

Integrative Medicine and Nutrition – Compliance Issues

February 22, 2022
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Integrative medicine encompasses many features such as homeopathy, cardiology, and acupuncture. Nutrition is another type of healthcare that physicians are using as part of their treatment plans. According to the American Board of Physician Specialties, integrative medicine means more than just recommending a standard dietary intake of vegetables, fruit, dairy, and protein. Integrative nutrition means *“ascertaining the individual dietary requirements of patients in order to develop personalized plans that optimize macro- and micro-nutritional intake.”*

The Board states that dietary guidelines should consider the following:

- *“Taking into account a patient’s lifestyle (sedentary vs. active).*
- *The influence of nutritional balance on overall health.*
- *How a mindful approach to eating patterns can contribute to better health.*
- *The ability of food (as opposed to nutritional supplements) to meet nutritional requirements.”*

Doctors who provide nutrition advice or work with nutritionists need to understand the federal and state rules that might affect this working relationship. Referrals between the doctor and a nutritionist practice may violate Stark Law or the Anti-Kickback Statute. Doctors and nutritionists need to understand how HIPAA affects the exchange of electronic patient information. Doctors and nutritionists need to understand what licensing requirements apply, the California law on the corporate practice of medicine, the unauthorized practice of medicine, and what type of supervision by the doctor is required.

A failure to understand the compliance issues can result in fines and possible loss of license and liberty.

How do physicians and medical practices incorporate nutrition into their medical treatments?

There are many different nutritional theories and approaches. Integrative medicine generally moves beyond traditional approaches such as surgeries, medications, and physical therapy. Integrative medicine, according to Today's Dietician, seeks to combine conventional medicine with “complementary and alternative medicine (CAM). One school, the Institute for Integrative Nutrition, even combines the two concepts by using the term *“integrative nutrition.”*

Alternative medicine generally includes *“unconventional healing modalities ranging from acupuncture, aromatherapy, biofeedback, and reflexology to healing touch.”* Integrative medicine also focuses on the mind and spirit as well as the body. Generally, nutritionists focus on a combination of food, vitamins, minerals and supplements to improve a patient’s health. For example, conventional medicine might use medications and therapy to treat depression whereas nutritional medicine focuses on herbs, dietary supplements, and diet.

Today's Dietician states that some of the components of integrative medicine include:

- **Food-mood connection.** Doctors and registered dietitians (RDs) examine how certain foods and supplements can affect emotional eating, depression, and behavior. Some studies show that a diet of fruit, vegetables, and healthy fats can *"alleviate depression and decrease irritability among the elderly and adolescents compared with a diet high in processed foods and sugar."*
- **Food cravings and addictions.** RDs focus on examining the factors (the type of food, when cravings occur, the patient's emotional state, and the *"release of specific chemicals related to cravings and addictions"*) that affect a person's well-being. For example, there are studies that show that food addictions are similar to drug addictions.
- **Dietary trends.** Doctors and RDs keep current with the latest food trends such as raw food diets and the Paleo diet.
- **Antioxidants and phytonutrients.** *"Nutritionists examine antioxidants and phytonutrients at the cellular level and how they relate to gene expression."*

Dietitians also examine many broader food issues such as *"food sustainability, food production methods, buying local food, organic vs. conventional farming practices, genetically modified foods, food marketing, and food labeling."*

RDs should, according to the principles of quality integrative nutrition set forth in Today's Dietician:

- Conduct an initial assessment that involves taking a thorough medical history
- Evaluate the client's medications, including those sold over the counter as well as supplements.
- Examine the patient's food habits
- Review the patient's emotional relationship with food
- Discuss whether the patient has any food or medication allergies.

Doctors and RDs should also consider evidence-based treatments such as pain management, gastrointestinal health, and autoimmune diseases – and migraine headaches and depression.

- **Migraine headaches.** Doctors and RDs work (often together) to determine the causes of migraine headaches which include caffeine, refined sugars, foods with monosodium glutamate (MSG), and other products. Unbalanced blood sugar levels and sinus problems may also cause migraines. Medical treatments and medical supplements are some of the possible remedies.
- **Depression.** Treatments often include medications, psychological counseling, and regular exercise. Nutrients *"have a positive impact on the brain neurotransmitters norepinephrine, dopamine, and serotonin. Depending on the number of nutrients a client consumes, nutrients can influence the quantity of neurotransmitters produced. RDs who counsel clients suffering from depression should ask clients if they experience episodes of emotional eating since depression can cause it."* Some of the vitamin and mineral supplements that may help relieve supplements include:

- Omega-3 fatty acids
- Folic acids
- SAME
- B vitamins
- Herbal supplements
- Turmeric
- Boswellia

- Other products including licorice and aloe vera.

Anti-inflammatory foods help with depression and other medical disorders. Inflammatory foods are known factors in “*arthritis pain, atherosclerosis, inflammatory bowel disease, and eczema.*”

Today’s Dietician states that:

- “*Whether recommending herbal or vitamin and mineral supplements, it’s important for RDs to know how the supplements are absorbed and impact the body, and to consult with their clients’ physicians before recommending them or any aspect of an integrative plan.*”
- “*Dietitians should use supplements from only reputable sources because the supplements’ quality can influence tolerance and effectiveness.*”
- “*Dietitians need to know the contraindications and drug interactions associated with each supplement and be cognizant of how the nutritional treatments may affect patients with various other health problems. It’s also important to monitor patients for any side effects or adverse events.*”

Integrated medicine and nutrition – the unauthorized practice of medicine

We’ve written about the broad legal issues involved with integrative medicine before. The discussion of the current uses of nutrition to help patients with a range of physical and emotional disorders shows that there is often a fine line between giving patients medical advice and giving patients nutritional advice. As a general starting point, doctors and registered dietitians (or other nutritionists) need to understand when physicians must control, supervise, monitor, or provide nutritional decisions.

California has the following laws that apply to nutritionists and physicians who fail to properly their medical practice with the nutritionist’s healthcare practice:

ARTICLE 3. License Required and Exemptions

2051. The physician’s and surgeon’s certificate authorizes the holder to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions.

2052. (a) Notwithstanding Section 146, any person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person, without having at the time of so doing a valid, unrevoked, or unsuspended certificate as provided in this chapter or without being authorized to perform the act pursuant to a certificate obtained in accordance with some other provision of law is guilty of a public offense...[Certain punishments apply].

In addition, the Medical Board of California regulates the practice of medicine. Failure to comply with these regulations may result in the loss of a medical license and other consequences.

Our skilled healthcare lawyers explain the laws and regulations that apply to the integrative practice of nutrition. We also review what proactive steps physicians, registered dietitians, nutritionists, and other healthcare nutritional professionals should take to reduce the risk of non-compliance.

5 LEGAL ISSUES FOR INTEGRATIVE HEALTH PRACTITIONERS IN THE NEW YEAR

With 2015 right around the corner, here are 5 legal and regulatory issues that integrative health practitioners need to know.

The corporate practice of medicine and integrative nutrition

California, like most states, requires that the patient care and the financial interests of the physicians be separated so that doctors are making decisions based on the best interests of the patient and not the financial interests of the medical practice.

As medical practices expand the healthcare professionals who are part of the practice and the owners of the practice need to make sure that the practice is run by the physicians – and not by any nonphysicians such as non-physician nutritionists – and not by corporations or related businesses.

The law that governs the corporate practice of medicine is the Moscone-Knox Professional Corporation Act. This law requires that only doctors licensed in California can own a medical practice. There is an exception which doctors and nutritionists should review with experienced healthcare lawyers. Provided the majority of the owners are state-licensed physicians, non-physicians can own a minority interest in the medical practice.

Integrative nutrition and the Health Insurance Portability and Accountability Act (HIPAA)

HIPAA regulates the electronic exchange of patient health information. HIPAA applies to healthcare providers, insurance companies, and other entities. The law applies to *“claims, benefit eligibility inquiries, and referral authorization requests.”*

When doctors work with dietitians and nutritionists, there is often the need to share a lot of information. As discussed above, dietitians need to understand a patient’s medical history, what medications the patient is taking, and many other medical issues. Whether the doctor or nutritional practitioner is bound by HIPAA depends on how the patient information is shared and what the information is used for.

Protocols should be set in place to properly share information while respecting the patient’s rights and privacy. One factor that may affect whether HIPAA applies is whether the nutritionist bills the insurance carrier for their medical care. Another factor involves the business relationship between the physician practice and the nutritionist – for example, whether the nutritionist is an employee of the medical practice or independent from the physician practice

Integrative nutrition and Stark Law, the AKS, and patient referrals.

Medical and nutritional practices need to understand how Stark Law (a civil law) and the Anti-Kickback Statute (a criminal law) apply to their business relationships. When a medical practice refers patients to a nutritional practice (and vice-versa), the referral must be based on what is the best medical care for the patient and not the financial health of the healthcare practices. Skilled healthcare lawyers explain what conduct violates Stark Law or the Anti-Kickback Statute (AKS), whether any exceptions/safe harbors apply, and what steps should be considered to meet the exceptions/safe harbors.

Stark Law essentially prohibits physicians who bill Medicare or Medicaid from referring patients to a nutritional practice – if any physicians or the practice itself has a financial interest in the nutritional practice. Stark Law also applies to referrals from the nutritional practice to a medical practice.

Stark Law exceptions may be permitted, if the proper steps are taken, to permit a nutritional practice (or medical practice) to lease office space, rent medical equipment, maintain bona-fide employment relationships, keep personal service arrangements from the other practice. Other exceptions may also apply.

The AKS prohibits referrals based on any type of inducement such as cash, vacations, meals, or medical directorships. The AKS generally applies when bills are submitted to federal agencies such as Medicare, Medicaid, and TRICARE. The AKS uses “safe harbors” which are similar but not identical to the Stark Law exceptions to help justify certain financial relationships between a medical practice and a nutritional practice.

Both Stark Law and AKS violations may result in the filing of a False Claims Act lawsuit.

STARK LAW EXCEPTIONS THAT MIGHT APPLY TO YOU

In today's video, we discuss some exceptions to Stark Law, which deals with improper referrals by physicians and healthcare practitioners.

RECENT STARK LAW AND ANTI-KICKBACK STATUTE CASES

Medical providers must abide by Stark Law and the AKS. Referrals must be based on what is best for the patient. If profit is the driver, the providers will often pay a substantial settlement or [...]

Additional integrative nutritional compliance issues

FDA does regulate dietary supplements. Doctors and nutritionists who prescribe or recommend dietary supplements should review the FDA dietary supplement regulations with an experienced healthcare lawyer.

There are also regulations that govern the marketing and advertising of dietary supplements, medical practices, and nutritional practices.

California generally requires that healthcare providers comply with the state's informed consent requirements.

Integrative nutritional practices offer more care options for patients and more opportunities for doctors and nutritionists. Physicians and nutritionists need to understand when the care they provide may constitute the unauthorized practice of medicine, may violate the corporate practice of medicine, may fail to comply with Stark Law or the AKS, and may violate other federal and state laws and regulations.

Physicians, medical practices, registered dietitians, and nutritionists should contact Cohen Healthcare Law Group, PC to discuss their federal and state compliance issues. Our experienced healthcare attorneys help healthcare providers understand and address their legal requirements.

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