What to Look for in the CME Activity Proposal

All questions require a response with the exception of questions 20 and 21 which may or may not be applicable to the activity and question 12A which only requires a response for renewal activities.

Section A: General Information & Activity Planners

Question 1 - General Information & Activity Planners

- Have they inserted a submission date? If this is revised based on your comments has the date been updated?
- If this is a renewal, have they listed the title and dates from the previous year's offering?
- Do we have full information for at least one course director (CD) and course administrator (CA)?
- If the only entries are one CD and the CA, based on the content of the course, does it appear that there should be additional activity planners? If so, please request that the CD confirm there are no additional planners.
- Do at least 50% of the CDs have an HMS faculty appointment?

Section B: Tuition and Fee Wavers

Ouestion 2 – Tuition and Fee Waivers

- Have they indicated how many fee waiver applicants will be accepted?
- If they have indicated that no Fee Waiver Applicants will be accepted, this must be approved by Faculty Dean for Continuing Education, Sanjiv Chopra, MBBS, MACP. To make a determination of acceptability, we need the following information:
 - Tuition cost
 - Course participant limit
 - New course or renewal

Section C: Activity Description/Overview

Question 3 - Activity Description/Overview

- We are using this section to develop marketing materials and we now need to make sure it
 includes the following components in addition to anything else the Course Directors choose to
 write: some indication of practice gaps, educational needs, and what educational methodologies
 will be used.
- If there is anything stated that gives you pause or is exclusively focused on knowledge acquisition, a comment should be made.
- Have they listed other courses, especially Harvard courses, which may conflict or are offered
 within two months of the activity? If other similar Harvard courses are offered within less than 2
 months, the course CANNOT be approved and this issue needs to be sent to Director of
 Compliance, Danna Muir.

Section D: Educational Planning

Question 4 – Target Audience

• Does the answer include fields of health professionals, specific specialties of the learners and geographic locations from which the intended learners are drawn?

Question 5 – Practice Gaps

• Does the response clearly identify at least one practice gap and not just an educational need? If it is a multiday review course, does it identify several practice gaps?

Question 6 – Educational Needs Underlying the Gaps

- Is at least one of the checkboxes selected to indicate if the needs are knowledge-based, competence-based, or performance-based?
- Does it state the reason why the educational need exists?

Ouestion 7 – Desired Change

- Is at least one of the checkboxes selected to indicate if the desired change is focused on competence, performance, or patient outcomes?
- Is the desired change realistic based on the practice gaps and underlying educational need?
- Is the desired change realistic based on the learning objectives?
- Is the desired change realistic based on the activity's educational format and methodologies?

Question 8 - Barriers to Change

• Are the barriers identified actual learner barriers? If they are barriers related to the design of the course (i.e. there is too much information provided in the course for learners to incorporate into their practices) this must be changed.

Ouestion 9 – Sources of Needs Data

- Do the sources of needs data identified match with the practice gaps and educational needs identified?
- Based on the information provided, are they realistic?

Question 10 – Document Needs Assessment Sources

- Do the sources match what was stated in the practice gaps and educational needs responses? (Non compliant example: the gaps indicate that there is new knowledge that learners need to incorporate into their practice but the references cited are all quite old)
- Do the sources match the responses from Question 9?

Question 11 – Competencies

- Has at least one competency checkbox been selected?
- Do the identified competencies match the agenda/content information provided? Based on the content, are too many competencies selected? Too few?

Question 12 – Agenda/Content

- Has an agenda been attached?
- Have the day and date for each day of the course been identified?
- Are the lengths of each session clearly identified?
- Are breaks clearly identified?
- Are breaks provided so that participants are not sitting for 3.5 hours or longer?
- Has time for transferring between rooms been identified as needed?
- Are sessions with titles such as "Meet the Professor" described so that you can determine if education is taking place?
- Do any of the sessions appear to be non-certifiable?
- Are confirmed faculty identified?
- Are the institutions/employers of faculty members identified?
- Have opportunities for participant interaction been identified (e.g. Q&A, case-based discussion, hands-on skills stations, small group discussion, etc)?
- Does the education appear to be balanced and non-commercially biased?
- Does the course have any sessions that would qualify for opioid/pain management or end-of-life care credits under the MA Board of Registration in Medicine regulations?

Question 12A – Changes Incorporated Since Last Offering

- This question is only required for renewal courses
- Have they described any changes that demonstrate that the course has been updated? If not, this
 needs to be discussed with the Director of Compliance, Danna Muir, prior to giving the course an
 approval status.

Question 13 – Faculty Selection

- Are at least 40% of the faculty from Harvard?
- If this is a new activity, have at least 70% of the faculty been confirmed?

Question 14 – Employees of Commercial Interests

• If they have indicated that employees of commercial Interests are involved in the course, the Director of Compliance, Danna Muir must be informed so she may follow-up to see if their involvement is appropriate.

Question 15 – Scope of Practice

Does the response link the educational content of the activity to the identified learners?

Question 16 – Learning Objectives

- Are the learning objectives stated based on what the learner will be able to do after participation rather than what the activity will teach them? (Non-compliance example: Review advances in the field of...)
- Are active verbs used to convey what the learner will be able to do as a result of the education? (Non-compliance examples: understand, review, gain an appreciation of, etc.)
- Do the verbs used match the identified desired changes (i.e. do they indicate changes in knowledge, competence, performance or patient outcomes specific to the activity)?

Question 17 – Activity Format

- Is the correct activity type selected? (Definitions of activity types can be found in the appendix)
- If any form of enduring material/distance learning or live streaming CME has been indicated in addition to any other form of live event, DCE (via Associate Director of Distance Learning, Andi Long) must be made aware of this before the proposal can be approved. We approve very few of these activities because we don't currently have the infrastructure to oversee them.

Question 18 – Educational Methodologies

- Do the selected methodologies support the desired change?
- Do the selected methodologies match what was indicated in the agenda?
- Were there any methodologies selected that appear to be a misunderstanding?
- Have they articulated how the learning format AND educational methodologies will support the learning objectives and desired result of the activity? If there are multiple formats selected, does this question address each of the formats?

Question 19 – Evaluation

- At a minimum, has "intent to change been selected"?
- If evaluation methods have been selected that would require more than a survey instrument (e.g. faculty observation, hands-on skill stations), does the response indicate how such methods will be implemented?
- Does the level of evaluation match the desired change?
- Have they indicated how the data will be used once it is analyzed?

Question 20 – Non-education Strategies

- Most responses will be "not applicable" and this is fine
- If non education strategies have been identified, are they legitimate strategies? (Non-compliance: A syllabus will be provided)

Question 21 – Collaboration and Partnership

• This question may not be applicable to all courses and may be left blank.

Question 22 – Activity Funding

• Has a method of funding been selected?

Question 23 – Commercial and Foundation Support

- Has the question been answered?
- If they have indicated in-kind support will be provided, does the response include the type of in-kind support?
- If commercial support is being sought, does the response list at least two commercial interests? (HMS's COI Policy requires at least 2 commercial supporters if commercial support is being sought.)

Question 24 – Exhibits and Promotion

• Has the question been answered?

Section E: Credit Sought

Question 25 – Credit Sought

• Has the question been answered?

Section F: Logistics

Question 26 – Logistics

• If the course will be listed on the HMS DCE website, question D must show that HMS DCE is providing registration services; the Course Director may also do so but at a minimum, DCE must be selected.

Course Approval and Net Income Distribution Form

- Has the correct form been completed? Standard or Community Program?
- Has the form been signed?
- Does the budget make sense? Any concerns?
- Have they listed who will be receiving honoraria and how much each person will receive?
- Do the honoraria amounts listed conform to the HMS DCE Policy on Honoraria?
- If the honoraria amounts listed do not conform to the HMS DCE Policy on Honoraria, have the amounts been justified?
- If the honoraria amounts listed do not conform to the guidelines, the proposal and NID form must be sent to the Director of Compliance, Danna Muir, for approval of such amounts. The proposal can still be approved but it must be noted that the rates are being reviewed and have NOT been approved.
- Has the Net Income Distribution information been completed?

Disclosure and Content Attestation Forms for Course Directors

- Does the Course Director have any conflicts of interest? If so, the proposal must be peer-reviewed by a physician chosen by DCE. Please indicate in your approval email which course director has a conflict and that such a medical review is needed.
- If no conflicts of interests exist, please indicate in your email that no COIs exist.

Preliminary Approval Emails for Renewal Courses Should Contain the Following Information:

- The proposal with comments
- The agenda with comments
- If any comments/changes have been made and in what questions those changes/comments can be found
- Any questions or special notes (e.g. questions to Dr. Chopra regarding approval for non-acceptance of fee waiver applicants)
- If employees of commercial interests are involved in the course

- Findings of the review of Course Directors' disclosures Are there any conflicts of interest present? (If so please indicate that a medical review of the proposal is needed.) Are there remaining questions that will need someone else's review to determine if COIs exist?
- If any form of distance learning/enduring materials are indicated as being offered if so Associate Director of Distance Learning, Andi Long must be included on the email
- Describe any issues there may be with honoraria amounts listed

Final Approval Emails for Renewal Courses Should Include the Following Information:

- The approved proposal
- The approved agenda
- The credit calculation spreadsheet and any important information related to the calculation of credit
- If there are any remaining comments or changes that need to be made and in what questions those changes/comments can be found
- What the course is designed to change (i.e. competence, performance, or patient outcomes)
- If similar Harvard courses are being offered within 2-3 months of this course, this must be identified
- If the course will be receiving commercial support (only include if it will be) if so, cc Jane Doctoroff
- If the course will be seeking exhibits or advertisements (only include if it will be) if so cc Jane Doctoroff
- If employees of commercial interests are involved in the course
- If any form of distance learning/enduring materials are indicated as being offered if so Andi Long must be included on the email
- If the NID form is complete and signed
- If not previously indicated in a preliminary approval:
 - Findings of the review of Course Directors' disclosures Are there any conflicts of interest present? (If so please indicate that a medical review of the proposal is needed.) Are there remaining questions that will need someone else's review to determine if COIs exist?
 - o Describe any issues there may be with honoraria amounts listed