

Legal Compliance Issues for American Medical Tourism Health Practices

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American physicians are among those who are trying to determine how to take advantage of foreign medical tourism. The National Institutes of Health recently studied how medical tourism works abroad by examining some of the issues involved with foreign health care in Guatemala. While the study focuses on Guatemala, the study also indicates many of the concerns that may apply if an American physician wants to encourage foreigners from around the world to come to the US for American medical care and an American vacation.

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The study focused on Americans seeking healthcare based on their health needs while living in America – and not because the American became ill or injured while vacationing in Guatemala or because the American was living mostly abroad. Foreign countries are encouraging Americans to seek medical help in foreign countries and adding a vacation in that country while they recuperate. American doctors are encouraging foreign patients to come to America for treatments and care.

The study found the following concerns:

- The education and regulation of the health providers is a major concern
- The accreditation of the physicians and the health facilities is another concern. While Americans traveling abroad need to be concerned with substandard care, American physicians who offer medical services to foreigners need to ensure that their accreditations are current for the types of medical services they provide.
- Medical providers in America need to understand when services in the US might be illegal if the services were performed abroad.
- As medical tourism expands, there will be additional American regulations that regulate “*medical tourism brokers, on-line sites, or specialized training programs or certifications in medical tourism.*”
- The rights and duties regarding patient privacy and security of medical records needs to be addressed. Many foreign patients who receive treatment in America will want to take their medical records with them.
- The FDA and FTC may have concerns about which medications, cosmetics, medical devices, and other medical products are used on foreign patients
- Many other regulatory and safety issues may apply to medical practice by American physicians.

Corporate practice of medicine

Many states regulate the corporate practice of medicine.

“No matter how many times we address corporate practice of medicine and fee-splitting, they keep coming up in our practice, because in the arena of health and wellness services, non-doctors ultimately want to bring doctors into their venture.”

The two laws that govern the corporate practice of medicine in California are:

- **The Medical Practice Act, Business and Professions Code.** This law requires that anyone who practices or tries to practice (or holds themselves out as practicing) medicine must have a valid certificate to practice medicine that hasn't been suspended or revoked.
- **The Business and Professions Code, within the Medical Practice Act,** requires that *“Corporations and other artificial entities shall have no professional rights, privileges, or powers.”*

This means that when a California medical practice sets up a second business to encourage foreign patients to come to the US for treatment and for foreign doctors to recommend patients to come to California, that these second businesses may be practicing medicine without a license and may be engaging (along with the California medical practice) in the corporate practice of medicine.

An experienced healthcare attorney will explain that medical and clinical activities must be kept separate from the business of the non-medical company. The attorney may offer alternative arrangements such as the creation of a management services organization so that the business and medical practices can be separated.

Fee-splitting

California medical practices that work with other companies may be at risk for Stark Law violations and Anti-Kickback statute violations – especially if the physician has a financial interest in the related company. Stark Law protects patients by requiring that physicians not refer patients to designated health companies (such as other medical providers, testing services, therapy services, and medical device companies) if the physician or an immediate family member has a financial interest in the designated health service.

The Anti-Kickback Statute (AKS) provides that physicians cannot offer or receive remuneration (cash payouts, expensive vacations, sham directorships) in order to refer patients to the entity providing the inducement/kickback.

The purpose of both Stark Law and the AKS is to ensure physicians advise patients based on the patients' best interests and not the financial interests of the physicians. The laws also help to preserve the integrity of the healthcare system among other healthcare providers who play by the rules.

Regulators of medical tourism ventures need to ask:

- Whether there were any improper referrals
- Whether the entity used to market and promote foreign patients is a designated healthcare facility
- Whether such items as travel arrangements qualify as inducements/kickbacks
- Whether the designated health facility or secondary company is receiving part of the patient fee

Marketing and advertising

These days, much of the advertising that a medical practice does involves the Internet. Internet marketing can generally be

read anywhere in the world. The Federal Trade Commission (FTC) is a federal agency which monitors most forms of advertising, including website and social media advertising, to ensure that the representations are honest and that consumers/patients are not deceived. The FTC has the power to take enforcement actions against any medical practice that engages in dishonest marketing. When necessary, the FTC may employ translators to determine the meaning and veracity of advertising in foreign countries.

Physicians and medical practices that target foreigners who might want to come to the US for medical treatment need to review their online (and offline) advertising with an experienced FTC healthcare lawyer.

A main condition behind the enforcement authority of the FTC is that the FTC can require that each and every claim be substantiated. The physicians and medical practices that make claims need to have a reasonable basis for those claims. For example, if physicians assert that their treatments are only available in the US or only work well in the US, they need to have a reasonable basis for implying those treatments aren't available or effective in other countries.

"A firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act."

"Absent an express or implied reference to a certain level of support, and absent other evidence indicating what consumer expectations would be, the Commission assumes that consumers expect a "reasonable basis" for claims. The Commission's determination of what constitutes a reasonable basis depends, as it does in an unfairness analysis, on a number of factors relevant to the benefits and costs of substantiating a particular claim. These factors include: the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable. Extrinsic evidence, such as expert testimony or consumer surveys, is useful to determine what level of substantiation consumers expect to support a particular product claim and the adequacy of evidence an advertiser possesses."

FDA Regulatory Compliance

The Federal Drug Administration has authority to regulate American drugs, medical devices, dietary supplements, biologics, and cosmetics. A major incentive for foreigners to come to the US is that these medical products aren't available in their home country. Likewise, Americans often travel abroad to obtain access to drugs and other products and devices that haven't been FDA approved.

FDA has the authority to inspect practices, inspect products, and inspect online and offline marketing materials to ensure that the products FDA regulates aren't adulterated, that there aren't misrepresentations about the products, that products haven't been improperly classified, and to ensure other safety issues regarding the products.

Physicians who work in the field of medical tourism need to review with experienced healthcare lawyers when the products the physicians use on behalf of foreign patients may violate FDA rules and regulations. Physicians also should review with the attorney if and how FDA can expand its regulatory powers outside the United States.

In addition to compliance issues in the medical tourism sector, experienced attorneys can also help with issues of corporate structure, physician contracts, and many other business matters.

Practical considerations

An experienced healthcare lawyer will review the medical tourism practice of a California doctor by examining many issues such as:

- Identifying which bills should be paid to the professional medical corporation

- Identifying which bills the patient should pay to the medical tourism company for travel and related services
- Helping to ensure that the American medical practice isn't paying any third-party medical practice (especially one that the physician has a financial interest in) for giving referrals or receiving referrals
- When and how the medical tourism company might be able to charge either the California medical practice or a foreign medical practice for management and marketing services so that the company would likely meet the requirements of the California law against the corporate practice of medicine, and also meet Stark Law exceptions or the AKS safe harbor. For example, written contracts based on fair market value and commercial practices that are not based on the amount or quantity of referrals may be valid if other conditions are also met.

American physicians who want to encourage foreigners to come to the US for medical treatment need to be very careful of how they set up their medical practices and their relationships with any other companies such as a marketing or advertising company. If there are questions about whether any company is practicing medicine without authorization, that company may be charged with corporate practice of medicine. If the relationship between the physician practices and the management practices or other medical practices revolves around the payment of any fee, discount, or monetary matter, everyone involved may be subject to Stark Law and the Anti-Kickback Statute. All claims by the medical practice and the business practice may be reviewed by both the FTC and the FDA.

Contact Cohen Healthcare Law Group, PC for legal counsel on healthcare transactions, regulatory compliance, and FDA and FTC law. Our experienced healthcare & FDA attorneys advise healthcare companies and healthcare providers ranging from medical centers, to integrative and functional medicine practices, cosmetics and supplement companies, and medical device manufacturers.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.