COURSE DESCRIPTION

Patient use and acceptance of complementary and alternative medicine (CAM) therapies in the United States is increasing. However, many legal issues remain unresolved surrounding provider oversight, inconsistent legislative mandates regarding definitions about standards of care and scope of practice, liability issues for providers and organizations, and lack of knowledge about CAM therapies.

The outcome of this course is for the learner to describe the major legal issues facing biomedical providers and integrative health providers, state laws relating to the regulation, credentialing concerns, malpractice and liability issues, and third-party reimbursement.

COURSE OBJECTIVES

Upon completion of this course, you will be able to do the following:

1. Describe state law issues relating to the regulation of medical and CAM providers.

2. Describe key elements of the credentialing process for physicians and CAM providers.

3. Describe liability issues for health care organizations.
4. Explain the relationship between CAM therapies and health literacy, health freedom, and access to treatment.

5. Identify key issues related to herbal medicine and dietary supplements in patient care.

6. Identify key issues related to referrals to CAM providers.

7. Identify essential elements in the disciplinary process for health care providers.

8. Describe third-party reimbursement issues related to CAM therapies.

9. Define “willing provider laws.”

10. Explain key issues related to reimbursement, health care fraud, and experimental or medically unnecessary treatments.

NOTE: This course is designed to provide an overview of these issues. The information is educational only and is not meant to substitute for appropriate legal counsel and/or ethical advice. Anyone interested in specific issues related to practice should consider consulting and retaining an attorney familiar with his or her specific situation and the pertinent laws of the state(s) and issue(s) in question.
INTRODUCTION

There are many dynamic legal issues related to complementary and alternative medicine (CAM) and the practice of CAM therapies that impact today’s health care environment. The National Center for Complementary and Integrative Health (NCCIH), CAM is a group of diverse medical and healthcare systems, practices, and products that are not generally considered part of conventional medicine. Although scientific evidence exists regarding some CAM therapies, there are still questions to be answered about whether these therapies are safe and whether they work for the purposes for which they are used (Cady, 2009). However, as this environment continues to change, these issues are certain to evolve as well.

What is law? Zetler & Bonello (2012) define it as the sum total of rules and regulations that govern a society is governed and which are created by people and exist to regulate all persons in that society. Laws are never separate from the current political, social, and economic influences of the time and location in which they are created. Understanding the law is an obligation of all health care providers and is essential to their safe and effective practice. Laws are important for health care practitioners because they (Zetler & Bonello, 2012):

- provide a framework that establishes which actions are legal when caring for patients;
- help establish boundaries for the actions of independent health providers;
- differentiate the responsibilities of health care providers from other types of health professionals; and
- maintain a standard of practice that holds health care providers accountable for their practice.

STATE LAW REGULATION OF MEDICINE AND HEALTH CARE PROVIDERS

While many mistakenly believe that the practice of medicine is legislated at the federal level, it is actually the states and state laws that authorize specific individuals to practice medicine. State laws establish licensing boards that admit or exclude others from the practice. This power was designed to protect the health, safety, and welfare of citizens from unskilled and unlicensed practitioners and to protect the public from “ignorant, unprepared, quacks and fakers” (Cohen, 1998, p. 24). Yet, licensing has been and remains, in large part, a political process. As a political process, licensing has also excluded, suppressed, or marginalized those individuals in a healing practice who use modalities outside the paradigm of biomedicine (or conventional medicine).

Each state has a medical licensing statute or medical practice act that supports its policing power. While the definitions of the “practice of medicine” differ by states, all states include some of the following defining elements in their medical practice acts (American Society for Dermatologic Surgery, 2016; Cohen, 1998; Federation of State Medical Boards, 2002; Washington State Legislature, 2011):

- **Diagnosing, preventing, treating, and curing disease, ailment, injury, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality**

  Individuals who practice medicine are allowed to use these terms in their care delivery process. These words are usually used in conjunction with
the terms disease, injury, deformity, and mental or physical condition. Registered nurses, for example, are not permitted to “treat” a patient.

- **Holding oneself out to the public**

  This is described in some state laws as “publicly professing” to be a physician or surgeon or assuming the duties that relate to the practice of medicine.

- **Intending to receive a gift, fee, or compensation for the above**

  This definition is, in most states, tied to diagnosing and treating diseases but some states (such as Hawaii, Louisiana, and Utah) specifically state that individuals can be held to practice medicine even if they do not receive any compensation.

- **Attaching such titles as MD to one’s name**

  In approximately half of the states, an individual is considered to be practicing medicine if one or more of the following is attached to his or her name: doctor, doctor of medicine, doctor of osteopathy, physician, surgeon, Dr., MD, DO, or other words or abbreviations intended to indicate to others that the individual is licensed to practice medicine and engages in the duties characteristic of the practice of medicine (Cohen, 1998, p. 27). There are some state variations, however. For example, in Delaware, using the word healer in connection with one’s name is considered practicing medicine.

- **Maintaining an office for reception, examination, and treatment**

  In many states, maintaining an office in which an individual receives care, or a practitioner examines, treats, advises, or corrects for any human condition constitutes practicing medicine.

- **Performing surgery**

  Approximately half of the states include the performance of surgical procedures in their definition of practicing medicine. This is the narrowest and most tailored criteria for prohibiting practitioners who lack the proper education and training from engaging in the practice of medicine.

- **Using, administering, or prescribing drugs or medicinal preparations**

  More than 50% of states include the use, administration, or prescription of drugs or medicine in their definition of practicing medicine. Very few have
defined the word *drug*, however. Some have provided broad definitions; this poses problems for nonmedical providers who offer herbal and nutritional therapies as part of their practice.

According to Cohen (1998), the breadth of these medical practice acts puts at least three groups at risk of prosecution for unlawfully practicing medicine:

1. **Non-licensed providers** (such as those practicing naturopathy, massage therapy, hypnosis, and therapeutic touch)

2. **Licensed providers** (including biomedical physicians, advanced practice nurses, and naturopaths) who employ or refer patients to those practicing medicine unlawfully and thereby expose themselves to liability for “aiding and abetting” unlicensed medical practitioners

3. **Licensed providers** (such as chiropractors, massage therapists, and licensed naturopaths) who are seen to violate their legally authorized scope of practice by engaging in the diagnosis and treatment of disease

For all health care providers, individual state laws, licensing boards, practice acts, and regulations also define the practitioners’ scope of practice. Individuals are prohibited
from practicing outside their scope of practice. These laws, licensing boards, and regulations also describe the education and training requirements for health care providers.

State laws are primarily responsible for licensing the following individuals (American Academy of Physician Assistants, 2017; Cohen, 1998; Federation of State Medical Boards, 2002):

- Specialists who practice within the parameters of biomedicine (such as dentists, veterinarians, pharmacists, physical therapists, nurses, and podiatrists)
- Specialists who practice directly under biomedical physicians’ supervision (such as physician assistants and respiratory therapists)
- Providers of complementary and alternative medicine (such as acupuncturists and chiropractors)

Credentialing and Privileging of Physicians and Allied Health Care Providers

The process of credentialing and examination of credentials for health care providers is designed to ensure the providers meet specific health care (and health center) standards (U. S. Department of Health and Human Services, 2016a).

**Credentialing** is the process of obtaining, verifying, and assessing a practitioner’s education, training, residency, licenses, certifications, competency, malpractice and adverse occurrences, clinical judgment, and character through investigation and observation. It is used to evaluate the qualifications and practice history of a practitioner (American College of Medical Quality, 2010; The Joint Commission, n.d.).
Credentials are the documented evidence of licensure, education, training, experience, and other qualifications. A provider’s credentials (licenses, certificates, and diplomas) help define and describe his or her professional qualifications to advise and treat patients. Whether the individual is a biomedicine physician or any other type of CAM practitioner, the assurance that he or she is qualified remains equally important (NCCIH, 2016a).

There are two main types of practitioners who can be credentialed:

- **Licensed independent practitioners (LIPs)** are individuals allowed by law and by a health care facility to provide undirected or unsupervised care and services consistent with individually granted clinical responsibilities and terms of licensure (The Joint Commission Resources, 2007). Scope of practice may vary from state to state and The Joint Commission allows hospitals to define professionals who are considered LIPs as long as they conform to state laws. Physicians, dentists, oral and maxillofacial surgeons, and podiatrists are the most common examples of LIPs. However, in some states, nurse practitioners, clinical psychologists, registered dietitians, chiropractors, and clinical social workers may also be LIPs.

- **Allied health professionals (AHPs)** are defined as those healthcare professionals trained or licensed to assist, facilitate, or complement the work of other specialists in the healthcare system, such as traditional (biomedical) physicians, dentists, podiatrists, nurses, and pharmacists. However, each hospital uses the AHP designation differently (since the definition can vary by state) and so the term can be applied to certified registered nurse anesthetists (CRNAs), nurse practitioners, or physician assistants. Often, medical staff bylaws of hospitals will define the terms. Allied practitioners are prohibited from practicing medicine.

Credentialing begins at the state level and continues when a health care provider seeks to practice at a health care organization. For biomedical practitioners, the dominant form of state-sanctioned credentialing is mandatory licensure. The Federation of State Medical Boards (FSMB) promotes public health and safety, and maintains high standards of performance by medical boards through effective and fair medical regulation and discipline (FSMB, 2017).

Medical licensing has been criticized as protecting the licensed individual, not the patient, by insulating traditional (biomedical) physicians from the economic threat of other providers. Licensing originated in the “colony of New York in 1760 as a means to prevent ‘ignorant and unskilled persons’ from ‘endangering the lives and limbs of their patients, and many poor and ignorant persons, who have been persuaded to become their patients’ ” (Cohen, Ruggie, & Micozzi, 2007, p. 27).
Licensure does offer some level of consumer protection but it has been ineffective in controlling incompetent or fraudulent practitioners. In addition, medical licensing boards are staffed by individuals drawn from, and committed to protecting, the licensed profession and so the medical licensing boards can be seen as continuing to perpetuate the interests of those parties, and not the interests of the patients (Cohen, 1998).

For the nonlicensed holistic provider, licensure offers the following benefits (Cohen, 1998):

1. It elevates the image of the profession by creating a minimum level of professional competence required for practice.
2. It calms public and legislative concerns over quality control.
3. It allows professionals to maintain control over their own profession by creating guidelines, rules, etc.
4. It provides a recognized basis for hospital privileges, insurance reimbursement, and other professional opportunities.

Biomedical physicians, because they are authorized by state laws to diagnose and treat disease, can also provide CAM therapies (such as nutritional counseling, biofeedback, herbal medicine, and hypnotherapy). At the same time, states may or may not allow other licensed health care professionals (conventional or CAM) to provide these therapies or they may not have laws that address the question (NCCIH, 2016a). This creates confusion and frustration among health care providers and consumers alike.

Credentialing differs from privileging in that privileging defines a health care practitioner’s scope of practice and the clinical services he or she may provide. Privileging is based on demonstrated competency and is a data-driven process. Privileges are granted by an appropriate authority (often a health care organization or network) and include well-defined limits (American College of Medical Quality, 2010; The Joint Commission, n.d.).

Privileging involves four distinct activities (The Joint Commission Resources, 2007):

1. Determining which clinical procedures or treatments will be offered and supported by the organization
2. Determining the training and experiences required for authorization to perform the clinical procedures and treatments
3. Determining whether applicants for privileging meet the requirements and then officially granting or denying the requested privileges
4. Monitoring the individuals who are granted privileges to ensure they remain competent and practice within their scope of granted privileges.

Credentialing and privileging ensure that the mission of the health care organization—meeting the needs of patients by providing quality care—is met effectively and safely. Both processes are the result of a confidential, protected, peer-review (usually medical staff) process with qualified and objective participants. The patient mix of a health care organization and referrals to outpatient clinics or other specialists are never a factor in the credentialing process. The decision to deny, grant, or renew privileges is an objective, evidence-based process. According to the American College of Medical Quality (2010), the peer-review process uses criteria that:

- have been established through legal, professional, and administrative practices;
- have been endorsed by a formal consensus process;
- are publicly available; and
- are directly related to high-quality, safe patient care.

The Joint Commission requires all individuals who are permitted by law and by the hospital or health care organization to provide patient care services independently in the hospital or health care organization to have specified clinical privileges, whether or not they are members of the medical staff. Even health care providers who can provide care independent of medical supervision and are permitted by their licensing statutes and hospital rules to do so, must receive formal clinical privileges (Cohen, 2005).

The foundation of a credentialing and privileging program is an organization-wide, high-quality, cost-effective competency assessment program. But what does competency mean?

The Joint Commission defines competency as an individual’s capability to perform up to a defined expectation and a person’s having the knowledge, skills, ability, and behaviors to perform tasks correctly and skillfully (The Joint Commission Resources, 2007). Nursing competency is defined in a similar fashion (Whalen, 2006).

- **Knowledge** involves the preparation for performance (through coursework, tests, licensure, and experience).
- **Skill** is the demonstration of that knowledge through direct observation or specific outcomes of the performance.
- **Competence** is usually assessed and verified in the job setting through performance appraisals.
Competency skills include the following (The Joint Commission Resources, 2007):

1. **Cognitive skills**, which involve the ability to analyze situations, anticipate future events, and think critically so one can be proactive rather than reactive

2. **Psychomotor skills**, which involve the ability to perform physical tasks learned from skill-based training, books, and lectures

3. **Interpersonal skills**, which involve attitudes, interests, values, emotions, appreciation, and the ability to work effectively with others

Cultural and linguistic competence is also critical and involves attitudes, skills, behaviors, and actions that enable an individual to work respectfully and effectively with individuals from culturally diverse backgrounds.

**Credentialing of CAM Practitioners**

Current laws and statutes governing the credentialing of CAM practitioners arose from the competition, health care factions, and professional monopolies of the 1800s and 1900s. The suppression and resulting decline of health care practices outside mainstream medicine occurred as a result of several events during this time (Cohen, 2005):

- Medical licensing laws ensured that only those meeting criteria set by traditional practitioners of medicine could legally practice.
- Nonconforming providers were expelled from medical societies.
- The public campaigned against “irregular” practitioners, partly as a result of the political power of “traditional” practitioners and organizations to which they
belonged and the negative publicity they dispersed about “irregular” practitioners.

- Medical ethical codes forbade associating and consulting with complementary and alternative medicine practitioners.

- The American Medical Association became the dominant voice in the U.S. healthcare system.

Despite these events, acceptance of CAM providers in the United States is growing rapidly. Globally, approximately 80% of the world’s population relies on non-Western, “traditional medicine” such as Ayurveda, acupuncture, traditional oriental medicine, and folk medicine and considers biomedicine to be “alternative” medicine. The ability to credential these providers is essential if integrative health care is to evolve in the United States (Cohen, 2005).

Credentialing CAM practitioners is essentially the same process as credentialing traditional physicians and allied health professionals; however, there is no standardized, national system for credentialing CAM practitioners. The extent and type of credentialing varies widely between CAM professionals and among the various states. Usually, if a state regulates a CAM professional, that state uses some or all of the criteria utilized for (biomedical) physician credentialing (NCCIH, 2016a). For example, practitioners who practice dependently under the supervision of a medical doctor (MD) or doctor of osteopathy (DO) usually go through a similar credentialing process as the physician, although it is often not as rigorous as the process traditional physicians must go through. In addition, the credentialing process often occurs through the human resources department or through departments specific to the practitioner’s specialty (such as physical therapy, nutrition, or exercise physiology). The medical staff office is usually not involved (Cohen, 2005).

Some institutions may set standards regarding liability risk and may therefore have credentialing criteria that examines whether a certain level or kind of claim (in either the malpractice or disciplinary area) is sufficient to prevent hiring a specific candidate. For example, an organization may be willing to dismiss unproven claims of negligence while choosing not to dismiss claims about allegations of sexual abuse that went to trial (Cohen, 2005).

Additional criteria that can be set by organizations when considering whether or not to credential CAM providers can include the number of years in practice; references by MDs, DOs, and other conventional practitioners; and assessments conducted at site visits in the CAM practitioner’s current practice. In addition, organizations can check the National Practitioner Databank, a national register of biomedical physicians, dentists, and health care practitioners developed by the federal government (U.S. Department of
Health and Human Services, 2017). Chiropractors have their own inter-jurisdictional Chiropractic Information Network—Board Action Database, called CIN-BAD, which is run by the Federation of Chiropractic Licensing Boards (Federation of Chiropractic Licensing Boards, 2017).

Developing a credentialing process for complementary and alternative medicine providers that is more extensive than that done for traditional physicians and LIPs serves three objectives for an organization (Cohen, 2005):

1. It provides consumers with the ability to access CAM therapies in a safe, effective manner.

2. It increases the availability of a standardized structure that is familiar and considered reputable and dependable by
   - clinicians who make referrals to CAM practitioners,
   - health care organizations providing care to patients,
   - third-party payers, and
   - patients seeking specific complementary and alternative medicine treatments or provider(s).

3. It supports the global, systemic integration of biomedicine and complementary and alternative medicine.

Once formal clinical privileges are granted, they cannot be removed arbitrarily. Their removal is subject to due process rules (the legal requirement to protect the rights of individuals under the law). In addition, hospitals often have rules governing the introduction of CAM therapies. The CAM therapies need to be presented to relevant hospital committees and may need to be evaluated in light of the scope of practice of various health care providers. Organizations usually examine the guidelines developed by the various state boards of nursing, the Federation of State Medical Boards, and other relevant licensing boards when making their decision about which CAM therapies to allow.

According to Cohen (2005), with the recent upsurge in the use and acceptance of complementary and alternative medicine therapies, new questions continue to arise about the credentialing process of CAM providers. Conventional medical attitudes about control of regulatory and reimbursement structures are no longer in alignment with patient values, beliefs, and desires. As a result, legislative changes reflecting social and regulatory changes may trump the medical community’s recognition of these therapies as effective and important. Ultimately, scientific evidence serves to enlighten both
legislative actions and medical behaviors. This evidence is essential to the ongoing refinement of the U.S. health care system.

**Professional Certification: What Does It Mean?**

Certification is a process by which an individual proves that he or she has the education, experience, knowledge, and skills to perform certain tasks. Professional certification is usually bestowed once the individual passes an exam that is administered by an organization or association that adheres to a set of standards prescribed for a particular industry. Certain CAM professional organizations may offer their providers certifications. Certification is almost always a prerequisite for state licensure. For example, many states require certification by the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM). Professional certification may also require continuing education in the particular area of study. The specific numbers of contact hours and requirements vary by state (NCCIH, 2016a).

**Education and Training**

For some CAM providers, the U.S. Department of Education (DOE) authorizes specific organizations to accredit education and training programs. Two examples are the Council on Chiropractic Education (authorized by the DOE to accredit chiropractic colleges) and the Accreditation Commission for Acupuncture and Oriental Medicine (authorized to accredit acupuncture programs). DOE accreditation only applies to education and training programs, not to licensing (NCCIH, 2016a).
Some national organizations have written and/or oral examinations for graduates of DOE-accredited schools. Examples include (NCCIH, 2016a):

- The National Board of Chiropractic Examiners
- The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM)
- The American Association of Naturopathic Physicians
- The National Certification Board for Therapeutic Massage and Bodywork

**Liability Issues for Health Care Organizations**

Health care institutions that employ traditional or complementary and alternative medicine professionals face two types of malpractice exposure (Cohen, 2000):

1. **Direct liability** (also called “corporate negligence”) for an act or omission of the organization. This means the organization has been directly negligent to the patient, either by doing something careless to injure the patient or by carelessly neglecting to do something that should have been done, resulting in injury to the patient. An example would be an organization’s failure to properly supervise a CAM (or conventional) health care professional.

2. **Vicarious liability** (also called *respondeat superior*) for an act or omission of the individual provider. This means the organization failed to do something it should have done. A health care organization is responsible for the acts of its employees (or “agents”). An example of vicarious liability would be when a nurse fails to check the patient’s vital signs according to policy.

These two theories of liability apply whether CAM or conventional therapies were used.

**Safe and Adequate Facilities**

A primary requirement of any health care organization is the provision of safe and adequate facilities and equipment for its patients and staff. Some equipment (such as an X-ray machine) is easy to design so patients can be protected. This requirement can be challenging, however, for mind-body interventions that rely on intuition, subtle energies, and other dimensions of the human experience that are not easily measurable in current scientific terms. These interventions may include (Cohen, 2000):

- Meditation
- Hypnosis
- Imagery
As Cohen (2000) sagely notes, “Neither the language nor the paradigm of current legal rules has caught up to the shifting and multidimensional currency of a system of care in which consciousness and intention are viewed together with biochemical, pharmacological, and physiological perspectives as crucial factors in patient healing” (p. 62).

While certain basic safety measures apply to both traditional physicians and CAM practitioners (such as the effective use of an X-ray machine or the use of sterilized needles in acupuncture), other safety requirements may require a delicate balance between the health care organization’s obligation to monitor the quality of care being provided while at the same time “protecting the therapeutic encounter and the notion of sacred healing space” (Cohen, 2000, p. 62).

**Health Literacy and Health Freedom**

Health literacy is defined as the ability to seek, find, understand, and appraise health information from various sources and then apply that knowledge to address or solve a health problem (Norman & Skinner, 2006). If some providers deliver care that is inaccessible to much of the rest of the population for which it was intended, then the very individuals whom health care providers are seeking to help will be unable to obtain or use the information. This can dramatically (and sometimes tragically) affect health. In addition, a society in which a large percentage of its members are functionally illiterate is a society that struggles economically, socially, and politically (Norman & Skinner, 2006).
In the United States, nearly 9 of 10 adults have difficulty using the everyday health information that is routinely available in health care facilities, the media, and communities. Limited health literacy is associated with poorer health outcomes and higher health care costs because it affects the ability of an individual to search for, and use, health information, adopt healthy behaviors, and act on important health alerts (Office of Disease Prevention and Health Promotion, 2017). Globally, the statistics are also concerning. A recent report about literacy in the United Kingdom (UK) has shown that one in six young people leave school unable to read, write, or add numbers properly. Millions of adults in the UK are also functionally illiterate and millions more have difficulty with numbers as well (Crown, 2006).

Many individuals seek health information on the Internet, which also can be challenging. Over 65% of the World Wide Web’s content is in English, so non-English speaking individuals may find it difficult to obtain understandable information that meets their needs (Norman & Skinner, 2006).

The concept of health care freedom and the corresponding concept of health literacy are critical in the delivery of effective, ethical, conventional or CAM health care. According to Cohen (1998), when patients face serious or life-threatening diseases in which conventional biomedicine has failed or presents unacceptable side effects or risks, or when patients simply want to utilize CAM therapies, those patients have a right to care for their own bodies and choose therapies for their situation without the federal government filtering their access to those therapies. This right to health care freedom continues to be debated. In addition, the issue of how to effectively address health literacy is a subject of increasing interest and concern.
Access to Treatment

Providing access to potentially useful therapies while simultaneously protecting the public from harmful therapies is the goal of many regulatory agencies. Inequities in the ability to access care (due to geographic, social, economic, or political issues) can have far-reaching effects and can mean the difference between life and death.

Regulations about new drugs, nutritional treatments, medical devices, etc., can often be at odds with an individual’s right to privacy and autonomy. For example, according to Cohen (1998), in *United States v. Rutherford*, the U.S. Supreme Court rejected the efforts of terminally ill cancer patients to obtain laetrile on the basis that the drug is ineffective and unsafe. The Court determined that while a patient has a right to decide which treatments he or she might undergo, the selection of a particular treatment or medication is within the area of governmental interest in protecting public health and is outside the constitutional right to privacy.

The Access to Medical Treatment Act (AMTA) was introduced in 2005 to Congress to (Civic Impulse, 2017):

- give individuals the right to be treated by a health care practitioner *with any medical treatment the patient desires*, including treatment that is not approved, certified, or licensed by the Secretary of Health and Human Services; and
- authorize health care practitioners to provide any method of treatment to such an individual if certain requirements are met.
The AMTA was never passed.

As the use of CAM therapies grows, access to these treatments will become an increasingly important issue when examined in the context of the ethical concepts such as autonomy and health care freedom.

**Herbal Medicine and Dietary Supplement Issues**

Herbal medicine and supplements are probably the fastest growing segments of CAM therapies. Most patients do not tell their (traditional) physicians about their herbal and/or dietary supplement use. Often patients are concerned about what their biomedical physicians will think, and most of these physicians either do not ask or are not very knowledgeable about herbs and/or supplements.

Regulation of dietary supplements is probably the greatest area of controversy in CAM at the present time. Lawmakers, consumers, providers, and supplement manufacturers are engaged in intense debates about how these supplements should be regulated and how those regulations should be enforced. Skidmore-Roth (2010) notes that, currently, the lack of regulation is probably the single biggest issue affecting the reliability of commercial herbal products in the United States.
In the United States, clinical trials are used to demonstrate the safety, efficacy, and reliability of drugs. Expensive and time consuming, clinical trials can take anywhere from 8 to 18 years and cost hundreds of millions of dollars. As a result, drug manufacturers patent their products to recover their investment and make a profit. Naturally occurring herbs, on the other hand, have numerous elements that interact with each other to create a result. Isolating a particular element and testing its efficacy is difficult. In addition, naturally occurring herbs cannot be patented, so no economic incentive exists to do research on them and only limited research is underway on whole plants and crude extracts (Freeman, 2008; Skidmore-Roth, 2010).

The U.S. government has not supported the quality control or patenting of herbs because herbs have not been “discovered” (in the sense of other medical/pharmaceutical discoveries) and manufacturers are therefore not motivated to invest much in testing or promoting them. There is also a limited supply of well-educated botanists and traditional healers and only a handful of ethnobotanists who can catalog the medicinal properties of plants (Leddy, 2006). Herbal medicine in the United States has therefore yet to be subjected to the same level of scientific scrutiny as traditional medical treatments and, as a result, has not gained wide acceptance by mainstream medicine. This might be one of the reasons that clients do not disclose their use to their health care practitioners (Skidmore-Roth, 2010).

Current food and drug laws, the courts, Congress, and the Food and Drug Administration (FDA) were all developed within the paradigm of the traditional biomedical model, which promotes a culture of medical paternalism and supports the notion that patients have to be protected from “worthless” or dangerous treatments. As a result, rules and legal decisions have emphasized the dangers of access to untested treatments rather than supporting the paradigm of patient choice or health care.
freedom. The enactment of these laws places dietary supplements in a category that causes legal and clinical confusion (Cohen, Ruggie, & Micozzi, 2007; FDA, 2016a).

In the United States, the Food and Drug Act of 1906 addressed the quality issue of medicinal drugs. The Federal Food, Drug, and Cosmetic Act of 1938 addressed safety, and a 1962 amendment to the 1938 act required proof of therapeutic efficacy.

European and American phytomedical manufacturers have petitioned the FDA to allow well-researched European herbs the status of “old drugs” so they would not have to undergo the prohibitively expensive new drug application process. They have not had much success (Freeman, 2008). Medicinal herbs are regulated as dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) of 1994, which was amended in 1998. Medicinal herbs are considered safe unless proven unsafe by the FDA.

Manufacturers are permitted to provide information about their herbs but are not allowed to endorse any particular product. The information may not be misleading, and it must be physically separated from the product. No medical claims are allowed on dietary supplement labels. The labels can state only the structure and function of the product, directions for use, warnings, side effects, contraindications, safety data, and a description of the product’s properties (FDA, 2017; Freeman, 2008; Holt & Kouzi, 2002; Skidmore-Roth, 2010). Labels must state that the product is a dietary supplement, contain a disclaimer that the FDA has not evaluated any health claims, and state, “This product is not intended to diagnose, treat, cure, or prevent any disease” (FDA, 2016b).

Given the lack of regulation of herbal products, the content and quality of active chemical constituents can vary widely from manufacturer to manufacturer (Holt & Kouzi, 2002). This is partly due to the fact that the way an herb is grown, harvested, processed, and stored affects its strength and quality. Some manufacturers voluntarily adhere to so-called good manufacturing practices (GMPs), but herbal products can be produced without meeting these compliance standards and they can be marketed without prior FDA approval of their efficacy and safety (Leddy, 2006; Micozzi & Meserole, 2015; Skidmore-Roth, 2010).

In Europe, herbs are more readily accepted than in the United States. For example, Germany is probably the world leader in developing herbal safety and efficacy standards (Freeman, 2008), and the German Commission E Monographs are considered to be the definitive source of information on herbs and the most authoritative herbal evaluations currently available. Commission E is a German governmental body like the U.S. FDA and is comprised of health care professionals including physicians, pharmacists, pharmacologists, and toxicologists, as well as representatives of the pharmaceutical industry and laypersons. As of 2001, Commission E had published monographs about 400 herbs. German law allows manufacturers to market herbs with
drug claims if the herb has been proven safe and effective, and prescriptions for herbs in Germany are reimbursable by insurance (Freeman, 2008; Holt & Kouzi, 2002; Skidmore-Roth, 2010; Trivieri & Anderson, 2002).

The European Economic Community (EEC) developed a set of guidelines that outline standards for the quality, quantity, and production of herbal remedies and set forth labeling requirements for member countries to meet. These guidelines state that a substance’s historical use is a valid way to document safety and efficacy in the absence of any contradictory scientific evidence. In Europe, herbal remedies fall into three categories (Leddy, 2006):

- **Prescription drugs**, which include injectable forms of phytomedicines (from plant sources) and those used to treat life-threatening diseases. (This group is the most rigorously controlled.)

- **Over-the-counter (OTC) phytomedicines**

- **Herbal remedies**, including products that have not undergone rigorous clinical testing but have not demonstrated any serious incidents

In 1989, Europe formed the European Scientific Cooperative on Phytotherapy (ESCOP) to achieve consistent regulation of all drugs, including herbs. ESCOP has been developing monographs similar to Germany’s, based on sound clinical and scientific evidence. Eventually, these monographs are slated to be integrated into the European Pharmacopeia (Skidmore-Roth, 2010; Trivieri & Anderson, 2002).

In China, herbal medicine is the backbone of the medicinal system. In 1984, the People’s Republic of China implemented the Drug Administration Law, which characterized traditional herbal preparations as “old drugs,” exempt from testing for efficacy or side effects. New herbal products are overseen by the Chinese Ministry of Public Health (Leddy, 2006). Developing countries have minimal regulation and oversight regarding the use of their herbal remedies, even though they are a staple of medical treatment.

**Lack of Standardization**

When, where, and how an herb is grown can greatly affect the strength of its chemical components. Habitat, ambient temperature, rainfall, hours of daylight, altitude, wind conditions, and soil characteristics can all influence an herb’s quality and potency. In addition, whether an herb is grown naturally in its native habitat or cultivated affects its potency (Micozzi & Meserole, 2015; Mosihuzzaman & Choudhary, 2008; Skidmore-Roth, 2010).
Complicating the standardization concern is the fact that healers often use crude drugs or unprocessed herbs (Leddy, 2006). Most herbs do not yet have standardized doses, and manufacturers do not always produce preparations with consistent strengths. Crude herbs can vary in chemical composition from batch to batch or from plant to plant, and even herbalists themselves disagree about dosages. Current research is insufficient to allow standardization (Mosihuzzaman & Choudhary, 2008).

Understanding the names of herbs can also be complicated since many names can be associated with a given plant, and in some cases a given name can refer to several species of plants. There is lack of agreement even in the scientific community about the formal names of plants (Holt & Kouzi, 2002).

**Potential Toxicity**

Herbs must be used with care. Many are toxic if used incorrectly. For example, one herb that is safe to use topically can be highly toxic if taken internally. Some herbs contain potent liver toxins, systemic toxins, carcinogens, mutagens, or teratogens. Special consideration needs to be given when treating pediatric, geriatric, or pregnant clients. The effects of herbs on children, for example, are mainly unknown and a few herbs are outright dangerous. Commercial preparation may introduce toxic substances during the manufacturing process and, because of the lack of standardization, pose a real threat (Skidmore-Roth, 2009).

Americans have been conditioned to rely on synthetic, commercial drugs to provide quick relief. Herbal products can interact with either prescription or nonprescription drugs, and, since consumers often don’t tell their health care providers about herbal
therapies they are taking, serious or deadly consequences can result. “Natural” does not mean safe (Leddy, 2006).

**Food and Drug Law History**

Food and drug laws are designed to protect the public from unsafe, ineffective, or fraudulent treatments by ensuring the safety of foods and drugs. These laws are based on a long history of concerns over adulterated foods.

Ancient civilizations used a variety of processes to ensure safe food, but modern legislation addressed the issue by developing the following laws (Cohen, 1998):

- **1820—U.S. Pharmacopeia Created:** Eleven physicians met in Washington, D.C to establish the *U.S. Pharmacopeia*. This was the first compendium of standard drugs for the United States.

- **1848—Drug Importation Act:** Passed by Congress, this act required U.S. Customs Service inspection to stop the entry of adulterated drugs from overseas.

- **1906—The Pure Food and Drug Act:** This was the first of more than 200 laws that provide public health and consumer protections. It made the manufacture, sale, or transportation of adulterated, misbranded, poisonous, or deleterious foods, drugs, medicines, and liquors a misdemeanor (FDA, 2009a). It also paved the way for the development of the Food and Drug Administration.

- **1938—The Food, Drug, and Cosmetic Act (FDCA):** This act was passed after a legally marketed toxic elixir killed 107 people, including many children. According to Cohen (1998), this set of laws:
- Gave the FDA authority to oversee the safety of foods (and food additives such as food coloring), drugs, medical devices, dietary supplements, and cosmetics
- Gave the FDA authority to issue standards for food and to conduct factory inspections
- Expanded the definitions of adulteration and misbranding

**1962—The Kefauver-Harris Drug Amendments:** These amendments resulted from the thalidomide tragedy of Europe in the 1960s. They added the requirement that a new drug be proven effective as well as safe for its intended use before FDA approval. Clinical trial managers are required to give participants full information about the benefits and risks of drugs being studied (FDA, 2009b, 2016c). This law exempts animal drugs and animal feed additives that have been shown to induce cancer but which leave no detectable levels of residue in the human food supply (FDA, 2016c).

**1976—The Medical Device Amendments:** These amendments to the Federal Food, Drug, and Cosmetic Act followed a U.S. Senate finding that faulty medical devices caused 10,000 injuries and 731 deaths. They applied safety and effectiveness safeguards to new devices by establishing three regulatory classes for medical devices based on the degree of control necessary to assure the devices are safe and effective (FDA, 2017).

**1976—Vitamins and Minerals Amendments (“Proxmire Amendments”):** These amendments prohibit the FDA from establishing standards that limit the potency of vitamins and minerals in food supplements or regulating them as drugs solely because of their potency (FDA, 2016c).

**1990—The Nutrition Labeling and Education Act (NLEA):** This act, which amended the FDCA, requires most foods to contain nutrition labeling and requires food labels that contain certain health messages to comply with specific requirements (FDA, 2016c). It was designed to provide clear information about the relationship of nutrition to disease.

**1994—The Dietary Supplement Health and Education Act (DSHEA):** This act reaffirms that supplements are to be regulated as “foods,” not drugs, and exempts them from required new drug testing. This statute was enacted because of overwhelming consumer interest in making vitamins, minerals, herbs, and other substances freely available. It fundamentally changed the way the FDA regulates these substances (Cohen, Ruggie, & Micozzi, 2007).
Despite the impact of the DSHEA and numerous unresolved issues regarding dietary supplements, their use continues to grow.

**Energy Healing**

For thousands of years, shamans, medicine men, and healers from traditions all over the world have used spiritual energy flowing through sound, rituals, hands, movement, and thought. The idea of a universal, healing, spiritual energy that permeates all living things is common to many traditions including Hinduism, Native American healing, traditional Chinese medicine, and cultures found in Tibet, South America, Japan, Polynesia, and India (Cohen, 2000).

According to Cohen (2000), in biomedicine, the “institutionalized counterparts of tribal shamans” (p. 71) are traditional physicians, surgeons, nurses, psychotherapists, and others who use carefully regulated and professionally determined, scientifically validated therapeutic techniques. While some also incorporate therapeutic touch, healing touch, Reiki, and various forms of energy healing, many legal and ethical questions arise in connection with energy healing. They include (Cohen, 2000):

- Is the practice of energy healing legal? If so, to what extent?
• Does credentialing as a minister, for example, provide appropriate legal protection?

• Are energy healing and medicine distinct fields of practice?

• How does the role of “touch” impact issues of personal space, privacy, and intimacy within a professional relationship?

• Can medical practice acts be enforced against healers who merely claim to intuitively scan a patient’s biofield?

• If biomedical physicians collaborate with energy healers, do they risk disciplinary sanction for “unprofessional conduct” in aiding and abetting an individual who is illegally practicing medicine?

• What ethical issues are involved in energy healing with regard to the boundaries of birth and death?

Until CAM practitioners are politically organized into a coherent profession and receive separate statutory authorization, they are subject to medical practice acts that make the unlicensed practice of medicine (including energy healing) a crime. Thus, if a CAM practitioner “diagnoses,” “treats,” or claims to “treat” or “cure” anyone, he/she is practicing medicine according to U.S. law. Issues to consider include (Cohen, 2000):

• How those who practice energy healing in a religious context would be differentiated from other energy healers

• How to reconcile the governmental control of energy healing with the belief that bureaucratic interference violates the “soul” of their profession

• How to create a sufficient body of knowledge about energy healing

At some point, “each individual makes a personal journey through the landscape of health” (Cohen, 2000, p. 89). In the case of medicine men, shamans, or spiritual healers, the delivery of health care may often occur in public with members of the community present as the practitioner/healer mediates between the patient and the spirit world. Currently there are legal concerns about how to regulate medicine men, shamans, or spiritual healers because of the interplay between First Amendment rights and community practices. The First Amendment prohibits Congress from making any laws that “prohibit the free exercise” of “religion.” If the three basic elements of energy healing (centering, scanning of the human energy field, and directing healing energy to the patient) are considered religious, what role does the law play in regulating this form of healing? This question, along with others such as whether or not there should still be
a distinction between religion and medicine, the mind and the body, and subjective beliefs versus objective realities, all require further examination (Cohen, 2000).

Legal, ethical, clinical, and social models need to be reviewed (and revised) to accommodate these changing medical models (Cohen, 2000).

MALPRACTICE, LIABILITY, CONSENT AND REFERRAL ISSUES FOR HEALTH CARE PROVIDERS

Malpractice involves a deviation from accepted standards of practice in the health care community and results in injury or harm to a patient. These standards vary by county, state, and other jurisdictions. Malpractice liability rules are meant to protect patients against the negligence of health care providers. Negligence is defined as “practicing below the standard of care, resulting in injury to the patient” (Cohen, Ruggie, & Micozzi, 2007, p. 32).

Malpractice Defined

A finding of malpractice or negligence usually requires that the following exist (Cohen, 2007):

- There was a duty to provide a particular standard of care.
- The standard of care provided was below the generally accepted professional standards.
- The patient suffered harm caused by the provider’s failure to meet the professional standard of care.
- The patient’s injury is one for which there are damages.

Complementary and alternative medicine is currently characterized by therapies that are not widely taught in most medical schools or used in most U.S. hospitals. Traditional physicians who use these therapies or integrate them into their care are considered, by many of their colleagues, to be departing from more traditional standards of practice and are, therefore, at risk for malpractice. However, including CAM therapies in a treatment regimen does not necessarily mean the physician is providing substandard care, even though some courts make that equation (Cohen, Ruggie, & Micozzi, 2007).

Courts and legislatures also use FDA approval and generally accepted medical guidelines as a way of determining the current standard of care. Many complementary and alternative medicine therapies lack either FDA approval or are not considered “accepted medical guidelines” by the biomedical community so the courts and
legislate view those who use CAM therapies as failing to practice the standard of care.

The best risk management strategy for traditional physicians and CAM providers is to establish a rapport with the patient, using effective communication, to discuss the various therapeutic options available for the specific clinical condition, as well as their risks and benefits. Many malpractice lawsuits arise from miscommunication, lack of communication, misunderstandings, and the resulting hostility on the part of the patient and/or family members when there is a less-than-optimal clinical outcome. Clear, respectful communication reduces liability potential immensely. Another way to reduce malpractice risk is to rigorously research the particular CAM therapy and then appropriately educate the patient and/or family members so they understand the reason for the use of the therapy for their particular condition.

For CAM providers, additional risk management strategies include monitoring the patient for any adverse reactions between conventional and CAM therapies, such as adverse drug-herb interactions. From a liability perspective, the more acute and severe the patient’s condition, the more important it may be to monitor and treat the patient using conventional therapies. In addition, the more curable the condition is using conventional medicine, the more likely the court is to see the failure to provide such standard care as negligent (Cohen, 2007).

Fraud

The tort of fraud occurs when a health care provider deceives the patient and does so with intent to deceive. Fraud is not the result of negligence or an honest mistake. To avoid liability for fraud, some healers try to describe the potential results of their treatments in spiritual, rather than physical, terms; for example, results might be
described in terms of “healing’ versus “curing.” The courts view medicine broadly, however, and ignore the distinction between healing and curing (Cohen, Ruggie, & Miccozzi, 2007). This means CAM practitioners need to fully disclose all they know about a particular treatment to the patient and/or family so the decision to use a treatment is based on complete information.

**Referrals to CAM Providers**

Referrals to complementary and alternative medicine providers raise many issues for traditional physicians, whether they choose to refer or fail to refer to them.

A physician usually does not bear any malpractice liability for merely referring a patient to a specialist or other health care practitioner (including a CAM practitioner) unless the following are present (Cohen, 2000):

- The decision to refer itself demonstrates a lack of due care and results in patient injury (“direct liability”)
  - Direct liability results when the selection of the specialist or other treating practitioner is negligent. One example is when the patient’s condition is not amenable to or is aggravated by the CAM therapies offered by the practitioner or if the referring physician knows or has reason to know of such facts.
  - Direct liability requires proof of causation. The patient must show that the negligent referral was responsible for the injury.
To avoid this type of liability exposure, the physician needs to increase his or her knowledge of CAM therapies and fully understand the risks and benefits. This knowledge must be balanced with the risk of the physician and CAM practitioner being viewed as “engaging in a concerted action for a common purpose.”

- The treating practitioner is viewed as an agent, employee, or assistant of the referring physician (“vicarious liability”). This is also referred to as respondeat superior. Examples include the following.
  - A treating practitioner who is an actual agent, employee, or assistant of the physician and has to answer to the physician’s supervision and control (such as a medical resident)
  - A referring physician who knows or has reason to know that the provider to whom he or she has referred is incompetent
  - A situation in which there is a concerted action for a common purpose, such as a joint treatment plan, especially if both the referring physician and treating practitioner are employed jointly and are diagnosing and treating the case together
  - Physicians employed by the same hospital or health plan or within an integrated health care clinic
  - Physicians therefore need to keep referrals at “arm’s length” and ensure that practitioners to whom they refer are independent contractors with no supervisory or conceivable employment ties to the referring physician. This may be difficult to achieve.

- The two practitioners, although acting independently, have inflicted an indivisible injury on the patient (“joint and several liability”).
  - Some courts divide up the liability according to fault while others hold each practitioner responsible for all damages.

- The physician’s duty is one of continuing care and responsibility, which the courts do not see as ended by referral to the CAM provider. This duty requires ongoing supervision and oversight (“continuing duty”).
  - An example would be the liability of a physician who fails to prescribe the proper dose of medicine and the pharmacist who fills the prescription. In this case, the physician remains liable.
Criminal Liability

Criminal liability may occur when a practitioner aids or abets the crime of the unlicensed practice of medicine.

Aiding and abetting means furnishing assistance to an individual who is engaged in unauthorized medical practice. This commonly occurs in two ways (Cohen, 2000):

1. When the physician refers the patient to an unlicensed practitioner, such as a lay homeopath or an energy healer, who is deemed to be practicing medicine; and

2. When a referral is made to a licensed provider, such as a licensed acupuncturist or chiropractor, and that provider legally exceeds his or her authorized scope of practice.

Health care institutions have to carefully balance the risks of direct versus vicarious liability when considering whether to credential and privilege specific health care providers. Strict credentialing and strict quality control measures (such as onsite visits to providers, strict utilization review, and peer review) are essential in reducing exposure to liability.

Assumption of risk asserts that an individual who undertakes a particularly risky or dangerous activity knows the activity might be risky or dangerous and bears all responsibility for any injury that results from engaging in the activity (Nolo, 2017). Assumption of risk provides a way for the patient to select treatments that are outside the traditional biomedical norm and despite the physician’s objections. This could provide a shield to medical malpractice liability for the use of complementary and
alternative medicine if the patient, in consultation with his or her physician, chooses to use a particular CAM therapy as part of an integrated treatment plan (Cohen, 2000).

There is little case law on malpractice against CAM providers probably because patients have different expectations of them than of biomedical providers. CAM providers can be vulnerable to malpractice if they assume too much responsibility for the patient’s biomedical condition and fail to refer patients to appropriate biomedical professionals when needed. In addition, when there is an overlap between the CAM provider’s expertise and training and that of the biomedical physician, CAM providers may be held to a higher standard of care, rather than the appropriate standard of care for their profession. For example, since chiropractors (pursuant to their legal authority) can take X-rays, conduct routine blood tests or urinalyses, and perform physical exams, they can be judged according to the biomedical standard of care and charged with malpractice if they fail to perform a specific procedure (Faass, 2001).

While many CAM therapies are often noninvasive, they are not necessarily risk free. To ensure patient safety, it is essential for the CAM or biomedical health care provider to:

- Assess the clinical risk of a particular treatment and acknowledge it so patients remain fully informed.
- Document the literature supporting the therapeutic choice.
- Provide adequate informed consent.
- Monitor the patient effectively during and after the course of treatment (as appropriate).
- If making referrals, be informed about the credentials of the CAM provider.

**Informed Consent**

A critical element in patient care is the doctrine that an individual has the right to determine what will be done with his or her own body. The goal of informed consent is to protect the patient against nonconsensual interference with his or her body in medical matters.

Informed consent is a relatively recent trend in biomedicine. For thousands of years, physicians actually felt that deception was a normal part of the practice of medicine. In ancient Greece, for example, patient participation in care was considered undesirable. This continued through medieval times and the Era of Enlightenment. By the 1800s, the medical profession was divided about whether to disclose a dire diagnosis to the patient. However, during the 18th and 19th centuries, the concept of assault and battery rose from English Common Law and formed the foundation for the idea that a surgeon
must obtain authorization from a patient before performing surgery or that surgeon would be liable for a breach of duty (Murray, 1990).

The events that led to the implementation of informed consent principles in scientific research and later in clinical practice were the experiments conducted by Nazi physicians in concentration camps. The Nuremberg Code was developed after the war, and since that time the scientific community has continued to revise informed consent principles to ensure that research participants (and patients) are treated ethically (Escobedo, Guerrero, Lujan, Ramirez, & Serrano, 2007).

Informed consent is a process of communication between the patient and the health care provider that results in the patient (or authorized surrogate) agreeing to undergo a specific treatment or intervention. It involves discussing the following (American Cancer Society, 2017; American Medical Association, 2016; Coulson, Glasser, & Liang; 2002):

- The patient’s specific diagnosis (if known)
- The nature and purpose of proposed treatments and/or procedures
- The risks and benefits of proposed treatments and/or procedures
- Alternative treatments and procedures
- The risks and benefits of alternative treatments and/or procedures
- The risks and benefits of not undergoing a treatment and/or procedure

Informed consent also includes the opportunity for patients to ask questions so they fully understand the treatments and/or procedures proposed. If these issues have been addressed, the patient is usually asked to sign a consent form. This is a legal document that allows the health care provider to continue with the treatment plan. The form usually names the specific procedure/treatment to be performed, states the provider who will be performing the procedure/treatment, and may include the risks. Informed consent includes the process and actions that allow the patient to learn and think about a treatment before it is done. The consent form itself is not “informed consent” (American Cancer Society, 2017; American Medical Association, 2016). This communication process is both an ethical and legal obligation to patients in all 50 states. At the present time, it does not protect patients’ interests outside biomedicine.

From the physician’s point of view, informed consent means the following (American Cancer Society, 2017):

- A nurse or physician must make every effort to ensure that patients understand the purpose, benefits, risks, and other options for treatments or tests for their particular health issue.
• The consent must be obtained before starting any procedure.

• As long as patients are mentally able to make their own decisions, care cannot begin until they give their informed consent.

• If the patient is a minor (under age), has a serious mental disability, or cannot give consent, then consent must be given by a parent, legal guardian, or person authorized by the court (often a family member who knows what the patient would want).

• Patients have the right, at any time during the treatment process, to change their minds.

What is the physician’s legal obligation to disclose the availability of CAM modalities in clinical practice? As of 2011, no court has expressly ruled that a physician must disclose the availability of complementary and alternative medicine along with conventional medical care options to address a patient’s condition.

According to Cohen (2000), the answer to this question has not yet been fully answered in the literature, either, partly because of the lack of satisfactory scientific evidence and medical consensus to support the regular use of such therapies. Since most traditional physicians are not fully familiar with CAM therapies, which fall outside the conventional realm of medical education and clinical practice, most physicians are not likely to even consider them or raise the issue during an informed consent discussion. Other treatments have been supported by studies published in medical literature but they are still not generally accepted or adopted by traditional physicians in the United States. For example, surgeons may not advise their patients that there are studies demonstrating that chiropractic care may be more effective and less invasive in treating their lower back pain than surgical treatments (Cohen, 2000).

Other concerns include the following (Cohen, 2000):

• The promise to “do no harm” often prevents biomedical physicians from giving patients “false hope” based on their incomplete information or incomplete knowledge about CAM therapies.

• The physician’s lack of knowledge concerning the benefits and risks of certain therapies (particularly complementary and alternative therapies) may prevent him or her from offering other treatment options.

• Traditional (biomedical) physicians who are concerned about the liability of diverting patients away from conventional care to what they may consider “dangerous or inefficacious” therapies.
Arguments favoring disclosure to patients about complementary and alternative therapy options stem from a deep respect for patients’ autonomy. Such disclosure might also (Cohen, 2000):

- Satisfy the patient’s interests in CAM information and options
- Increase the patient’s treatment options
- Enhance the patient’s confidence in the physician’s knowledge and willingness to describe what lies outside such knowledge
- Loosen medical intolerance for therapies outside of biomedicine
- Increase medical innovation
- Reduce misunderstandings between traditional physicians, allied health providers, and CAM practitioners
- Lower malpractice risk

The current method of informed consent fails to address the medical profession’s growing exploration of, and patient demand for, complementary and alternative medicine therapies. As these therapies grow in credibility, the physician’s duty to obtain informed consent must also evolve (Cohen, 2000).

**THE DISCIPLINARY PROCESS**

State laws, including licensure regulations, control and provide guidelines for professional practice. If these regulations and guidelines are not followed, penalties for misconduct or unprofessional conduct result (Cohen, 1998).
Some states include in the definition of “unprofessional conduct” any departure from or failure to conform to the standard, accepted, and prevailing medical practice. Thus, any practitioners who incorporate CAM therapies are at risk for sanctions, since they have deviated from standard biomedical practice (Cohen, 1998).

The disciplinary process involves several steps including (Cohen, 1998; Washington State Department of Health, 2011):

- Preliminary process
  - A complaint to the state medical board (can be anonymous)
  - An investigation (which can include issues other than those triggered by the complaint)
  - Filing and service of charges
  - Notice of a hearing
- Adversary proceedings
  - Hearing panel in front of appropriate state board
- Licensing board hearing (makes the decision and issues an order)
- Penalty
  - Censure and reprimand
  - Suspension
  - Revocation or annulment of license or registration
  - Fine
  - Further education
  - Public service

State medical board records are confidential records.

**Judicial Opinions on Unprofessional Conduct**

Only a few cases of “unprofessional conduct” have resulted in published judicial opinions, probably because these treatments pose an economic challenge to medicine. These cases demonstrate the risks physicians face when using complementary and alternative therapies, including damage to their reputation, practice, and livelihood.
Since complaints can be lodged anonymously, they may be motivated by many means, including jealousy and competition, and they are not screened for probable cause or personal animosity (Cohen, 1998).

Some states are trying to limit the medical boards’ disciplinary authority in cases of physicians offering innovative, experimental, or complementary and alternative treatment, especially if informed consent was obtained and other criteria were met. Some state statutes are placing on state medical boards the burden of proving that treatments lack efficacy and are creating a legitimate peer review for clinical practice outside the biomedical norm in the United States. Although these state medical freedom acts are still controversial, they respect the rights of patients to choose their health care and are moving in a progressive direction (Cohen, 1998).

THIRD-PARTY REIMBURSEMENT

Traditionally, reimbursement has been dominated by the biomedical view of what constitutes health care. Third-party reimbursement has been available for therapies that cure rather than heal, even if the therapies are toxic, invasive, or potentially lethal or if the individual remains emotionally, spiritually, and physically shattered by the treatment. An example is chemotherapy used for cancer patients, which is often covered, while coverage for complementary and alternative care has been denied (Cohen, 2015).

Historically, health insurance developed from a relationship between employers who contracted with physicians to care for employees who had work injuries. The focus was on caring for disease rather than providing “health” care. However, the definition of health and how health is obtained and maintained is shifting to include prevention, good nutrition, stress management, and management of spiritual and energy issues. As these factors, and others, are seen as the precursors to disease, many feel that they are appropriate items for health care reimbursement (Cohen, 1998).

While some individuals depend on third-party reimbursement for access to complementary and alternative medical care, others spend amounts of their own monies for care. Even if they have health insurance, most individuals find that their plans do not cover most, or any, CAM therapies (NCCIH, 2016b). This is largely due to the insufficient evidence of safety, efficacy, and cost-effectiveness of the therapies. Some insurers offer policyholders discounted access to a network of CAM providers (Cohen, 2007). As a result, in 2007 alone, adults in the United States spent more than $33 billion in CAM treatments, products, classes, and materials during the preceding 12 months (NCCIH, 2016b).

Many factors determine whether a therapy/treatment is reimbursed by third parties (Casto, 2015; Cohen, 1998):
• Insurance models (they determine the nature and level of medical care the patient receives)
• The Access to Medical Treatment Act
• State medical freedom acts
• Key court cases

CAM providers need to be sure their clients understand the following before treatment occurs (NCCIH, 2016b):

• Is the provider in the insurance network? If not, are there additional costs associated with the visit?
• What is the cost of each appointment (including the first appointment, which may be more expensive than subsequent appointments)?
• What is the cost of additional tests, equipment, supplements, etc.?
• Does the provider accept the individual's insurance plan?
• Does the provider or the insured file the claims?
• Are there payment options (such as payment plans or sliding scale fees)?
• Does the individual need to pay a deductible and/or copayment?
• Is a preauthorization or referral needed for the care?
• Is there a limit to the number of visits or annual dollar amount paid out?

Until insurers begin to cover complementary and alternative therapies, it will be difficult to integrate holistic modalities into the U.S. health care system. Some insurers are experimenting with coverage that reimburses various types of holistic care. As this continues to evolve, licensing laws, scope-of-practice rules, professional organizations, ethical codes, standards of care, and malpractice and disciplinary rules relevant to the types of providers within holistic health care networks will also evolve.

**Willing Provider Laws**

Any willing provider (AWP) and freedom of choice (FOC) laws require insurers to grant network participation to health care providers who are willing to join and meet the network requirements and policy conditions. AWP laws do not require managed care plans to contract with all providers but they do require managed care plans to explicitly state the evaluation criteria for admission to the plan and ensure “due process” for
providers who want to contract with the plan (Hellinger, 1995; USLegal, 2014). They also allow patients to go outside the network to obtain covered services from non-network providers (FOC laws) (Ohsfeldt, Morrisey, Nelson, & Johnson, 1998). They forbid insurers from discriminating against or among providers. For example, if physicians, chiropractors, and physical therapists offer rehabilitative care, the contract holder (e.g., the hospital) must make the contract available to any of the three providers.

The first state to enact an AWP law was Wisconsin, in 1980, and it applied only to pharmacy services.

**Experimental or Medically Unnecessary Treatments**

![Image of medicine bottles and syringe]

Even when patients are covered by their private insurance policies, employee benefit plans, managed care contracts, or other types of insurance, treatment from complementary and alternative medicine providers may be denied as falling within the “experimental treatment” or “medically unnecessary” exclusion. **Medical necessity** is defined as accepted health care services and supplies provided by a health care entity that is appropriate for the specific evaluation and treatment of a disease, condition, illness, or injury and consistent with the appropriate standard of care (American College of Medical Quality, 2010). Consider these issues (Antman, et al., 2001; Cohen, 1998):

- The notions of what is considered experimental are often culturally and politically determined and will vary.
- The term “medically unnecessary treatments” was developed to limit insurers’ reimbursement for patients who “over-consume” care.
• Insurers argue that complementary and alternative therapies are “experimental” or “medically unnecessary” because they do not enjoy the same level of scientific support as biomedical treatments. The problem with this perspective is that the definition of what is experimental or medically necessary often depends on the composition of the professional community determining the scope of acceptable treatments.

Health Care and Insurance Fraud

Health care fraud and abuse result in financial losses estimated in the billions of dollars every year. Medicare and Medicaid are the largest purchasers of health care in the world; they comprise approximately 20% of all U.S. federal government spending and are a prime target for health care fraud activity (Staman, 2013). Health care and insurance fraud can be sanctioned under many different methods including the state medical board disciplinary rules as well as federal and state criminal and civil fraud laws. Penalties can range from the exclusion of individuals and entities from participating in federal health care programs to fines and imprisonment (Staman, 2013).

In 1989, the enactment of the Ethics in Patient Referrals Act, commonly known as the Stark law, prohibited certain physician self-referrals for designated health services (DHS) that may be paid for by Medicare or Medicaid. The act states that if a physician (or immediate family member of a physician) has a “financial relationship” with an entity (such as a surgery center or imaging center), the physician may not make a referral to the entity for the provision of DHS for which payment may be made under Medicare or Medicaid. This law was designed to prevent physicians from making referrals based solely on financial gain (versus medical need) and therefore prevent overutilization and increases in health care costs. There is a “whole hospital exception” to the Stark law, which allows the physician to make a referral to a hospital in which he/she has an investment if that physician is authorized to perform services at the hospital and the investment was in the whole hospital and not just a subdivision of it (Staman, 2013).

Because CAM treatments are not generally accepted by the biomedical community (responsible for setting up the regulatory structure in the first place) or the FDA, providing treatments and submitting claims might be deemed fraudulent. The definition of fraud, like the definition of quackery, has historically been used to indict the rivals of biomedicine. Legally, fraud involves “a mental state, intent to deceive, and an act of deception” (Cohen, 1998, p. 107). Lawmakers, in their attempt to preserve and protect the public’s health, must avoid discrimination against complementary and alternative providers.
SUMMARY

There are many dynamic legal issues related to (CAM) and the practice of CAM therapies that impact today’s health care environment. Health care professionals who utilize CAM therapies must be knowledgeable about the laws that govern their practice to ensure their patients receive optimal care. Since the use of CAM therapies in the United States has evolved and increased during the past several decades and shows no sign of slowing down, related legal issues are certain to evolve as well.
REFERENCES


