The Texas Medical Board (Board) proposes the repeal of current Chapter 171, concerning Postgraduate Training Permits, §§171.1 – 171.6.

The Board also proposes new Chapter 171, concerning New Complementary and Alternative Medicine Standards, §171.1 and §171.2.

Also, the Board contemporaneously proposes the repeal of current Chapter 200, concerning Standards For Physicians Practicing Complementary And Alternative Medicine, §§200.1 – 200.3.

The Board has determined that due to the extensive reorganization of Chapters 160-200, repeal of Chapter 171 is more efficient than proposing multiple amendments to make the required changes.

The proposed new sections are as follows:

New §171.1, Definitions, defines terms used in the chapter.

New §171.2, Required Consent and Disclosure, details the required written consent and disclosure form required prior to the patient's treatment by the physician using complementary or alternative medicine.

Scott Freshour, General Counsel for the Texas Medical Board, has determined that, for each year of the first five years the proposed repeals and new sections are in effect, the public benefit anticipated as a result of enforcing these proposed sections will be to remove redundant language from rules, simplify the rules, and make the rules easier to understand.

Mr. Freshour has also determined that for the first five-year period these proposed repeals and new sections are in effect, there will be no fiscal impact or effect on government growth as a result of enforcing the proposed sections.

Mr. Freshour has also determined that for the first five-year period these proposed repeals and new sections are in effect there will be no probable economic cost to individuals required to comply with these proposed sections.

Pursuant to Texas Government Code §2006.002, the agency provides the following economic impact statement for these proposed repeals and new sections and determined that for each year of the first five years these proposed repeals and new sections will be in effect there will be no effect on small businesses, micro businesses, or rural communities. The agency has considered alternative methods of achieving the purpose of these proposed repeals and new sections and found none.

Pursuant to Texas Government Code §2001.024(a)(4), Mr. Freshour certifies that this proposal has been reviewed and the agency has determined that for each year of the first five years these proposed repeals and new sections are in effect:

(1) there is no additional estimated cost to the state or to local governments expected as a result of enforcing or administering these proposed repeals and new sections;

(2) there are no estimated reductions in costs to the state or to local governments as a result of enforcing or administering these proposed repeals and new sections;

(3) there is no estimated loss or increase in revenue to the state or to local governments as a result of enforcing or administering these proposed repeals and new sections; an

(4) there are no foreseeable implications relating to cost or revenues of the state or local governments with regard to enforcing or administering these proposed repeals and new sections.

Pursuant to Texas Government Code §2001.024(a)(6) and §2001.022, the agency has determined that for each year of the first five years these proposed repeals and new sections will be in effect, there will be no effect on local economy and local employment.

Pursuant to Government Code §2001.0221, the agency provides the following Government Growth Impact Statement for these proposed repeals and new sections. For each year of the first five years these proposed repeals and new sections will be in effect, Mr. Freshour has determined the following:

(1) These proposed repeals and new sections do not create or eliminate a government program.

(2) Implementation of these proposed repeals and new sections does not require the creation of new employee positions or the elimination of existing employee positions.

(3) Implementation of these proposed repeals and new sections does not require an increase or decrease in future legislative appropriations to the agency.

(4) These proposed sections do not require an increase or decrease in fees paid to the agency.

(5) These proposed repeals and new sections do not create new regulations.

(6) These proposed repeals and new sections do repeal existing regulations as described above. These proposed new sections do not expand or limit an existing regulation.

(7) These proposed repeal and new sections do not increase the number of individuals subject to the sections' applicability.

(8) These proposed repeals and new sections do not positively or adversely affect this state's economy.

Comments on the proposal may be submitted using this link: https://forms.office.com/g/sytKBdXtLz. A public hearing will be held at a later date. Comments on the proposal will be accepted for 30 days following publication.

The repeal of the rules is proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Board to recommend and adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine; and enforce this subtitle. The repeal of the rules is also proposed in accordance with the requirements of Texas Government Code, §2001.039, which requires a state agency to review and consider its rules for readoption, readoption with amendments, or repeal every four years. No other statutes, articles or codes are affected by this proposal.

<rule>

§171.1. Purpose.

§171.2. Construction.

§171.3. Physician-in-Training Permits.

§171.4. Board Approved Fellowships.

§171.5. Duties of PIT Holders to Report.

§171.6. Duties of Program Directors to Report.

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The new rules are proposed under the authority of the Texas Occupations Code Annotated, §153.001, which provides authority for the Board to recommend and adopt rules and bylaws as necessary to: govern its own proceedings; perform its duties; regulate the practice of medicine; and enforce this subtitle. The new rules are also proposed in accordance with the requirements of Texas Government Code, §2001.039, which requires a state agency to review and consider its rules for readoption, readoption with amendments, or repeal every four years. No other statutes, articles or codes are affected by this proposal.

<rule>

§171.1. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the contents clearly indicate otherwise

(1) Alternative medicine--methods of diagnosis, treatment, or interventions that are not generally considered as conventional treatment or medicine and may or may not be regulated by the FDA. These treatments may be offered for potential for therapeutic gain that are not unreasonably outweighed by the risk of such methods.

(2) Complementary medicine--the use of a combination of conventional medicine and some form of alternative medicine.

(3) Conventional medicine--methods of diagnosis, treatment, or interventions are generally considered routine treatments and medicine by the majority of licensed physicians.

(4) Off-label usage--use of an FDA approved drug, treatment, or device in a manner that has not been approved, or proven safe and effective, by the FDA or to treat a disease or medical condition for which it is being offered. Off-label use may be alternative, complementary, or conventional medicine.

§171.2. Required Consent and Disclosure.

(a) Prior to providing any complementary or alternative drug, treatment, device, or intervention, the physician and patient must review and execute the below disclosure and consent form. The fully-executed form must be included in the patient's medical records. Other than translation into another language or format for the patient, this form may not be changed, modified, or altered in any manner other than by adding additional pages with supplemental information as necessary.

(b) The physician practicing complementary and alternative medicine must follow all statutes and rules including requirements for maintaining adequate medical records. Physicians must also document and maintain within the medical record the information either as set forth in the form below or in an alternate format that contains at least the information requested in the form below:

Figure 1:22 TAC §171.2

COMPLEMENTARY AND ALTERNATIVE MEDICINE
TREATMENT DISCLOSURE AND CONSENT FORM

This form is required to be completed prior to the initiation of therapy and maintained as part of the patient's medical record.

Treating Physician: _____

Patient Name: _____

This "Consent" includes detailed information about the treatment plan, anticipated laboratory and diagnostic testing, potential benefits, and possible risks of the complementary and alternative (CAM) treatment being offered.

You should take your time and carefully read through the Consent. Ask any questions you may have. When you are satisfied that your questions have been fully answered, you will be asked to sign the Consent, thereby giving your consent to receive the complementary and alternative (CAM) treatment being offered by the treating physician. At no time should you allow yourself to be pressured into agreeing to or receiving the CAM treatment. Once you give consent to receiving the CAM treatment, you may withdraw your consent at any time.

As the treating physician, I am required to go over this Consent in detail with you, and it must be kept as part of your patient record.

As the physician, I understand that I am required to keep an accurate and complete medical record, including my discussion with the patient whether off-label use or CAM is administered.

_____ _____

Physician signature Date

REQUIRED DISCLOSURE AND PATIENT ACKNOWELDGMENT:

The treating physician and patient shall go over each line and initial where indicated. "N/A" may be used where not applicable.

The condition(s) or diagnosis for which the CAM treatment(s) are being offered are:
(List all)

a. _____
b. _____
c. _____
d. _____

The CAM treatment(s) being offered for the above noted condition(s) or diagnosis are:
(List all and link to specific condition or diagnosis for each CAM treatment(s):

a. _____
b. _____
c. _____
d. _____

1. Assessment. (Initial each line or write "N/A" if not applicable)

_____ Description given to patient of conventional methods of diagnosis and non-conventional methods of diagnosis;

_____ An appropriate medical history and physician examination of the patient has been completed;

_____ The conventional medical treatment options have been discussed with the patient and referral input, if necessary;

_____ Any prior conventional medical treatments and the outcomes have been obtained (including whether conventional options have been refused by the patient);

_____ Assessment completed of whether the complementary health care therapy could interfere with any other recommended or ongoing treatment.

2. Disclosure - the following were discussed in detail and all questions answered. (Initial each line or write "N/A" if not applicable)

_____ The objectives, expected outcomes, or goals of the proposed treatment, such as functional improvement, pain relief, or expected psychosocial benefit;

_____ The risks and benefits of the proposed treatment;

_____ The extent the proposed treatment could interfere with any ongoing or recommended medical care;

_____ A description of the underlying therapeutic basis or mechanism of action of the proposed treatment purporting to have a reasonable potential for therapeutic gain that is written in a manner understandable to the patient;

_____ If applicable, whether a drug, supplement, or remedy employed in the treatment is:

> _____ approved for human use by the U.S. Food and Drug Administration (FDA);
>
> _____ exempt from FDA preapproval under the Dietary Supplement and Health Education Act (DSHEA); or
>
> _____ a pharmaceutical compound not commercially available and is subject to clinical investigation standards.

_____ Documented treatment plan that is tailored for the individual needs of the patient and considers the patient's 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 favorable risk/benefit compared to other treatments for the same condition;

_____ There is a reasonable expectation that the treatment will result in a favorable patient outcome, including preventive practices;

_____ The expectation that a greater benefit for the same condition will be achieved than what can be expected with no treatment; and

_____ The periodic review of the treatment will be made at reasonable intervals considering:

a. the patient's progress under the treatment prescribed, ordered or administered; and

b. any new information about etiology of the complaint in determining whether treatment objectives are being adequately met.

_____
(Patient’s Name Printed)

_____
(Patient’s Signature)

_____
Date

COMPLEMENTARY AND ALTERNATIVE MEDICINE
TREATMENT DISCLOSURE AND CONSENT FORM

This form is required to be completed prior to the initiation of therapy and maintained as part of the patient's medical record.

Treating Physician: _____

Patient Name: _____

This "Consent" includes detailed information about the treatment plan, anticipated laboratory and diagnostic testing, potential benefits, and possible risks of the complementary and alternative (CAM) treatment being offered.

You should take your time and carefully read through the Consent. Ask any questions you may have. When you are satisfied that your questions have been fully answered, you will be asked to sign the Consent, thereby giving your consent to receive the complementary and alternative (CAM) treatment being offered by the treating physician. At no time should you allow yourself to be pressured into agreeing to or receiving the CAM treatment. Once you give consent to receiving the CAM treatment, you may withdraw your consent at any time.

As the treating physician, I am required to go over this Consent in detail with you, and it must be kept as part of your patient record.

As the physician, I understand that I am required to keep an accurate and complete medical record, including my discussion with the patient whether off-label use or CAM is administered.

_____ _____
Physician signature Date

REQUIRED DISCLOSURE AND PATIENT ACKNOWELDGMENT:

The treating physician and patient shall go over each line and initial where indicated. "N/A" may be used where not applicable.

The condition(s) or diagnosis for which the CAM treatment(s) are being offered are:
(List all)

a. _____
b. _____
c. _____
d. _____

The CAM treatment(s) being offered for the above noted condition(s) or diagnosis are:
(List all and link to specific condition or diagnosis for each CAM treatment(s):

a. _____
b. _____
c. _____
d. _____

1. Assessment. (Initial each line or write "N/A" if not applicable)

_____ Description given to patient of conventional methods of diagnosis and non-conventional methods of diagnosis;

_____ An appropriate medical history and physician examination of the patient has been completed;

_____ The conventional medical treatment options have been discussed with the patient and referral input, if necessary;

_____ Any prior conventional medical treatments and the outcomes have been obtained (including whether conventional options have been refused by the patient);

_____ Assessment completed of whether the complementary health care therapy could interfere with any other recommended or ongoing treatment.

2. Disclosure - the following were discussed in detail and all questions answered. (Initial each line or write "N/A" if not applicable)

_____ The objectives, expected outcomes, or goals of the proposed treatment, such as functional improvement, pain relief, or expected psychosocial benefit;

_____ The risks and benefits of the proposed treatment;

_____ The extent the proposed treatment could interfere with any ongoing or recommended medical care;

_____ A description of the underlying therapeutic basis or mechanism of action of the proposed treatment purporting to have a reasonable potential for therapeutic gain that is written in a manner understandable to the patient;

_____ If applicable, whether a drug, supplement, or remedy employed in the treatment is:

_____ approved for human use by the U.S. Food and Drug Administration (FDA);

_____ exempt from FDA preapproval under the Dietary Supplement and Health Education Act (DSHEA); or

_____ a pharmaceutical compound not commercially available and is subject to clinical investigation standards.

_____ Documented treatment plan that is tailored for the individual needs of the patient and considers the patient's 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 favorable risk/benefit compared to other treatments for the same condition;

_____ There is a reasonable expectation that the treatment will result in a favorable patient outcome, including preventive practices;

_____ The expectation that a greater benefit for the same condition will be achieved than what can be expected with no treatment; and

_____ The periodic review of the treatment will be made at reasonable intervals considering:

a. the patient's progress under the treatment prescribed, ordered or administered; and

b. any new information about etiology of the complaint in determining whether treatment objectives are being adequately met.

_____
(Patient's Name Printed)

_____
(Patient's Signature)

_____
Date