of aesthetic, alternative and elective medical and wellness treatments. While the menu at medispas and medical aesthetic practices varies, most offer some combination of the following treatments and products, among others:

- **Non-invasive aesthetic services**, such as facials and dermaplaning.
- **Invasive cosmetic aesthetic services**, including dermal fillers and injections.
- **Body-sculpting services**, such as LED light therapy, laser liposuction, cool sculpting, body wrapping and infrared therapy.
- **Fillers**, including cheek enhancements, lip fillers and fat dissolvers.
- **Colonic irrigation** and weight-loss services.
- **IV hydration** for nutrient replenishment, vitamin supplementation, inflammation reduction and weight management.
- **Skin rejuvenation procedures**, including chemical peels, laser hair removal, microneedling and microdermabrasion.
- **Energy therapies**, such as reiki, acupressure and acupuncture.
- **Nonprescription health products**, including dietary supplements, nutraceuticals, essential oils and skin care products.

The medical aesthetics industry offers healthcare providers the opportunity to broaden their scope of services and exercise their entrepreneurial skills. However, providers must be aware of the risks involved in introducing cosmetic and non-traditional services into an established clinical practice or launching a stand-alone operation. Potential allegations are numerous, including bodily injury to patients/clients, adverse reactions, lack of informed consent, failure to supervise, and delay in properly responding to complications, among other pitfalls.

Market Fast Facts

The medispa and aesthetics industry is currently driven by new provider types, alternative practice settings and advances in technology. According to the [American Med Spa Association](#) ...

- **Medical aesthetics generate \$15 billion annually in the U.S.**, accounting for nearly half of global sales.
- **There are approximately 9,000 practice locations in North America**, a 48 percent increase since 2018.
- **Four-fifths of medical aesthetic practices are single locations**, generating \$122,000 in monthly revenue, on average.
- **Two-thirds of medispa practices are owned by a single entity**, mostly either physicians or surgeons.
- **Approximately 20 percent of medispa owners specialize in plastic surgery**, oculoplastic surgery or cosmetic dermatology.
- **Adults between 35 and 54 years old comprise the largest client bracket**, and women account for 88 percent of all clients.

This edition of *inBrief*[®] is designed to help owners of medispas and aesthetic practices, as well as associated providers, address major risk factors and consistently deliver safe, high-quality care. A case scenario, below, examines potential complications that may occur following a common aesthetic procedure. In addition, this article offers ten practical strategies intended to help strengthen ownership structure and licensing status, enhance regulatory compliance and staff competence, bolster policies and procedures, and minimize exposures related to the sale of healthcare products.

Ten Risk Management Recommendations

As the below closed claim demonstrates, aesthetic treatments can go awry very quickly. The following strategies can help protect patients/clients from harm, as well as mitigate professional liability in the event of an untoward occurrence:

1. Consult legal counsel with respect to ownership, licensure and accreditation status. State statutes vary considerably with respect to what constitutes a medspa and who can own one. An attorney well-versed in healthcare law can help prospective owners and licensed providers answer the following questions, among others, and facilitate a sound and compliant ownership structure:

- **Do the services offered qualify as the “practice of medicine,”** as defined by applicable state statute or regulation? Note that states vary widely on the question of what aesthetic and wellness treatments qualify as the practice of medicine, and also how these treatments are regulated. For example, intravenous hydration generally falls under the practice of medicine, but the statutes regulating this procedure are state-specific.
- **Does the state hold to the legal doctrine known as the “Corporate Practice of Medicine,”** allowing only a physician or physician-owned corporation to receive payment for medical services?
- **Do state licensure regulations restrict ownership of medispas to licensed physicians,** or can nurse practitioners (NPs) serve as owners if the state recognizes independent practice? And can other types of healthcare professionals – such as RNs, dentists and chiropractors – have a financial interest in the operation as long as a physician retains majority control?
- **Can only a licensed physician serve as medical director?** Or can this position be occupied by an NP in an independent practice state, a physician assistant pursuant to a collaborative practice agreement, or any other provider type?

Scenario: Arterial Occlusion Following Dermal Filler Injections

A registered nurse (RN) administered a series of facial rejuvenation treatments – consisting of a dermal filler injection and other injectable products – to a 42-year-old female client. Immediately following the procedure, the nurse documented minimal swelling and no sign of an adverse reaction. However, within an hour of discharge, the client alerted the nurse to facial bleeding, pain and numbness, which escalated over the ensuing 24 hours to reports of severe pain, continued numbness and inability to move her lip. In response to these complaints, the nurse directed the client to apply ice and take ibuprofen. The following events transpired over the next week:

Second day post-treatment: The client reported swelling and numbness extending to her nose and cheeks. The RN advised her to continue ice applications and to take an antihistamine. The RN also conveyed the client’s concerns to the medspa’s medical director, who in turn recommended a full medical evaluation. However, the client did not comply with the request.

Third day post-treatment: The client opted for treatment in a local emergency department, unaffiliated with the medspa, where a provider diagnosed her with cellulitis and prescribed steroids and antibiotics.

Fifth day post-treatment: A primary care physician (PCP) assessed the client and found severe facial swelling, discoloration of the skin due to subdermal bleeding, an ulceration of the upper lip and weakness of the facial nerve. Additional antibiotics were prescribed.

Sixth day post-treatment: The client self-referred to a dermatology clinic, where she was diagnosed with severe thickness necrosis of the upper lip, secondary to an arterial occlusion caused by dermal filler injections.

The client required hyperbaric oxygen treatments and plastic surgery to reconstruct missing portions of her upper lip. For a period of weeks, she could neither eat solid food nor control oral secretions. A lawsuit was subsequently filed against the RN, the medspa firm, its medical director and the PCP, asserting improper injection technique and delayed response to adverse reactions. Expert witnesses testified that the defendants did not adhere to the standard of care, which required expeditious treatment of the injection site with nitroglycerin paste and early administration of steroids, in order to mitigate vascular compromise and avoid tissue necrosis.

Although defense experts opined that arterial occlusions may occur in the absence of negligence, the defense was weakened on several points, including failure to initiate prompt treatment, limited physician oversight of the RN, and insufficient documentation of both informed consent and RN-client communication. Notably, all post-procedure contacts took place via personal text messaging, as the RN was away from the clinical setting on personal business. The claim was eventually settled for a total incurred of over \$300,000.*

* As a side note, a [2019 study](#) revealed that laser-induced burns and misplacement of dermal fillers – often due to lapses in technique and patient/client selection – are the most common adverse events related to cosmetic procedures performed by non-physicians. Effective risk control measures should be developed in such key areas as informed consent, scope of practice, patient/client screening and assessment, supervision, patient/client follow-up, and staff training and documentation.

- **What duties should be articulated in a written medical director agreement**, e.g., to develop and approve policy, protocols and procedures; directly supervise providers; establish guidelines for care, delegated tasks, drug use and medical equipment utilization; schedule quality of care reviews; and respond to adverse events?
- **What actions are prohibited under federal fraud and abuse laws**, as well as state prohibitions, e.g., the practice of “fee-splitting” in which commissions are paid to medspa employees and kickbacks are received for the sale of healthcare products and other services?
- **What sort of accreditation should be sought**, and from what organizations or programs, e.g., National Medspa Association, Medspa Professional Accreditation?

2. Carefully select offered therapies and screen prospective patients/clients. Written selection criteria for each type of service should ensure that spa and aesthetic services are genuinely beneficial to patients/clients and are not offered merely to generate revenue. Through consistent screening, practices and providers select individuals who are deemed suitable for treatment, while avoiding those with contraindications.

3. Ensure that staff has appropriate education and training. Licensed and non-licensed staff should be competent to safely carry out their duties, particularly with respect to new procedures or therapies. Education and training should be documented in personnel files and noted in job performance reviews, including when and where training sessions took place, as well as what information and skills were covered in the training courses and programs.

4. Obtain informed consent. Establishing realistic expectations is key to minimizing risk exposures associated with aesthetic services. By utilizing procedure-specific informed consent forms, providers can better manage expectations, capture pre-treatment discussions, and document patients’/clients’ understanding of the care they are about to receive. Forms should convey, at a minimum, the nature of the proposed care, its anticipated benefits, available alternatives and foreseeable risks, including potential complications. Patients/clients also should be asked whether they have any questions about the proposed care, with both queries and responses noted in the healthcare information record.

5. Thoroughly document provision of services. Deficient records might place facilities at a serious disadvantage in the event of a legal claim or regulatory action. While requirements vary among states, depending upon the type of practice and services offered, clinical records should minimally include the following information:

- **Notes on patient’s/client’s lifestyle**, relevant medical history and physical contraindications.
- **Informed consent documentation**, including questions asked and answers given.

- **Calibration and time synchronization** of equipment or devices.
- **Description of treatment rendered** and any reactions, including the results of skin “patch tests.”
- **Findings of post-treatment monitoring** or assessment.
- **Directions or recommendations given at discharge** and a list of aftercare contacts, including the recommendation to seek emergency care, if indicated.

6. Develop sound policies for patient/client monitoring and follow-up. Generally speaking, monitoring activities requiring independent diagnosis or assessment of clinical data should not be delegated to non-licensed assistive personnel. Written policy should govern the process of delegating monitoring responsibilities to RNs and other licensed professionals, specifying when delegating providers must exercise direct supervision pursuant to state laws, as well as when they should be notified of unexpected outcomes or patient/client concerns. Policy also should stipulate that patients/clients be contacted the day after treatment (or sooner if clinically indicated) to check on their status, with the encounter noted in the healthcare information record. In addition, have legal counsel vet policy statements regarding statutory requirements for staff supervision.

7. Stay current on pertinent regulations, especially concerning scope of services. The medspa and aesthetic industry is regulated by a number of entities, including but not limited to state boards of health and divisions of professional licensing; state medical, nursing and cosmetology boards; state attorney general offices; and such federal agencies as the FDA, OSHA and the Office of the Inspector General. In the event that definitions, rules and requirements appear to differ among regulatory bodies, discuss these inconsistencies with legal counsel. In general, the most stringent guideline should be followed.

In addition, remain knowledgeable about state laws regarding delegation of clinical tasks and supervision of licensed and unlicensed providers. Determine how state laws define the doctor-patient/client relationship and what duties – such as obtaining a history or performing a pre-procedure physical – may be safely delegated. Also, keep in mind that whenever a case exceeds the training, skills and/or legally delineated scope of practice of staff members, the patient/client should be referred to an appropriate specialist.

8. Verify appropriate insurance coverage. In collaboration with insurers, conduct a risk assessment of the practice, examining potential liability exposures, as well as statutory and regulatory compliance issues. Discuss results with legal counsel and insurance company representatives to ensure the adequacy of insurance coverage and the effectiveness of risk-reduction efforts.

9. Review marketing materials. To prevent claims of false representation, ensure that all advertisements, brochures and testimonials conform to state and medical board advertising rules. Marketing materials should...

- **Accurately and clearly state provider qualifications,** credentials and experience.
- **Avoid making guarantees** as to the efficacy of treatments.
- **Identify the use of models,** in order to avoid inflated expectations regarding clinical outcomes, and clearly label “before and after” photos, noting the nature and duration of the depicted treatment.

10. Closely oversee the sale of nonprescription health products.

Selling products directly to patients/clients, or through third parties who give medical providers a portion of the proceeds, may have ethical and regulatory implications. Consider adopting the following strategies, among others:

- **Before selling any health products, consult with an attorney** to ensure the business practice does not violate state or federal fraud and abuse laws, such as prohibitions against financial kickbacks.
- **Disclose to patients/clients any financial interest in the sale of health products,** both verbally and in writing.
- **Perform due diligence before entering into licensing agreements,** distributorships, or sponsorships with outside companies or clinics for the promotion of products or services.
- **Document the risks, benefits and limitations of products sold** in the healthcare information record, along with any issues relating to toxicity, adverse interactions and ineffectiveness, as well as actions taken in response.

Medispas and related aesthetic services continue to grow in popularity, number and range of services. Before venturing into this expanding field, however, providers and organizational leaders must be knowledgeable about legal standards and requirements, as well as safety considerations. The strategies outlined here may help serve as a starting point in the ongoing effort to review and enhance risk control policies and programs.

Quick Links

Resource Organizations

- [American Med Spa Association \(AmSpa\)](#)
- [National Medspa Association \(NMSA\)](#)

Articles

- [“The Importance of Managing Esthetician Client Records: Legal and Practical Considerations.”](#) Posted on the website of Hale Cosmeceuticals Inc., October 8, 2023.
- Moeller, M. [“Physician Assistants Head Toward Greater Autonomy.”](#) Posted on the website of the American Med Spa Association, July 26, 2023.
- Moeller, M. [“Update: Nurse Practitioners Have Full Practice Authority in These States.”](#) Posted on the website of the American Med Spa Association, September 21, 2023.
- Moeller, M. [“Who Can Own a Medical Spa?”](#) Posted on the website of the American Med Spa Association, November 22, 2021.

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