Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice

Approved by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., as policy April 2002

Introduction

Physicians, indeed all health-care professionals, have a duty not only to avoid harm but also a positive duty to do good— that is, to act in the patient's best interest[s]. This duty of beneficence takes precedence over any self-interest.[1]

Because of the increasing interest in and use of complementary and alternative therapies in medical practices (CAM), state medical boards have a responsibility to assure that licensees utilize CAM in a manner consistent with safe and responsible medicine. On behalf of the Federation of State Medical Boards and its continued commitment to assist state medical boards in protecting the public and improving the quality of health care in the United States, the Special Committee for the Study of Unconventional Health Care Practices (Complementary and Alternative Medicine),[2] undertook an initiative in April 2000 to develop model guidelines for state medical boards to use in educating and regulating (1) physicians who use CAM in their practices, and/or (2) those who co-manage patients with licensed or otherwise state-regulated CAM providers.

CAM is a fluid concept that has been defined differently by various organizations and groups. For the purposes of these guidelines, the Committee has chosen to use the term CAM as defined by the National Institutes of Health (NIH) National Center for Complementary and Alternative Medicine (NCCAM) (see Definitions). The Committee acknowledges that some therapies deemed CAM today may eventually be recognized as conventional, based on evidence over time.

This initiative focuses on encouraging the medical community to adopt consistent standards, ensuring the public health and safety by facilitating the proper and effective use of both conventional and CAM treatments, while educating physicians on the adequate safeguards needed to assure these services are provided within the bounds of acceptable professional practice. The Committee believes adoption of guidelines based on this model will protect legitimate medical uses of CAM while avoiding unacceptable risk.

The intention of the Committee is to provide guidelines that are clinically responsible and ethically appropriate. These guidelines are designed to be consistent with what state medical boards generally consider to be within the boundaries of professional practice and accepted standard of care.

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Section I. Preamble

The (*name of board*) recognizes that the practice of medicine consists of the ethical application of a body of knowledge, principles and methods known as medical science and that these objective standards are the

basis of medical licensure for physicians of the state of (name of state). These standards allow a wide degree of latitude in physicians' exercise of their professional judgment and do not preclude the use of any methods that are reasonably likely to benefit patients without undue risk. Furthermore, patients have a right to seek any kind of care for their health problems. The Board also recognizes that a full and frank discussion of the risks and benefits of all medical practices is in the patient's best interest.

There are varying degrees of potential patient harm that can result from either conventional medical practices or CAM:

- Economic harm, which results in monetary loss but presents no health hazard;
- Indirect harm, which results in a delay of appropriate treatment, or in unreasonable expectations that discourage patients and their families from accepting and dealing effectively with their medical conditions;
- Direct harm, which results in adverse patient outcome.

Regardless of whether physicians are using conventional treatments or CAM in their practices, they are responsible for practicing good medicine by complying with professional standards and regulatory mandates. In consideration of the above potential harms, the (name of board) will evaluate whether or not a physician is practicing appropriate medicine by considering the following practice criteria. Is the physician using a treatment that is:

- **effective and safe?** (having adequate scientific evidence of efficacy and/or safety or greater safety than other established treatment models for the same condition)
- **effective, but with some real or potential danger?** (having evidence of efficacy, but also of adverse side effects)
- **inadequately studied, but safe?** (having insufficient evidence of clinical efficacy, but reasonable evidence to suggest relative safety)
- **ineffective and dangerous?** (proven to be ineffective or unsafe through controlled trials or documented evidence or as measured by a risk/benefit assessment)

Inasmuch as the (name of board) is obligated under the laws of the state of (name of state) to protect the public's health, safety and welfare and recognizes that the standards used in evaluating health care practices should be consistent, whether such practices are regarded as conventional or CAM, the Board recognizes that a licensed physician shall not be found guilty of unprofessional conduct for failure to practice medicine in an acceptable manner solely on the basis of utilizing CAM. Instead, the Board will use the following guidelines to determine whether or not a physician's conduct constitutes a violation of the state's Medical Practice Act.

Section II. Definitions

For the purposes of these guidelines, the following terms are defined as indicated:

Complementary and Alternative Therapies in Medical Practices (CAM)

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, herbs, homeopathy, therapeutic massage, and traditional Oriental medicine to promote well-being or treat health conditions. People use CAM treatments and therapies in a variety of ways. Therapies may be used alone, as an alternative to conventional therapies, or in addition to conventional, mainstream therapies, in what is referred to as a complementary or an integrative approach. Many CAM therapies are called holistic, which generally means they consider the whole person, including physical, mental, emotional and spiritual aspects.[3]

Conventional Medical Practices

Conventional medical practices refer to those medical interventions that are taught extensively at U.S. medical schools, generally provided at U.S. hospitals, or meet the requirements of the generally accepted standard of care.

Section III. Guidelines

The (*name of board*) has adopted the following guidelines when evaluating the delivery or co-management of CAM:

1. Evaluation of Patient

Parity of evaluation standards should be established for patients whether the physician is using conventional medical practices or CAM.

Prior to offering any recommendations for conventional and/or CAM treatments, the physician shall conduct an appropriate medical history and physical examination of the patient as well as an appropriate review of the patient's medical records. This evaluation shall include, but not be limited to, conventional methods of diagnosis and may include other methods of diagnosis as long as the methodology utilized for diagnosis is based upon the same standards of safety and reliability as conventional methods, and shall be documented in the patient's medical record. The medical record should also document:

- what medical options have been discussed, offered or tried, and if so, to what effect, or a statement as to whether or not certain options have been refused by the patient or guardian; that proper referral has been offered for appropriate treatment;
- that the risks and benefits of the use of the recommended treatment to the extent known have been appropriately discussed with the patient or guardian;
- that the physician has determined the extent to which the treatment could interfere with any other recommended or ongoing treatment.

2. Treatment Plan

The physician may offer the patient a conventional and/or CAM treatment pursuant to a documented treatment plan tailored to the individual needs of the patient by which treatment progress or success can be evaluated with stated objectives, such as pain relief and/or improved physical and/or psychosocial function. Such a documented treatment plan shall consider pertinent medical history, previous medical records and physical examination, as well as the need for further testing, consultations, referrals or the use of other treatment modalities.

The treatment offered should:

- have a favorable risk/benefit ratio compared to other treatments for the same condition;
- be based upon a reasonable expectation that it will result in a favorable patient outcome, including preventive practices;
- be based upon the expectation that a greater benefit will be achieved than that which can be expected with no treatment.

3. Consultation and/or Referral to Licensed or Otherwise State-Regulated Health Care Practitioners

The physician may refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives and may include referral to a licensed or otherwise state-regulated health care practitioner with the requisite training and skills to utilize the CAM therapy being recommended. However,

the physician is responsible for monitoring the results and should schedule periodic reviews to ensure progress is being achieved.

4. Documentation of Medical Records

The physician should keep accurate and complete records to include:

- the medical history and physical examination;
- diagnostic, therapeutic and laboratory results;
- results of evaluations, consultations and referrals;
- treatment objectives;
- discussion of risks and benefits;
- appropriate informed consent;
- treatments;
- medications (including date, type, dosage and quantity prescribed);
- instructions and agreements;
- periodic reviews.

Records should remain current and be maintained in an accessible manner, and readily available for review.

5. Education

All physicians must be able to demonstrate a basic understanding of the medical scientific knowledge connected with any method they are offering or using in their medical practices as a result of related education and training.

6. Sale of Goods from Physician Offices

Due to the potential for patient exploitation, physicians should not sell, rent or lease health-related products or engage in exclusive distributorships and/or personal branding;

- Physicians should provide a disclosure statement with the sale of any goods, informing patients of their financial interest; and
- Physicians may distribute products to patients free of charge or at cost in order to make products readily available.
- Exceptions should be made for the sale of durable medical goods essential to the patient's care, as well as nonhealth-related goods associated with a charitable or service organization.[4] [Language on the sale of goods from physician offices is contained in the report of the Special Committee on Professional Conduct and Ethics as adopted in April 2000.]

7. Clinical Investigations

As expected of those physicians using conventional medical practices, physicians providing CAM therapies while engaged in the clinical investigation of new drugs and procedures (a.k.a. medical research, research studies) are obligated to maintain their ethical and professional responsibilities. Investigators shall be expected to conform to the following ethical standards:

- Clinical investigations should be part of a systematic program competently designed, under accepted standards of scientific research, to produce data which are scientifically valid and significant.

- 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.[5]

Furthermore, investigators shall be expected to abide by all federal guidelines and safeguards, such as approval and monitoring of the clinical trial by an Institutional Review Board (IRB), when applicable, to ensure the risks to the patient are as low as possible and are worth any potential benefits.

In Conclusion

The Committee recognizes that legitimate standards of medical practice are rooted in competent and reliable scientific evidence and experience. However, these standards are subject to continual change and improvement as advances are made in scientific investigation and analysis. In addition, standards of medical practice to some degree, and the provision of medical services in individual circumstances in particular, are influenced by psychological, social, political and market forces. It is the responsibility of state medical boards to balance all of these considerations in fulfilling their mission of protecting the public through the regulation of the practice of medicine.

Public protection is carried out, in part, by ensuring physicians in all practices, whether conventional or CAM, comply with professional, ethical and practice standards and act as responsible agents for their patients. Accordingly, the Federation encourages state medical boards to adopt these guidelines to assist them in educating and regulating physicians who are (1) engaged in a practice environment offering conventional and/or CAM treatments; and/or (2) engaged in cooperative therapeutic relationships for their patients with a non-physician licensed or otherwise state-regulated health care practitioner offering CAM.

State medical boards should ensure a balance between the goal of medical practices being evidence-based while remaining compassionate and respectful of the dignity and autonomy of patients. This balance should also ensure informed consent and minimize the potential for harm.

The Federation reaffirms its commitment to cooperate with physicians and professional, governmental and other organizations and agencies in supporting the further study of all health care practices that offer promise.

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[1]Schneiderman L. Medical ethics and alternative medicine. The Scientific Review of Alternative Medicine. Spring/Summer 1998;2,(1):63-66.

[2]In 1995, the Federation established a special committee charged with developing strategies for recommendation to state medical boards for the regulation and discipline of physicians who engage in unsafe and/or deceptive health care practices. The Federation's House of Delegates adopted the Committee's recommendations as policy in April 1997. That same year, the Committee was charged with providing objective information to medical boards for their use in educating licensees, the public and state legislators on issues surrounding health care practices that may be potentially harmful and/or deceptive. In 2000, the Committee was charged with the development of these guidelines.

[3]NIH. General Information About CAM and the NCCAM, Publication M-42—June 2000, NCCAM Clearinghouse, Web version updated 02/21/01

[4]FSMB. Report on Professional Conduct and Ethics. HOD April 2000, Web version at www.fsmb.org, Policy Documents.

[5]AMA. Policy E 2.07: Clinical Investigation.