

Legal Compliance Issues for Various Types Of Integrative Medical Practices – Acupuncture

October 8, 2021

By Michael H. Cohen

Integrative medicine (also called complementary or alternative medicine) is the name for medicine that is not part of traditional standard care. Alternative medical therapies are currently being used in combination with traditional medicine as the safety and efficacy of these alternative therapies become clearer.

Integrative medicine is often used with people who have cancer, fibromyalgia, chronic fatigue, and chronic pain. Common types of integrative medicine include:

- Acupuncture
- Aromatherapy
- Animal-assisted therapy
- Massage therapy
- Music therapy
- Dietary supplements
- Meditation
- Functional medicine
- Spiritual healing
- Ayurvedic medicine
- Coaching

Generally, integrative medicine is offered to supplement conventional medical care – not to replace traditional medical care. Some types of alternative medicine are not advisable for certain conditions or people.

The [National Center for Complementary and Integrative Health](#) (NCCIH) is a US agency that conducts scientific research on complementary and integrative health approaches. This research includes examining the usefulness and safety of these therapies in improving people's lives.

Some of the legal issues acupuncture practitioners and the doctors who work with them need to understand

Integrative medicine providers usually operate independently from hospitals and medical practices. However, many physicians

do recommend integrative medicine for certain patients with certain medical disorders. For example, an orthopedist surgeon may recommend that someone who just received a new hip may benefit from treating with an acupuncturist to help manage the pain while the hip heals. Many medical spas and chiropractors work with integrative medicine practitioners.

How closely physicians and other medical practices work with integrative medical practices such as acupuncture can be problematic. If the relationship is too close or if there are improper incentives for referrals, the physicians and the integrative medication practitioners may be in violation of Stark Law or the Anti-Kickback Statute.

Acupuncture practitioners and other integrative practitioners need to understand California's or their own state's laws on the unauthorized practice of medicine. Doctors who also have acupuncturists need to understand what duties they need to perform and what duties they can assign to any medical providers who are not physicians.

California also has specific requirements on who can have an interest in a medical practice. An experienced healthcare lawyer can explain whether integrative medicine qualifies as the practice of medicine.

Other legal issues for integrative practitioners including acupuncture practitioners include:

- Medicare and Medicare coding requirements
- FDA laws and regulations
- HIPAA compliance
- State licensing requirements

State licensing requirements

Every integrative practitioner needs to review with their healthcare lawyer the state licensing requirements for their practice area. Many professions such as acupuncture and chiropractic medicine do have state licensing requirements. All professions should have education and certification requirements. A license to practice a specific type of medicine may be valid in California may not be valid in another state – and vice-versa.

Integrative medicine providers need to review the scope of their license. The providers need to understand when their services may cross over into unauthorized services – to the extent the providers could be charged with practicing a profession – such as psychology, medicine, or nutrition – without a license. Your healthcare lawyer will review which statutes apply to your practice, whether any medical boards regulate your practice, and whether any other rules apply. Your lawyer can also explain whether any exceptions apply.

Generally, an integrative medical practitioner cannot make a diagnosis or order treatments for any disease, injury, physical, or mental condition – and cannot recommend any products to treat any disease or disorder. Integrative medicine providers also need to be careful when they order lab results or review the lab results – or that could be considered the practice of medicine too.

For example, the California Board of Acupuncture regulates *“the practice of Asian medicine through acupuncture in California and is the sole issuer of acupuncture licenses in the state.”* The Board determines the standards for qualification – mainly through its licensing authority. As of 2021, there are more than 12,000 registered acupuncturists. The Board has the authority to investigate criminal conviction histories of applicants and licensees and to discipline licensees who *“may jeopardize the health, safety, and welfare of consumers.”*

The unauthorized practice of medicine is a crime.

Compliance with the Health Insurance Portability and Accountability Act (HIPAA)

HIPAA regulates the disclosure of personal health information in electronic form by covered entities. Covered entities include:

- **Healthcare providers.** Health providers include any healthcare provider *“who electronically transmits health information in connection with certain transactions. These transactions include claims, benefit eligibility inquiries, referral authorization requests.”*
- **Healthcare providers such as health insurance companies, Medicare, Medicaid, long-term care insurers, and other entities**
- **Health clearinghouses**
- **Business associates** (other than a covered entity's workforce)

If an integrative healthcare provider is required to comply with HIPAA, it is normally because they fit into the *“health provider category.”* Your healthcare lawyer can explain if your integrative medical practice is considered a *“health provider.”* Part of the answer may depend on how the integrative healthcare provider bills his/her client. Many acupuncturists and other healthcare providers do not submit bills to insurance companies because the insurance often doesn't cover the services.

We have discussed whether HIPAA applies to acupuncturists before. There's currently no clear-cut answer but there are many U.S. Department of Health & Human Services guidelines and discussions that suggest (again, there is no absolute answer) that acupuncturists are considered health providers who should comply with HIPAA – if and when they submit electronic health records.

Your lawyer can also explain whether any state laws protect the disclosure of healthcare information. In California, the disclosure of healthcare information is governed by the California Confidentiality of Medical Information Act.

Do acupuncturists have to comply with HIPAA when they share an electronic medical record?

Whether HIPAA applies to acupuncturists who share a medical record, is one of those arcane questions our healthcare lawyers get. The answer isn't all that easy to obtain. Like many healthcare & [...]

The corporate practice of medicine and integrative medicine

California, like most other states, provides that corporations or related business entities cannot conduct the practice of medicine. The reason laws regulate the corporate practice of medicine is to ensure that the physicians are making decisions based on the best needs of the patient and not the financial needs of the business. Corporate directors should not be able to tell doctors how to treat their patients. The law is formally known as the Moscone-Knox Professional Corporation Act.

The Moscone-Knox Professional Corporation Act requires that only state-licensed physicians are permitted to own a medical practice. The law also provides that non-physicians (for example nurses and medical technicians) cannot own a medical business. Non-physicians may generally own an interest in a medical corporation provided that the majority ownership of the corporation is in control of the physicians.

Your California healthcare lawyer can explain whether an integrative medical practitioner can own shares in a medical corporation. Additional corporate practice of medicine issues include when a physician can act as a medical director of the corporation and when they can't.

The issue of who can own shares becomes more complicated when physicians and integrative health providers (licensed or unlicensed) work together. There are also issues that you need to review with a healthcare lawyer involving what acts constitute the practice of medicine. The lawyer will work to explain what boards and laws regulate the definition of the practice of medicine.

One specific type of medical practice that can be especially problematic are medical spas. Medical spas often work with

acupuncturists and other integrative healthcare providers. If you run or work for a medical spa, you need to review the proper boundary lines and regulations.

The California Acupuncture Board's – Laws and Regulations Relating to the Practice of Acupuncture.

The Board

- **Defines Acupuncture Corporations.** *"An acupuncture corporation is a corporation which is authorized to render professional services, as defined in Section 13401 of the Corporations Code, so long as that corporation and its shareholders, officers, directors, and employees rendering professional services who are acupuncturists are in compliance with the Moscone-Knox Professional Corporation Act, this article and all other statutes and regulations now or hereafter enacted or adopted pertaining to that corporation and the conduct of its affairs."*
- **Regulates acupuncture corporation income.** *"The income of an acupuncture corporation attributable to professional services rendered while a shareholder is a disqualified person (as defined in Section 13401 of the Corporations Code) shall not in any manner accrue to the benefit of such shareholder or his or her shares in the acupuncture corporation."*
- **The name of the acupuncture corporation.** *"The name of an acupuncture corporation and any name or names under which it may render professional services shall contain words 'acupuncture' or 'acupuncturist' and wording or abbreviations denoting corporate existence."*

Referrals and financial relationships with integrative medical providers

There are two federal laws that govern referral arrangements between medical practices and integrative medicine providers. Stark Law is a civil law. The Anti-Kickback Statute is a criminal law.

- **Stark Law.** Stark Law applies to physicians who treat patients on Medicare or Medicaid. The law prohibits physicians from referring Medicare or Medicaid patients to designated health services (called ancillary services) in which the physician (or a member of the physician's family) has a financial interest. Doctors must work on behalf of the patient and not their own financial interests. Essentially, the doctor must recommend ancillary services based on what is best for the patient's health – without consideration of any financial arrangement between the doctor and the service.

Doctors need to be particularly careful when they align themselves with medical spas who often use a variety of integrative health services.

There are numerous exceptions to Stark Law. These exceptions, in large part, center around the requirement that the relationship between the physician and the ancillary service should – not consider the volume or value of the physician referrals or business generated by the physician and the service. The exceptions also require that the financial arrangements be based on fair market value and commercial reasonableness. Some of the Stark Law exceptions include:

- - Leasing office space
 - Renting medical equipment
 - Bona-fide employment relationships
 - Doctor recruitment
 - Personal service arrangements
 - Other statutory exceptions
- **The Anti-Kickback Statute (AKS).** The AKS is a criminal statute that forbids inducements in order to obtain referrals from physicians. Inducements can include cash, vacations, meals, appointments to directorships, and other benefits that would

not be paid or provided – except for the desire to obtain the referral. The AKS generally applies to any claim submitted to the federal government for payment including Medicare, Medicaid, and TRICARE. Violations of the AKS include civil and criminal penalties. Both the person or entity providing the inducement and the person or entity receiving the inducement can be charged under the AKS.

The AKS does have “safe harbors” which can justify a financial relationship between a physician and an integrative health service. These safe harbors are comparable (but not identical) to the Stark Law exceptions. An experienced California healthcare lawyer can explain how safe harbors work and how they differ from Stark Law.

Experienced healthcare lawyers will also explain how the Anti-Kickback Statute is similar to Stark Law and how it differs. In addition, the attorney will explain what state anti-referral laws apply to a medical spa practice. Skilled healthcare lawyers will also review whether the violations of Stark Law or the AKS can lead to charges the physician or practice violated the False Claims Act.

We discuss Stark Law, the AKS, and California’s anti-referral (the Physician Ownership and Referral Act of 1993 in our article titled [Quick Summary of Federal “Stark” Self-Referral & Anti-Kickback Law and California Self-Referral and Fee-Splitting Prohibitions](#).

Additional integrative medicine compliance issues

A few other of the many compliance issues integrative healthcare provides such as acupuncturists should review with their health care provider are:

- The informed consent requirements for procedures
- How the FDA regulates drugs, medical devices, cosmetics, dietary supplements, and other products
- How the FTC regulations the marketing and branding of your integrative healthcare practice
- [Crucial Issues for Aesthetic Medical Practices – Part One](#)
- The various California laws including the California Labor Code

Integrative health practices include many different professions. Each profession needs to understand the applicable healthcare compliance issues. The doctors who work with integrative health practices also need to understand the full range of healthcare compliance issues. These issues include licensing, the corporate practice of medicine, the unauthorized practice of medicine, HIPAA, anti-referral laws, and other federal and California laws.

Doctors and integrative healthcare practices should [contact](#) Cohen Healthcare Law Group, PC to discuss all the laws and rules that regulate their profession. Our [experienced healthcare attorneys](#) help integrative healthcare practices and medical practices with federal and state compliance requirements.

[Contact](#) our [healthcare law](#) and [FDA attorneys](#) for legal advice relevant to your healthcare venture.