Pre-Application for Initial CME Accreditation

Thank you for requesting a Pre-Application. Texas Medical Association (TMA) looks forward to supporting your efforts to become a TMA-accredited continuing medical education (CME) provider. The following document contains information regarding accreditation, expectations, eligibility to apply for TMA accreditation, an overview of the Pre-Application process, and the Pre-Application.

Purpose of Accreditation
Accreditation is a mark of quality CME activities that are planned, implemented and evaluated by accredited providers in accordance with Accreditation Criteria, Standards for Commercial Support, and policies. Accreditation assures the medical community and the public that such activities provide physicians with information that can assist them in maintaining or improving their practice of medicine, to help them bridge the gap between today’s care and what care should be. In addition, accredited CME activities are free of commercial bias and based on valid content.

The ACCME and TMA
The Accreditation Council for Continuing Medical Education (ACCME) is the organization that sets educational standards and policies for CME activities. ACCME accredits organizations that serve a national target audience of physicians and recognizes state medical societies as accrediting partners within the states that choose to operate as accreditors. If more than 30% of the physician target audience in your proposed CME Program comes from outside Texas and its contiguous states, or if your organization is an LCME-accredited school of medicine, contact the ACCME for national accreditation.

TMA is recognized by the ACCME as an accreditor of CME providers in Texas. TMA’s system of accreditation is equivalent to that of the ACCME’s national system of accreditation; therefore, you will see some references to ACCME policies, especially in the Standards for Commercial Support, which are trademarked by the ACCME. Additional information about the ACCME, headquartered in Chicago, IL, can be found at www.accme.org.

TMA’s Expectations
- For initial applicants, the accreditation process takes nine to eighteen months. Eligible organizations that decide to apply for TMA accreditation should be prepared to both describe and furnish evidence that demonstrates compliance with the accreditation requirements, therefore, organizations must plan, implement and evaluate at least two CME activities within the 24-month period prior to the submission of the Self-Study Report, one of these activities should be implemented prior to the submission of the Pre-Application, and used as the example in the Pre-Application. These two activities can be in joint providership with an accredited organization (ACCME- or TMA-accredited) or can be offered without formal CME credit.
- TMA expects its accredited providers to monitor their overall CME program on a regular basis for compliance with the accreditation requirements and to fulfill annual reporting requirements.
- Payment of certain fees is required to obtain and maintain TMA accreditation. Standard accreditation fees and other types of fees are provided in the TMA Accreditation Manual. The manual can be accessed at www.texmed.org.

Eligibility to Apply for TMA Accreditation
- Be located in Texas;
- Be developing and/or presenting a program of CME for physicians on a regular and recurring basis;
Serve a target audience of no more than 30% of physician learners from outside Texas and its contiguous states. Organizations with a national audience should apply for accreditation from the ACCME (www.accme.org);

Demonstrate an overall organizational commitment to the CME program, including physician support, budget support, staffing, and record-keeping resources;

Not be a commercial interest. A “commercial interest” is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients;

Not be developing and/or presenting a program of CME that is, in the judgment of TMA, devoted to advocacy on unscientific modalities of diagnosis or therapy;

Present activities that have “valid” content. Specifically, the organization must be presenting activities that promote recommendations, treatment or manners of practicing medicine that are within the definition of CME. Providers are not eligible for accreditation if they present activities that promote treatments that are known to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients; and

Demonstrate the capacity to comply with TMA accreditation requirements and policies.

When there is a question regarding eligibility, TMA reserves the right to make decisions on the issue.

Pre-Application Process
The first step in becoming accredited is completion of the Pre-Application for TMA Accreditation; after you have developed and offered one activity according to accreditation standards. The purpose of the Pre-Application is to provide you with an opportunity to explain your eligibility for TMA accreditation, as well as to demonstrate that your organization has mechanisms in place to fulfill TMA’s accreditation requirements in the CME activities that you are producing or have produced, and to attach examples to verify your descriptions. The materials are not reviewed for compliance with TMA accreditation requirements. TMA determines compliance during the initial accreditation process and bases compliance on three data sources: the Self-Study Report, evidence of performance-in-practice (activity file review), and the accreditation interview. Therefore, if TMA approves your Pre-Application, it is not a guarantee that your organization will receive Provisional Accreditation.

As you engage in the Pre-Application process, TMA encourages you to take advantage of resources available on our website. Accreditation Criteria, Standards for Commercial Support, and policies are included in the TMA Accreditation Manual.

Once your organization has submitted the Pre-Application and the non-refundable $250 fee, TMA will review the materials to determine your organization’s eligibility and to verify that mechanisms are in place for your organization to meet TMA requirements. You will receive a response within six weeks of the submission of the Pre-Application and fee — TMA may request additional information during this review period or notify your organization in writing whether or not it is eligible to continue with the initial accreditation process.

Please email the completed application and its attachments to casey.harrison@texmed.org. Contact TMA’s CME office at (800) 880-1300 ext. 1446 for any additional questions regarding the Pre-Application or accreditation requirements. Submit the $250 Pre-Application non-refundable fee to: Casey Harrison, CME, Texas Medical Association, 401 W. 15th St. #100, Austin, TX 78701.

The TMA looks forward to supporting your efforts to become a TMA-accredited CME provider.
Pre-Application for TMA Accreditation
Fill out the application form completely. Do not leave questions blank.

Section 1: Organizational Information

Name of organization as it should appear on TMA documents:

Primary CME Staff Contact
Name:
Title:
Telephone:
Email:
Full Mailing Address:

Chair of CME Committee
Name:
Telephone:
Email:
Full Mailing Address:

Chief Executive Officer or CME Designee
Name:
Title:
Full Mailing Address:
Email:

Others Who Should Receive Copies of CME Correspondence (if any)
Name:
Title:
Telephone:
Email:
Full Mailing Address:

A. Select the type of organization applying for accreditation from the drop-down menu below:
   Click here to choose an item.

B. Select a checkbox and provide the information requested for the organization type that most accurately describes your organization:

   □ Hospital or Medical Center
   Number of beds:
   Number of active medical staff:

   □ Multi-facility Hospital or Healthcare System
   List the facilities and/or organizations that comprise the applicant entity:
   Total number of beds:
   Total number of active medical staff:

   □ Specialty Society
   Number of members:

   □ Physician Group
   Number of members:
Consortium

List the facilities and/or organizations that comprise the applicant entity:

Other — please describe:

To be eligible for TMA accreditation, you must operate the business and management policies and procedures of its CME program (as it relates to human resources, financial affairs and legal obligations), so that your obligations and commitments are met. The following items ask for information to substantiate that this framework is in place.

C. Is your organization an employer of staff?  □ Yes (see below)  □ No (go to D)

If yes, attach the table of contents from your organization’s human resources and financial policies or procedures manual. (This is not your CME department’s policies.) If your organization does not have a policies or procedures manual, attach materials to demonstrate that the human resource, financial affairs, and legal obligations and commitments are met (e.g., organization’s bylaws, membership guidelines, etc.). Label your documentation: Attachment 1 — Policies and Procedures

D. Attach an organizational chart that shows the structure and staff reporting relationships for your CME Program. If your CME program is part of a larger institution, include an organizational chart that shows the position of the CME Program in relation to the institution’s overall structure. Label your documentation: Attachment 2 — Organizational Structure

E. If your CME Program has annual audited financial statements, attach a copy of these statements for the past year, or if your CME Program does not have annual audited financial statements, attach an income and expense statement for your CME Program for the past year. Label your documentation: Attachment 3 — Financial Statement

Section 2: Independence from Commercial Interests

F. The ACCME defines a “commercial interest” as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. A commercial interest is not eligible for accreditation. Answer yes or no to the following questions.

1. Does your organization, or a part of your organization, produce, market, re-sell, or distribute health care goods or services consumed by, or used on, patients?  □ Yes  □ No

2. Does your organization have a parent company that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients?  □ Yes  □ No

3. Does your organization have a sister company that produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients?  □ Yes  □ No

4. Does your organization advocate for an ACCME-defined commercial interest?  □ Yes  □ No

5. Does your organization have a parent company that advocates for an ACCME-defined commercial interest?  □ Yes  □ No

6. Does your organization have a sister company that advocates for an ACCME-defined commercial interest?  □ Yes  □ No

If you answered yes to any of questions 1-6 above, describe the organizational and procedural safeguards that are in place to ensure that the CME entity is separate from any commercial interest.
within the larger corporate structure of your organization: and **attach** an organizational chart to depict these safeguards. **Label** your documentation: **Attachment 4 — Independence**
Section 3: Educational Content

Organizations are not eligible for TMA accreditation if they present activities that promote recommendations, treatment or manners of practicing medicine that are (a) not within the definition of CME, or (b) known to have risks or dangers that outweigh the benefits or known to be ineffective in the treatment of patients. An organization whose program of CME is devoted to advocacy of unscientific modalities of diagnosis or therapy is not eligible to apply for TMA accreditation.

G. **Describe** the nature and scope of the content that you offer, or plan to offer, through your CME activities:

Accredited providers must demonstrate that all of the recommendations involving clinical medicine in a CME activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.

Accredited providers must demonstrate that all scientific research referred to, reported, or used in their CME activities in support or justification of a patient care recommendation conform to the generally accepted standards of experimental design, data collection and analysis.

H. **Describe** how your CME program and CME activities ensure that the expectations articulated above are fulfilled (e.g. planning, procedures, policy, monitoring):

Section 4: Mechanisms to Support Compliance with TMA Requirements

F. **Attach** your CME mission statement; and **highlight** on the copy of your CME mission statement where you state the **expected results** of the program described in terms of changes in competence, OR performance, OR patient outcomes. [Criterion 1]. **Label** your documentation: Attachment 5 — CME Mission Statement

For the next section, within the context of your organization’s processes and mechanisms, describe and demonstrate all of the steps your organization takes to incorporate the TMA’s requirements into your creation of CME activities. Several of the questions will ask you to provide information using the activity you provided that reflected the accreditation standards.

G. **Describe** the practices in place that demonstrate your organization:
   1. Identifies the professional practice gaps that the activities are addressing [Criterion 2]:
   2. Determines the educational need(s) (knowledge need, competence need, or performance need) underlying the gaps of your learners [Criterion 2]:

   Using the activity you provided,
   State the professional practice gap(s) of your learners on which the activity was based:

   State the educational needs that you determined to be the cause of the professional practice(s) gaps:

H. **Describe** the practices in place that demonstrate that your activities are designed to change either physician competence, or performance, or patient outcomes [Criterion 3]:

Using the activity you provided,
State what the CME activity was designed to change:
I. Describe the practices in place that demonstrate that your organization’s CME planning process is independent of the control of any ACCME-defined commercial interest; and the mechanisms implemented to ensure that you, as the accredited provider, will take to retain complete control of the CME content. Relate your description to each element of Criterion 7, SCS 1:

a) Identification of CME needs:
b) Determination of educational objectives:
c) Selection of presentation of content:
d) Selection of all persons and organizations that will be in a position to control the content of the CME:
e) Selection of educational methods:
f) Evaluation of the activity:

The use of employees of ACCME-defined commercial interests as faculty and planners of accredited CME is prohibited, except in the specific situations permitted by the ACCME that maintain independence as specified on the ACCME website (www.accme.org) related to: 1) reporting about research and discovery; 2) demonstrating the operational aspects of the use of a device; and, 3) controlling content that is not related to the products, services, or business lines of the commercial interest. A provider must demonstrate that it complies with ACCME requirements to ensure independence in these specific situations. Without such evidence, this practice will result in noncompliance with C7 (SCS 1.1). *See http://www.accme.org/education-and-support/video/tutorials/ensuring-independence-role-employees-accme-defined-commercial for more information on this topic.*

J. If your organization uses employees/owners of ACCME-defined commercial interests as faculty, planners or in any other role associated with your CME activities, please describe how you are doing so in accordance with the three circumstances listed above. If no, write in this section, “We do not use employees/owners in association with our CME activities.” [Criterion 7 (SCS1)]:

Mechanisms to identify and resolve conflicts of interest for individuals who are engaged in planning CME activities may vary. For example, mechanisms used to resolve conflicts of interest for speakers, may not be the appropriate mechanisms for planners and CME Committee members.

K. Show/Attach the mechanism(s) that you use to identify relevant financial relationships. This may be your disclosure form, if you use one, or other communications. Your process must (1) be inclusive of all the elements of the ACCME definition of a commercial interest, specifically that a commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients; and (2) capture the financial relationships of a spouse or partner; and (3) the financial relationships reported are not limited to “significant” relationships and include financial relationships in any amount occurring within the past 12 months that create a conflict. [Criterion 7 (SCS 2.1)]. On your mechanism(s), use the following letters, and label (a) the definition of commercial interest used, (b) how you capture the financial relationships of a spouse or partner; and (c) how the financial relationships reported are not limited to “significant” relationships and include financial relationships in any amount occurring within the past 12 months that create a conflict. Label your documentation Attachment 6 – Process to Identify Relevant Financial Relationships

L. Describe the mechanism(s) that you implement to resolve conflicts of interest for all persons in position to control educational content (i.e., speakers, authors, planners, reviewers, and any others who control content) prior to delivery of the educational activity. Mechanisms [Criterion 7 (SCS 2.3)]:

What documentation do you plan to provide to support how you resolved or will resolve conflicts of interest?

M. Describe the practices you have in place to demonstrate that you disclose to learners the following:
1. Presence or absence of relevant financial relationships for all person in control of content [Criterion 7 (SCS 6)];

2. Sources of commercial support for the activity if you received commercial support or plan to receive commercial support. [Criterion 7 (SCS 6)];

**Using the activity you provided,**

Attach documentation which shows (1) that you transmitted information about the presence or absence of relevant financial relationships to learners and, (2) if applicable, that you have disclosed the source of commercial support for the CME activity to learners in practice. Label your documentation: Attachment 8 – Disclosure to Learners

N. Do you accept or plan to accept commercial support for CME activities? ☐ Yes (see below) ☐ No (go to O)

If yes, describe your process(es) for the receipt and disbursement of commercial support, both funds and in-kind support. [Criterion 8 SCS 3)];

**Using the activity you provided,**

Attach one completed Written Agreement (signed by both parties as outlined in SCS 3.6) that demonstrates appropriate management of commercial support if your activity received commercial support, or a sample Written Agreement that will be used for activities that receive commercial support. Note: SCS 3.6 requires that both the commercial supporter and the provider sign the written agreement between the commercial supporter and the provider. Label your documentation: Attachment 9 — Written Agreement

O. Do you organize or plan to organize commercial exhibits for ACCME-defined commercial interests in association with any of your CME activities? ☐ Yes (see below) ☐ No (go to P)

If yes, describe how your organization ensures that arrangements for commercial exhibits do address the following:

1. Do not influence planning or interfere with the presentation [C9 (SCS 4.1)];

2. Are not a condition of the provision of commercial support for CME activities [C9 (SCS 4.1)];

P. Do you arrange or plan to arrange for advertisements in association with any of your CME activities? ☐ Yes (see below) ☐ No (go to Q)

If yes, describe how your organization ensures that advertisements or other product-promotion materials are kept separate from the education. In your description, distinguish between your processes related to advertisements and/or product promotion in each of the following types of CME activities: (a) print materials, (b) computer-based materials, (c) audio and video recordings, and (d) face-to-face. [C9 (SCS 4.2 and 4.4)];

Q. Using the activity you provided, attach the data or information generated from your CME activity about changes achieved in learners’ competence OR performance OR patient outcomes. [Criterion 11]. Label and bookmark this Attachment 10 — Change Data

R. Based on data and information from your program’s activities/educational interventions, provide your analysis of changes achieved in your learners’ competence, performance, or in patient outcomes, including the conclusions you have drawn as to whether, or not, your CME activities achieved the changes in learners the were designed to achieve, and why or why not. [Criterion 11]:
S. Based on data and information gathered, provide your program-based analysis on the degree to which the expected results component (changes in competence, performance, and/or patient outcomes) of your CME mission has been met through the conduct of your CME activities/educational interventions, including the conclusions you have drawn as to whether, or not, your CME mission has been met, and why or why not. [Criterion 12]:
Section 5: Attestation

Application Agreement to Policies and Conditions

- Texas Medical Association (TMA) shall have no financial obligation in connection with the organization and its sponsorship of continuing medical education.

- The applicant shall defend and indemnify TMA against any and all liability for claims asserted against TMA arising out of or in connection with TMA’s accreditation of this organization.

- The applicant agrees to fully adhere to all policies and guidelines as described in the TMA manual Continuing Medical Education Accreditation Requirements for Providers in Texas.

- Applicant acknowledges that published material on the accredited program and its activities may use TMA’s name only as required in the accreditation statement. All other references to TMA by name or logo are prohibited.

- It is understood that accreditation by TMA indicates only TMA’s verification that the program is in adequate compliance with TMA accreditation requirements and policies as adopted by the Committee on Continuing Education.

- Accreditation of the organization’s continuing medical education program does not indicate nor imply TMA’s endorsement of the program in any way.

- Applicant acknowledges that no individually identifiable patient health information should be included in this Pre-Application, a future Self-Study Report, or any other information submitted to TMA.

I have read, understand, and agree to the above TMA policies and conditions for the accreditation of our continuing medical education program.

Name of organization as it should appear on TMA documents:

Name of Primary CME Staff Contact:

Signature: __________________________ Date: ________________

Name of Physician Responsible for CME (i.e. Chair of CME Committee):

Signature: __________________________ Date: ________________

Name and Title of Administrator with CME Oversight (i.e. CMO, CEO):

Signature: __________________________ Date: ________________