

**INFORMATION PACKET  
MANUSCRIPT REVIEW**

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## **CME MISSION STATEMENT**

### **Context**

The Division of Continuing Medical Education at Loyola University Chicago – Stritch School of Medicine serves a Jesuit tradition of academic excellence in education, research and clinical care that embraces social responsibility, service to those in need, and respect for diversity of thought, opinion, and belief.

### **Vision**

At Stritch School of Medicine, the CME program seeks to see beyond the traditional administrative and crediting functions of medical education, and challenges itself to become a catalyst, advocate for, and a provider of education that promotes change, development and improvement. We recognize that as a CME program and provider we must model behaviors that place a premium on quality improvement if we are to successfully communicate this message and practice to our educators and learners.

### **Purpose**

We believe that CME facilitates and promotes the process of lifelong learning – a process that should help healthcare professionals at all stages of their professional development acquire the knowledge, attitude and skills necessary for contemporary medical practice.

Our CME program sees its purpose as providing high-quality, evidence-based educational opportunities that are designed to advance physician competence, enhance practice performance, promote patient safety, and, where possible, improve patient outcomes in the populations served by the healthcare providers we educate.

### **Target Audience**

We seek to serve not only the educational needs of healthcare professionals (physicians, allied health personnel, basic scientists, and researchers) within our institution but the needs of local, regional, and national healthcare providers and colleagues as well.

### **Types of Activities Provided**

As a CME provider at an academic tertiary-care medical center, our educational activities include department-specific, interdepartmental and specialty-specific conferences, symposia and seminars. These events take the form of live courses, live regularly scheduled series, and live internet activities. The educational design, instructional method and learning format for each event is chosen to best serve the educational needs and learning objectives of the planned educational activity.

### **Content**

Our activities offer a broad array of educational content targeted to the needs of the learners. Included among our educational offerings are updates in clinical medicine and basic science research, reviews of current or best practice recommendations for clinical care, learning modules in quality improvement, procedural and communication skill development exercises, as well as professional development in bioethics, leadership and patient safety.

### **Expected Results**

Following an educational activity, we expect that learners, when surveyed, will report expanded or reinforced knowledge. We expect that they will report greater confidence in their approach to clinical problems or express their intent to change their behavior and apply newly acquired strategies in their practice. We expect that when observed our learners will demonstrate competence and an effective use of targeted skills. Finally, if evaluated within the setting of clinical practice, we expect performance parameters to show improvement or a favorable impact on targeted patient outcomes to be demonstrated.

## DEFINITIONS

### ***Manuscript Review (for journals) Activity***

Manuscript review activities describe a learning process in which physicians, under the collaborative direction of a journal editor and an accredited provider, critically review assigned journal manuscripts.

### ***Joint Sponsorship***

Joint sponsorship refers to single CME activity sponsored by LUSSOM (the accredited provider) and a non-accredited institution.

### ***Co-Sponsored Activities***

Co-sponsorship refers to a single CME activity developed by two CME accredited providers.

### ***Educational Partner***

An educational partner is an institution outside of LUSSOM providing assistance in the educational planning of a CME activity accredited by LUSSOM (i.e. communication company, associations).

### ***Commercial Interest***

Any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients.

### ***Commercial Support***

Financial or in-kind (equipment or instrument use) contributions given by a commercial interest to the CME provider. Financial support in the form of an educational grant is used to pay all or part of the costs incurred for a CME activity. In-kind support is use of equipment or instruments for workshop demonstrations or hands-on labs within an activity.

### ***Financial Relationships***

Relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. Relationships of the person involved in the CME activity also include financial relationships of a spouse or partner.

### ***Conflict of Interest***

Conflicts created when individuals have both a financial relationship with a commercial interest **and** the opportunity to affect the content of CME about the products or services of that commercial interest. The potential for maintaining or increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of the CME – an incentive to insert commercial bias.

### ***Commercial Bias***

A personal judgment in favor of specific healthcare goods or services of a commercial interest.

## POLICIES AND PROCEDURES

Loyola University Chicago Stritch School of Medicine, Division of Continuing Medical Education (LUSSOM-CME) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to sponsor continuing medical education for physicians. The Division of CME has developed the following policies to guide the planning process of CME Category 1 educational activities.

### **Activity Application**

All enduring materials educational activities applying for Category 1 CME Credit must complete the appropriate application for CME credit. The application should be submitted a minimum of six months prior to the date of the activity. The complete application (including all required addenda) must be signed by the activity director and the Loyola department chairman and returned to the Division of CME.

### **Budget Estimate**

The CME budget estimate is included with the application. The CME budget estimate must be signed by the course director and the department chairman and returned to the Division of CME along with the credit application. Sponsoring department must submit a budget estimate listing all expenditures and income for production and distribution of media.

### **CME Committee Review**

The CME Committee reviews all activities submitted to the Division of CME for credit approval. The committee's responsibilities are to: (1) provide oversight for the conduct of LUSSOM-CME activities; including review and approval of continuing medical education activities, (2) insure that continuing medical education activities comply with Loyola's policies/procedures and are supportive of the CME Mission and (3) provide recommendations to the activity directors.

At initial review, the committee reviews both the credit application including all addenda (i.e. gap analysis data, schedule, speaker list, disclosure forms) and the budget estimate of all expenditures and income for production and distribution media for each activity. The Division of CME must receive the application and signed budget estimate by the 1<sup>st</sup> of the month for review at that month's review meeting. Committee will not review applications that are not complete. Committee will not review or approve any application submitted less than six months prior to the activity date.

### **Approval Status**

The journal editor will receive written correspondence regarding the activity's credit approval or denial, as well as, any concerns the committee may have identified.

### **Joint or Co-Sponsorship**

Manuscript Review activities will not be conducted with a joint or co-sponsor

### **Educational Partner**

*Manuscript Review activities will not be conducted with an educational partner.*

### **Accreditation from Other Disciplines**

It is acceptable for the sponsoring department to apply to disciplines that do not recognize CME credit (i.e. nursing, social work, podiatry, etc.) to request accreditation from that entity for an activity. All inquiries and applications must be done by the sponsoring department. The Division of CME does not apply to outside organizations for credit.

### **Disclosure**

Journal editor is responsible for obtaining a completed disclosure response form from every individual in a position to control the content of an educational activity (i.e. manuscript authors, journal editor, reviewers, planning committee members, etc.). Every individual in a position to control the content of an educational activity must disclose all financial relationships occurring in the past 12 months. Relationships include but are not limited to: grants or research support; employee; consultant; stockholder; or member of speaker's bureau. An individual identifying that they receive grant/research support must indicate whether they participate in any promotional activities for the commercial interest. An individual identifying that they are a member of a speaker's bureau, must also disclose the content of the material they present for the commercial interest. Activity director must complete a disclosure response form for him/herself. Disclosure information of authors must be provided to manuscript reviewers prior to their review of the manuscript. If an individual refuses to disclose relevant financial relationships, the activity director must disqualify them from being a part of the CME activity.

Authors must also disclose if they are discussing products that are investigational or not labeled for use under discussion. Manuscripts must give a balanced view of the therapeutic options. Use of generic names of products contributes to impartiality.

If trade names are used, those of several companies should be used. If scientific research conducted by a proprietary company is the basis for a manuscript, then the research must conform to the generally accepted standards of experimental design, data collection and analysis. Content of manuscript must be prepared independent of commercial interest input and free of any commercial bias.

Activity director must disclose any financial relationships the Loyola sponsoring department has with commercial interests whose products are discussed or who are supporting the educational activity. Journal editor must disclose any financial relationships the journal has with commercial interests whose products are discussed in the manuscript being reviewed.

The disclosure of a relationship does not suggest or condone bias. Disclosure is to provide information that might be of potential importance to their role in the manuscript review process.

Disclosure information must be communicated to reviewers so that they are aware of this information prior to starting the manuscript review.

### ***Conflict of Interest***

The ACCME defines a conflict of interest as present when a planner, speaker or author has BOTH a financial relationship with a commercial interest and the opportunity to affect content relevant to products or services of that commercial interest. The purpose for identifying and addressing potential conflict of interest is to ensure a proper balance, independence, objectivity and scientific rigor of the educational activity. Any conflicts of interest identified must be resolved in order for the individual to participate in the activity.

If a conflict of interest is identified in disclosure obtained from reviewer, the journal editor must resolve the conflict before the reviewer is allowed to participate. If the conflict is not able to be resolved, the reviewer will be ineligible to receive AMA PRA Category 1 Credit for the manuscript review.

*Methods to resolve a conflict include but are not limited to:*

- Limit individual's role in review to include areas of the manuscript that do not create a conflict;
- Limit individual's role in review to data and results of research allowing another reviewer to address implications and recommendations for clinical care.

If a conflict of interest is identified in disclosure obtained from journal author, the conflict is not resolvable and the reviewers of that manuscript will be ineligible to receive AMA PRA Category 1 credit.

In the case of the disclosure response form completed by the activity director, the department chair must review the disclosure information and identify any potential conflicts of interest. If a potential conflict is identified, department chair must take steps to resolve the conflict before the individual can continue in their capacity as activity director. If the conflict is not able to be resolved, the department chair must replace the activity director or postpone conference until another activity director can be identified.

The CME committee will examine the disclosure response forms as part of the review process to grant credit to the activity. Any questions or concerns identified during the review process regarding conflict of interest will be referred back to the activity director and must be addressed and resolved before CME credit will be granted for the activity.

If a speaker is added to the educational activity after CME credit has been granted, the activity director must follow the same procedure of obtaining, reviewing and resolving a conflict of interest. Form is then forwarded to CME coordinator who will review with the CME director. Any questions or concerns identified must be immediately addressed and resolved by the activity director. If the conflict is not able to be resolved, the activity director must disqualify the individual from participating in the CME activity. The activity director is responsible for verifying the speaker does not have any conflict of interest and that the additional disclosure information is communicated to participants so that they are aware of this information prior to starting the educational activity.

### ***Honoraria***

The physicians participating as manuscript reviewers may not receive an honorarium.

### ***Travel Reimbursement***

The physicians participating as manuscript reviewers may not receive travel reimbursement.

### ***Commercial Interest Support***

No funding or 'in-kind' support can be accepted for a manuscript review activity.

### **Activity Account**

The physicians participating in the manuscript review activity assume all fiscal responsibility for CME activity.

### **Opening Statement of Manuscript Review Media**

Prior to the participant starting the educational activity the following information must be communicated. In the case of web-based media, this information must be first screen the participant must view and cannot be a link that they may view.

- Identification of Loyola University Chicago Stritch School of Medicine as Sponsor of the activity
- Loyola's logo
- Accreditation statements
- Curricular goals and Course objectives
- Faculty list with credentials
- Disclosure information of complete editorial staff
- Target audience
- Process for acquiring CME credit
- Reviewer instructions for the review process and access to reviewer training

### **Obligation of Editors**

The Editor-in-Chief directs and supervises the policies of a journal and is responsible for maintaining its scientific and literary quality. The first obligation of an Editor-in-Chief and the journal Editors is to make certain that all authors receive confidential, expert, critical, and unbiased reviews of their work in a timely fashion. The editors and members of the editor's staff should not disclose any information about a manuscript submitted for review to anyone except the reviewers or authors or those working on their behalf.

An editor may not take part in the editorial management of any report of the editor's own research because that involves conflict of interest. An editor must also avoid conflict of interest in the editorial management of reports of research closely related to the editor's own research. An editor may not use unpublished information of any kind from a submitted manuscript without written permission of the author.

If an editor is presented with convincing evidence that the main substance or conclusions of a report published in an editor's journal is erroneous or determined to be the result of misconduct, the editor should facilitate prompt publication of a report pointing out the error and, if possible, correcting it. The report may be written by all the authors. In those cases where it is not possible, or there is disagreement, the Editor-in-Chief may consider the report written by some of the authors, academic or institutional sponsor, editor, or the Society.

### **Obligation of Reviewers**

The critical and confidential review of manuscripts is an essential element of research publications. Every scientist has an obligation to contribute to the peer review process by serving as a reviewer. Among the obligations of reviewers is the commitment to providing an expert, critical, and constructive scientific and literary appraisal of research reports in their fields of knowledge, skills, and experience in a fair and unbiased manner. In order to facilitate the prompt sharing of scientific results, it is also the obligation of each reviewer to complete their assignments promptly, within the editor's deadline. Should a delay in their review occur, the reviewer has the obligation to notify the editor at once.

Reviewers should not review a manuscript if: 1) they do not think that they are competent to assess the research described, 2) they believe there is a conflict of interest or personal or professional relationship with the author(s) that might bias their assessment of the manuscript, or (3) there is any other situation that could bias their review. Employment at the same institution as one of the authors does not automatically represent a conflict. Having previously reviewed the article for another journal does not disqualify a reviewer, although the editor should be informed so the reviewer's perspective can be considered. In circumstances when reviewers need to recuse themselves, they should notify the editor promptly, preferably with an explanation. If reviewers are uncertain whether they should recuse themselves, they should consult with the editor.

The reviewer should strive to provide accurate, detailed, and constructive criticisms, and the review should be supported by appropriate references, especially if unfavorable. The reviewer should also note whether the work of others is properly cited. If the reviewer notes any substantial resemblance of the manuscript being reviewed to a published paper or to a manuscript submitted at the same time to another journal, they should promptly report this to the editor.

No part of the manuscript under review should ordinarily be revealed to another individual without the permission of the editor. If a reviewer consults a colleague on a particular point, this fact, and the name of the collaborator or consultant, should be reported to the editor, preferably in advance. With these exceptions, a reviewer must obtain through the editor written permission from the authors to use or disclose any of the unpublished content of a manuscript under review.

### ***Issuing of Category 1 Credit***

Only manuscript reviewers are eligible to receive AMA PRA Category 1 credit, journal editor is not eligible. A maximum of three AMA PRA Category 1 credits may be awarded per review. Credits will only be awarded after the editor and reviewer have fulfilled all CME requirements and provided all required documentation to the CME office. Incomplete segments by either editor or reviewer will result in no AMA PRA Category 1 credit earned.

- The texts to be reviewed must be original contributions to the medical literature that require multiple reviewers, e.g. NOT book reviews.
- The journal editor, working with CME, will need to educate reviewers about the CME process.
- Each manuscript reviewed is a separate occurrence of the manuscript review activity for which the journal editor must provide the following to the CME office:
  - disclosures from all individuals in control of the educational content (authors, reviewers, journal editor, etc.);
  - evaluation of each individual manuscript reviewer which included judgement as to the quality of the review
- For each manuscript reviewed the journal editor must provide the following to each reviewer:
  - overview and instructions;
  - accreditation and designation statements;
  - disclosures from all individuals in control of the educational content (authors, reviewers, journal editor, etc.);
  - established objectives;
  - established criteria for content review;
  - provide training on manuscript review process
  - provide all needed instructions.
- Manuscript review assignments must be at a depth and scope that require:
  - review of the literature
  - knowledge of the evidence base for the manuscripts reviewed.
  - review of the evidence base must be documented by the reviewer.
- CME working with the journal editor must have an oversight mechanism to evaluate the quality of reviews submitted. Physicians who submit substandard reviews will not be allowed to continue as a reviewer and will not receive credit for substandard or subsequent activities.

### ***Non-Compliance***

LUSSOM reserves the right to withhold or withdraw accreditation from any manuscript review CME activity that is found to be non-compliant with any of the aforementioned policies and procedures.

## APPLICATION COMPLETION GUIDELINES

### Activity Type

The activity type has been determined from information provided by the activity director to the Division of CME. Accordingly the appropriate credit application and addenda packet have been provided for completion by the activity director.

### Education Planning

**Professional Practice Gap Determination:** The activity director with the assistance of his planning committee, if one is used, must conduct an analysis of the data to identify professional practice gaps (gaps in physician competence, practice performance or healthcare outcomes in patients). These professional practice gaps are the basis for developing the CME activity.

The final pages of this document contain information provided as an additional professional practice gap assessment tool to assist in the educational planning of activities. The web sites are sources that identify competency requirements, consortium measures, areas of need to better serve patients and public health priorities. Additional sites can be found by doing a web-search for "clinical gaps". Topics that attendees of previous CME activities identified as areas that would enhance their ability to provide quality patient care are also listed.

**Data Analysis:** The sources used for the Professional Practice Gap Analysis must be cited. Copies of the data/materials analyzed must be submitted with the application as documentation to support your findings.

**Analysis Summary:** After analysis is complete, summarize the findings of your data analysis and identify the professional practice gaps.

**Barriers to Overcome:** Identify any potential or real barriers facing the target audience in closing the professional practice gap(s) indicated (i.e. knowledge, skill, strategy, etc.).

**Educational Needs:** Cite the educational needs (changes to knowledge, competence, or performance) that will advance physician competence, enhance practice performance or improve healthcare outcomes in patients thereby closing the professional practice gap(s) identified in the analysis summary.

**Educational Aims:** Based on the physician target audience, the professional practice gap(s) identified and the educational needs cited, describe the educational aims of this activity.

**Professional Impact:** Describe the anticipated impact to be achieved with this educational activity on the professional practice gap(s) identified.

**Target Audience:** Based on the professional practice gap analysis identify the physician audience that will be the target for this activity.

**Prerequisites:** List any special background requirements of the target audience.

**Result:** Identify the desired result of this activity with regard to providing physicians with new abilities/strategies, assisting physicians to modify practice or improving patient outcomes.

**Competencies Addressed:** Identify the desirable physician attributes that this educational activity will address.

**Curricular Goals:** Based on the educational aims for this activity, provide statements of the knowledge, skills or attitudes to be addressed by this educational activity.

**Active Learning Objectives:** Based on the desired result identified for this activity, develop active learning objectives for each curricular goal. Learning objectives must describe in precise measurable terms what the learners will be able to accomplish at the conclusion of the educational activity. Learning objectives may include changes in problem solving, diagnostic or operative skills, improvements in knowledge, attitudinal changes or enhanced understanding of complex relationships.

**Educational Methodology:** The design of the educational activity should accommodate the identified educational needs and the stated learning objectives. The teaching/learning methods used should consider the target audience, knowledge level (skill level) of the participants, and be appropriate for the accomplishment of the learning objectives.

**Content Validity:** The activity must present recommendations involving clinical medicine based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. All scientific research referred to, reported or used in the CME activity in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis. CME activities must not promote recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or are known to have risks/dangers that outweigh the benefits or be ineffective in the treatment of patients. Presentations and materials must be prepared independent of commercial interests and free of commercial bias.

**Independence:** Educational planning of activity must be conducted without any input or control from commercial interests.

**Activity Evaluation:** An evaluation method must be selected and conducted at the conclusion of the activity to initially measure the success of the activity in achieving curricular goals, educational objectives and the intended professional impact.

**Outcomes Data:** Three-four months post-activity an electronic outcome analysis will be conducted for the activity by the Division of CME. The purpose of the analysis is to establish the extent to which the activity advanced physician competence, enhanced practice performance or improved healthcare outcomes in patients. A summary of the results will be provided to the activity director.