



## **Arizona Medical Board**

### **The Arizona Medical Board's Guidelines For Physicians Who Incorporate Or Use Complementary Or Alternative Medicine In Their Practice**

#### **Introduction**

Increasingly, physicians are integrating complementary or alternative medicine (CAM) therapies into their practices or referring patients to CAM practitioners. CAM refers to a broad range of healing philosophies (schools of thought), approaches and therapies that mainstream Western (conventional) medicine does not commonly use, accept, study, understand, or make available. A few of the many CAM practices include the use of acupuncture, ayurveda, herbs, homeopathy, naturopathy, therapeutic massage, and traditional Oriental medicine to promote well-being or treat health conditions.

The Arizona Medical Board (the Board) developed these guidelines for physicians who use CAM to assist them in doing so in a manner that is consistent with the Board's expectations and to inform the public of CAM and its uses in Arizona.

#### **Preamble**

The Board is responsible for regulating all physicians who hold an Arizona license to practice allopathic medicine. The Arizona Legislature and the Board have established standards that govern the practice of medicine. These standards allow physicians to exercise their professional judgment in treating patients and do not generally preclude the use of any treatment methods that are justifiably anticipated to benefit patients without undue risk. All physicians must meet these basic allopathic standards whether the physician practices allopathic medicine or some form of CAM or integrates both. All physicians, regardless of the type of medicine they practice, must practice in a manner that is safe and always with the patient's best interest in mind.

The standards used in evaluating health care practices must be consistent, whether such practices are regarded as conventional or CAM. The use of CAM is not in and of itself unprofessional conduct. Instead, the Board analyzes the

physician's conduct and patient care in each case to determine if the physician's conduct constitutes a violation of the Medical Practice Act.

## **Guidelines**

All licensed allopathic physicians, whether practicing conventional medicine or using CAM, must demonstrate a basic understanding of allopathic medicine and current medical scientific knowledge. If a physician uses CAM, the physician must also be able to demonstrate a basic understanding of the treatment modalities connected with any method offered or used in the physician's medical practice. Whether using conventional, CAM or integrative medicine, all allopathic physicians must meet the basic allopathic standard of care for diagnosing, treating and monitoring patients regardless of the intended treatment modality.

### **I. Diagnosing, Treating and Monitoring**

#### **A. Diagnosing**

The Board recognizes the difference between a physician's competency in meeting basic medicine requirements and a physician's skills in using a particular treatment modality. All physicians must take an appropriate history, review the patient's medical record, conduct a physical examination of the patient and obtain the necessary tests consistent with the allopathic standard of care to make an informed diagnosis regardless of the treatment modality employed to treat the illness or condition. In addition to the required conventional diagnostic methods, a physician may use additional safe and reliable methods to diagnose a patient's condition or illness.

#### **B. Treating**

After making an informed diagnosis, a physician may offer the patient conventional and/or CAM treatments as part of the treatment plan. The physician must tailor the treatment plan to meet the needs of the individual patient. The physician must design the treatment plan to timely and effectively treat the patient's diagnosis, provide for continued monitoring of the patient's condition or illness and perform all further testing, consultations, and referrals consistent with the standard of care. The treatment plan must establish how the physician will evaluate the treatment's progress and success, such as pain relief and/or improved physical and/or psychosocial function. The treatments offered should, at a minimum:

- have a favorable risk/benefit ratio compared to other treatments for the same condition;

- be based upon a well founded expectation that it will result in a favorable patient outcome, including preventive practices; and
- be based upon the expectation that a greater benefit will be achieved than can be expected with no treatment.

When analyzing a physician's treatment of a patient, the Board will evaluate whether the physician is practicing appropriate medicine by considering, among other things, whether the treatment was:

- safe and demonstrably effective,
  - (having evidence of safety with demonstrable and credible scientific evidence of efficacy)
- safe but not demonstrably effective,
  - (having evidence of safety, but with no or inadequate demonstrable and credible scientific evidence of efficacy)
- unsafe but demonstrably effective, or
  - (having evidence of significant side effects, but with demonstrable and credible scientific evidence of efficacy)
- unsafe and not demonstrably effective.
  - (proven or known to be unsafe with no demonstrable or credible evidence of efficacy)

The physician should consider treatments that are safe and demonstrably effective first when developing a treatment plan. The use of unsafe and not demonstrably effective treatments is experimental in nature and a physician who wishes to use such a treatment should only do so under rigidly controlled conditions that meet all State and National standards and protocols for research including submission of the proposed treatment to an Institutional Review Board for approval.

### C. Monitoring

When required by the standard of care, the physician must monitor the patient to determine if the treatment is successfully obtaining the expected results. All physicians must appropriately monitor a patient's health by assessing the patient's health, conducting additional physical examinations and/or obtaining additional tests consistent with the allopathic standard of care for patient monitoring. In addition to the required conventional monitoring methods, a physician may use additional reliable monitoring methods. The physician must recognize when the prescribed treatment is failing to achieve the desired or expected results. Once the physician determines the treatment is failing, the physician must:

- verify the accuracy of the original diagnosis and possibly modify the diagnosis,
- adjust the treatment plan, and/or
- refer the patient to another physician.

## II. Informed Consent

When a physician uses CAM, in addition to the medical information required to be documented by the relevant standard of care, the medical record must also document the medical options the physician and patient discussed. The physician must document the information provided to the patient and the treatments the patient accepted and which treatments the patient rejected.

Physicians must always obtain a patient's informed consent before treating the patient whether using conventional medicine, CAM or any experimental method. The patient's informed consent must be in writing if the physician uses CAM, experimental methods or if required by the standard of care. In obtaining the patient's informed consent, the physician, at a minimum, must provide the following information to the patient:

- The available treatment options and their known risks and benefits;
- The option of no treatment and its risks and benefits;
- The risks of early termination of a particular treatment;
- If the treatment will be performed at a different facility, the physician must identify the facility and explain any risks and benefits if there are any among the options of facilities;
- If the physician is recommending CAM or experimental treatments, the physician must also explain possible conventional treatments;
- The physician must inform the patient if the treatment is not scientifically established using conventional methods;
- The physician must also document and abide by any limitations the patient places on the consent.

## III. Referral and Consultation

A physician who does not utilize CAM may refer patients to a CAM practitioner for additional evaluation and treatment in order to achieve treatment objectives or to comply with a patient's request. The physician who refers the patient to specific practitioners is responsible for ensuring the referred to practitioner is licensed, if required, and practices competently and safely. In all situations where the referring physician continues to treat the patient, the referring physician remains responsible for monitoring the results from the referral and should schedule periodic reviews to ensure progress is being achieved. Patients should always advise their treating physician of any CAM treatments they receive and all CAM products they take or use.

## IV. Claims

In advertising a practice or while consulting with a patient, a physician may not make false or fraudulent claims. A physician may not claim that a particular

treatment can cure, alleviate or ameliorate a disease or condition unless the claim is supported by valid, conventional science. A physician's personal experience, patient testimony and other anecdotal evidence is not sufficient evidence to support a claim of a treatment's efficacy and safety. A physician may, however, inform the patients of his/her experiences with using a particular treatment. When advising patients on treatment options, a physician must disclose to the patient the physician's basis for making claims of the efficacy and safety of a particular treatment.

## V. Products

Some physician practices have begun selling healthcare related products directly to patients. The law does not directly prohibit this practice, but any fraud or misrepresentations would violate the Medical Practice Act. Due to the potential for conflicts of interests, however, physicians should not sell, rent or lease health-related products or engage in exclusive distributorships and/or personal branding. If a physician chooses to make products directly available to patients, the physician must disclose to the patient that the physician has a financial interest in the goods or services. This does not prohibit physicians from distributing products to patients for free or at cost in order to make products readily available or otherwise dispensing prescription drugs and devices. In addition, this should not deter physicians from selling durable medical goods essential to the patient's care.

## VI. Clinical Trials, Research and Experiments

As expected of those physicians using conventional medical practices, physicians providing CAM therapies while engaged in the clinical investigation of new drugs and procedures are obligated to maintain their ethical and professional responsibilities and meet all legal requirements governing research and clinical trials. Clinical investigations must be part of a systematic program competently designed, under accepted standards of scientific research, to produce data that are scientifically valid and sound. A clinical investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the patient involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation. Furthermore, to ensure the risks to the patient are as low as possible and are worth any potential risks or benefits, researchers must abide by all federal guidelines and safeguards, such as approval and monitoring of the clinical trial by an Institutional Review Board, when applicable.

## **Conclusion**

Legitimate standards of medical practice are rooted in competent and reliable scientific evidence. These standards, however, continually change as advances are made in scientific investigation and analysis. Some procedures that are

initially considered unconventional gradually become conventional, while the scientific community may discard common conventional procedures.

Patients have a right to seek the treatment that is most appropriate for them. But the Board must protect the public by ensuring that allopathic physicians in all practices, whether conventional or CAM, comply with professional, ethical and established practice standards. The Board will continue to protect the public by ensuring that all allopathic physicians, whether practicing conventional medicine, CAM or both, meet the standards of care the community expects of allopathic practitioners.