

INTERNATIONAL ASSOCIATION FOR
PHYSICIANS IN AESTHETIC MEDICINE

Presents

Practice Accelerator Series

*Key Legal Issues for
Medical Spas and
Aesthetic Medical
Practices*

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Key Legal Issues for Medical Spas and Aesthetic Medical Practices

The medical spa industry is exploding with potential business opportunities. Yet, many physicians and business owners open an aesthetic medical practice or join a medical spa with little awareness of the potential legal and regulatory pitfalls that await the unprepared clinician or entrepreneur.

Aesthetic medicine requires careful attention to the intersection of corporate practice of medicine, licensing, anti-kickback and fee-splitting considerations, and other legal and regulatory issues. Both physicians who want to either open a medical spa or add aesthetic medical procedures to their existing practice, and entrepreneurs who want to either open a medical spa or incorporate aesthetic medical procedures to a wellness center, can benefit from a better understanding of some of key legal issues involved. These legal issues are common to a variety of practices and organizations that offer emerging therapies beyond conventional medical care, whether in a medical spa or dermal clinic, a holistic health care facility, a wellness center, or an ‘integrative medicine clinic’ that includes complementary and alternative medical treatments (such as acupuncture, massage therapy, and dietary supplement recommendations) in its patient care.

Law Offices of Michael H. Cohen has written this overview of key legal issues facing medical spas and aesthetic medical practices, specifically for members of the International Association for Physicians in Aesthetic Medicine (IAPAM).

Legal Structure for the Business

Many physicians want to know what is the best business structure for a medical spa, or for their own medical practice when they affiliate with a medical spa. This is a complicated question that cannot be answered in a bullet point, as it involves a number of distinct legal issues.

The first has to do with the corporate structure itself. In general, incorporation provides limited liability, which means that the individuals running the business typically are insulated from the liabilities of the corporation, so long as the corporation is properly capitalized and administered with all the necessary corporate formalities. However, a physician or other professional can still remain liable personally for professional negligence. Further, different kinds of corporate structures can have different tax implications (for example, an LLC versus a “C” or “S” corporation). Finally, many states have a “strong” corporate practice of medicine doctrine, which means they require that physicians providing services to an institution be housed within a professional medical corporation. Non-physicians are ordinarily prohibited from owning shares in, or sharing profits or “splitting fees” with members of, the professional medical corporation.

Tip: Be sure to seek advice about the most tax-effective form of incorporation, possible application of the corporate practice of medicine within your state, and ways to help manage risk of professional liability by creating a proper legal structure for the business.

Clinical Practice Structure

Structuring the clinical practice structure for the physician, as well as for the medical spa or other health care institution, requires careful attention to state licensing laws. Most states define the “practice of medicine” in terms such as “diagnosing and treating disease,” and make the unlicensed practice of medicine a felony. Legal concerns can arise because courts define the terms “diagnosis” and “treatment” broadly. Non-MDs who have a state license as a professional health care provider have “limited” licensure, which means that the licensing statute and regulations circumscribe a more defined role for them than the ability to “diagnose” and “treat.” The range of professional activities legally available to non-MD health care providers is known as “scope of practice.” Because Non-MDs need to be careful not to cross the line from permissible, licensed activities that fall within their legally authorized scope of practice, into the unlicensed practice of medicine.

This caution applies both to allied health providers, such as nurses, psychologists, and even cosmetologists; and complementary and alternative medical practitioners such as chiropractors and acupuncturists. Physicians who are unaware of this caution, as well as the medical spas that employ them, can potentially be liable for aiding and abetting the unlicensed practice of medicine. This caution is even greater if a medical spa is utilizing providers who lack any form of state licensure. Even therapeutic practices such as recommending dietary supplements can come under scrutiny, as some courts have viewed such recommendations as medical “prescriptions” that fall outside the non-MD’s scope of practice.

The other side of the licensure coin is the question of which therapies require medical supervision, and which can be performed independently by a nurse-practitioner or other legally qualified provider. States differ on whether laser therapy for hair removal, for example, is considered a medical therapy, or can be furnished without MD supervision; and whether in the latter case, the physician can delegate the operation of the laser for hair removal to a registered nurse, licensed practical nurse, or a paramedic.

If physician supervision is required and the patient is nonetheless injured through the non-MD’s negligence, the physician can potentially be held liable on two different theories of negligence: “directly” liable for failing to properly supervise, and “vicariously” liable for negligence by the non-MD who will be seen as the MD’s agent.

Tip: Be sure to understand licensure, scope of practice, and supervision or referral requirements applicable to health care providers and therapists within the medical spa, holistic health and wellness center, or integrative medicine clinic.

Credentialing Health Care Providers

Medical spas and wellness centers face a dilemma when it comes to vetting practitioners. On one hand, if the organization does not ensure that it is hiring the most qualified, competent providers, and a patient is injured while under a practitioner's care within the spa or center, the organization can be considered negligent for failing to exercise due diligence in hiring. On the other hand, if the organization sets up a credentialing scheme, designed to ensure that affiliated practitioners have satisfactory qualification and competency, and a patient is injured while under the care of one of the practitioners, the organization may be considered negligent for failure to exercise due care in credentialing.

Credentialing is complex as it varies by state and profession. For example, while chiropractors are licensed in every state, massage therapists and acupuncturists are licensed in well over half the states, and naturopaths in over a dozen states. In many states, massage therapists are licensed at the level of their local communities (such as municipalities) rather than at the state level; local massage ordinances may regulate the massage establishment itself as well as the establishment's practitioners.

Tip: In general, it is better to establish some basic elements of a credentialing plan for quality assurance. In establishing criteria for hiring practitioners, medical spas and wellness centers should consider putting together minimum requirements regarding licensure; education; history of malpractice or discipline; relevant certifications; methods and treatment plans; and communication abilities. Physicians with aesthetic medical practices should be aware of the credentialing schemes designed by the medical spas with which they are affiliated in order to familiarize themselves with the level of training and competency of personnel with whom they may share patient referrals.

Medical Malpractice (Negligence) and Professional Liability Insurance

The legal definition of medical malpractice (or professional negligence) is: failure to use due care (or follow the standard of care) in treating a patient, and thereby injuring the patient. Generally, while licensed medical doctors are judged by medical standards of care within their specialties, each non-medical profession is judged by its own standard of care—for example, nursing; acupuncture; chiropractic; physical therapy; massage therapy. In cases where the practitioner's clinical care overlaps with medical care—for example, the chiropractor who takes and reads a patient's X-ray—then the medical standard may be applied.

States vary in their requirements for malpractice coverage, and individual insurers vary in the extent to which they cover aesthetic medical therapies and complementary and alternative medical therapies. Professional liability insurance policies tend to be dense and filled with jargon, making it difficult to determine exactly what is covered and what is excluded.

Complicating the picture is the fact that although ordinarily, physicians who refer a patient to a specialist do not necessarily have liability for any negligence on the part of the specialist, there are several, rather large exceptions to this rule that can be triggered by affiliation with a medical spa or holistic health and wellness center. Among these exceptions is “joint treatment,” a legal principle which holds practitioners liable for one another’s negligence if they are engaged in a concerted plan of therapeutic action for a given patient. Courts have been ambiguous about what exactly constitutes such concerted action, but the exception is broad enough that referrals back and forth within a medical spa or wellness center could potentially be viewed as “joint treatment.”

Tip: All health care practitioners within the medical spa should have their own professional liability insurance. The individual practitioner should determine the coverage available and the amount, if any, required by his or her state. Medical spas and practices should have general umbrella liability coverage.

Informed Consent

A lack of proper informed consent can serve as an alternative theory to medical malpractice. The legal obligation of informed consent is to provide the patient with all the information material to a treatment decision—in other words, that would make a difference in the patient’s choice to undergo or forgo a given therapeutic protocol. This obligation applies across the board, no matter what therapies are involved. Materiality refers to information about risks and benefits that is reasonably significant to a patient’s decision to undergo or forgo a particular therapy; about half the states judge materiality by the “reasonable patient’s” notion of what is significant, while the other half judge materiality by the “reasonable physician.”

Updating the patient about changes in medical evidence is an important part of the informed consent obligation. If the discussion involves an herbal product, for example, the practitioner should let the patient know that the fact that the product is marketed as “natural” does not necessarily mean the product is safe. Informing the patient about the changing medical evidence also may shift (in one direction or another) the patient’s willingness to accept the known risks and benefits of the CAM therapy, or even to use the therapy.

Tip: A well-structured informed consent that conforms to relevant state law should be a part of any aesthetic medical or other health care practice.

Professional Discipline

Professional discipline refers to the power of the relevant professional board—in the physician's case, the state medical board—to sanction a clinician, most significantly by revoking the clinician's license. Typically, the state medical board will revoke a physician's license for egregious behavior such as gross negligence, but medical board discipline also has been a concern when physicians deliver emerging therapies that may be therapeutically valid although they may not yet have garnered widespread approval.

Concern about potential state medical board discipline has arisen largely in the context of physician delivery of complementary and alternative medical therapies, such as ozone therapy, chelation therapy, homeopathy, and even nutritional care. Although not all aesthetic medical therapies could be considered complementary and alternative medical therapies, these two categories of therapies are linked in that they push forward the boundaries of conventional, 'illness-based' medical care to embrace a consumer orientation toward wellness, prevention, and a more holistic sense of self-care.

In response to concern about state over inappropriate discipline, some states have enacted "health freedom" statutes. These laws provide that physicians may not be disciplined solely on the basis of incorporating complementary care modalities. For example, New York Education Law § 6527 (4) (e) permits "the physician's use of whatever medical care, conventional or non-conventional, which effectively treats human disease, pain, injury, deformity or physical condition." More recently, the Federation of State Medical Boards has issued Model Guidelines for Physician Use of Complementary and Alternative Therapies (see below), reaffirming this same principle. Such rules, however, have not necessarily stopped state medical boards from bringing disciplinary investigations against physicians using a variety of emerging therapies.

Tip: Physicians, aesthetic medical practice, medical spas and others need to ascertain the extent to which individual, emerging therapies that embrace a more holistic model of health are likely to trigger undue medical board scrutiny.

Anti-Kickback and Fee-Splitting Considerations

Federal law prohibits physicians from receiving an illegal discount or payment in exchange for referring patients. The prohibited practice, also known as a “volume-based inducement,” is codified in the so-called “Stark” and federal anti-kickback laws, and often mirrored in state fee-splitting laws. These rules also have numerous exceptions (known on the federal side as “safe harbors”), such as rules that would allow physicians under certain circumstances to have legitimate fee-sharing arrangements within a professional medical corporation or a properly structured group practice.

Tip: Understanding and managing the referral prohibitions requires careful attention to employee ownership and profit-sharing arrangements; flow of payments between the providers and between organizational entities; and payments flowing to and from marketing companies, billing companies, laboratory services, suppliers, supplement and device manufacturers, and others.

Summary

This information has been taken from part of the course curriculum that will be taught at the International Association for Physicians in Aesthetic Medicine’s 2-day Aesthetic Medicine Symposium. For more information on the Symposium, please go to www.aestheticmedicinesymposium.com or call the association at 1-800-219-5108.

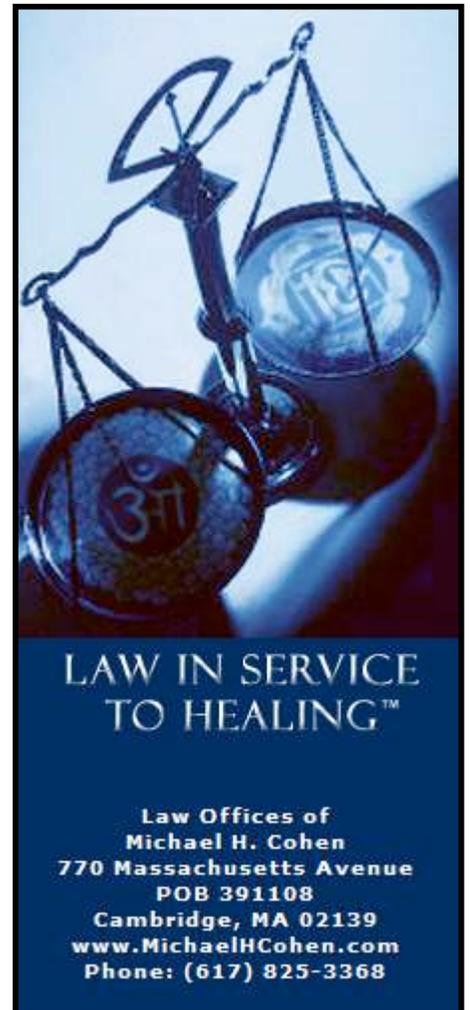
For more information and further resources regarding legal issues applicable to aesthetic medical practices and medical spas, visit the [Complementary and Alternative Medicine Law Blog](http://www.camlawblog.com) (www.camlawblog.com)

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About The Law Offices of Michael H. Cohen

Law Offices of Michael H. Cohen represents physicians, nurses, complementary care providers, medical spas, integrative medicine clinics, holistic health care and wellness centers, and similar organizations that are bridging spa treatments, holistic health and wellness care, and medical (or aesthetic medical, cosmetic, and beauty treatments)

The Law Offices has expertise in legal and regulatory issues including liability risk management, insurance, billing and reimbursement matters, business practice structure, FDA/dietary supplement and medical device regulation, laboratory requirements and medical/health board disciplinary issues. The law firm's principal, Michael H. Cohen, JD, MBA, has worked as a corporate lawyer on Wall Street, has written numerous books and articles on legal issues in complementary and alternative medicine, and has served on the faculty of Harvard Medical School and Harvard School of Public Health. Alan Dumoff, JD, MSW, who serves as Of Counsel to the firm, also has years of experience representing clinicians and clinics particularly in the integrative medicine, medical spa and wellness field.
Web: www.michaelhcohen.com



About the International Association for Physicians in Aesthetic Medicine (IAPAM)

The International Association for Physicians in Aesthetic Medicine is a voluntary association of physicians and supporters which sets standards for the aesthetic medical profession. The goal of the association is to offer education, ethical standards, credentialing, and member benefits. IAPAM membership is open to licensed medical doctors (MDs) and doctors of osteopathic medicine (DOs).

For more information, visit: www.iapam.com or call 1-800-219-5108

About the Aesthetic Medicine Symposium

Presented by the International Association for Physicians in Aesthetic Medicine (IAPAM), the Symposium provides the most current, comprehensive aesthetic medical training program for today's leading physicians. This 2-day Symposium will combine clinical hands-on training of the most profitable advanced skin care procedures with proven strategies to successfully integrate aesthetic medicine procedures into your practice or medical spa.

This program will cover all aspects of starting and operating an aesthetic medicine practice or medical spa, including:

- The business of aesthetic medicine.
- Steps on how to integrated aesthetic medicine procedures into your practice.
- Incorporating your existing patients within your aesthetic practice.
- Finding new patients.
- Choosing the right patient.
- How to perform patient consultations.
- Performing the most profitable Laser/Light treatments.
- Maximizing profits by offering Chemical Peels.
- Choosing Physician-grade Cosmeceutical Skin Care lines.

Leverage our faculty's decades of experience, and learn the keys to building a successful aesthetic medicine practice.

Key Learning Objectives:

Upon completion of this program, participants should be able to:

- Outline the steps needed to integrate Aesthetic Medicine procedures to your existing practice or opening a stand-alone medical spa.
- Understand skin physiological and anatomy associated with many aesthetic medicine procedures.
- Understand the patient selection criteria, risks and benefits of the following Aesthetic Medicine procedures:
 - Botox® injections
 - Dermal fillers, including: Hyaluronic acids (Restylane®, Hylaform®, and Hylaform® plus), Collagens (Cosmoderm™, Cosmoplast™), and Sculptra™
 - Chemical Peels for each skin type
 - Laser and Intense Pulsed Light modalities for facial rejuvenation and hair reduction
- Principles and safety of lasers and IPL devices, including Laser Safety according to ANSI.
- Perform soft tissue coagulation and non-ablative skin resurfacing for dermal remodeling and skin resurfacing using the latest fractional technology.
- Utilize 1064nm nd:YAG technology to treat leg veins.
- Understand how to perform many of the most profitable IPL and Laser procedures, including common complications.
- Identify the best practices for building a referral base for your practice.
- Identify the most effective marketing opportunities needed to increase your revenues by converting your existing patients to aesthetic medicine patients, and attracting new patients.
- Describe the target demographic for the top Aesthetic Medicine procedures.

For more information, visit:

www.AestheticMedicineSymposium.com

or Call 1-800-219-5108