CME Activity Guide

A lifetime of learning

SUNY Downstate Medical Center
Office of Continuing Medical Education
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INTRODUCTION

Purpose of Guide

The purpose of this Activity Development Guide is to facilitate the development and implementation of continuing medical education (CME) activities at SUNY Downstate Medical Center and our affiliated hospitals, and to ensure that these activities comply with the guidelines of the Accreditation Council for Continuing Medical Education (ACCME) for certification of *AMA PRA Category 1 Credit™*. It contains guidelines, checklists, reference materials and other information you will need to take you through the development process.

All of the necessary data forms required to implement your activity may only be found on the Office of Continuing Medical Education (OCME) website at [www.downstate.edu/ocme](http://www.downstate.edu/ocme). These forms must be completed each time you apply for *AMA PRA Category 1 Credit™*. Please retain this Guide as a handy reference. The OCME welcomes your calls, should you have any questions that have not been addressed in the Guide, or if you need assistance in planning your activity.
Mission

Office of Continuing Medical Education
State University of New York Downstate Medical Center

CME Mission Statement

The mission of the Office of Continuing Medical Education (OCME) is to provide and support a comprehensive continuing medical education (CME) program that meets the needs of those involved in teaching, medical research, and the delivery of health care.

The OCME’s purpose is to assist its diverse faculty in promoting quality medical care, patient safety and physicians’ competencies in their specialties by providing quality CME activities. This will be accomplished in the following manner:

1. The content of the Office of CME activities will include topics targeting medical specialties and subspecialties focusing on knowledge, competence, clinical performance of participants on topics such as Asthma, Obesity, Diabetes and Cardiovascular Health affecting the Brooklyn Community, and patient outcomes.

2. The OCME target audience will include practicing physicians, physician assistants, nurse practitioners, pharmacists, visiting guests and other health care professionals in the community. However, as a strong academic medical school, our programs have attracted national and international audiences.**

3. The types of activities that the OCME will provide encompasses regularly scheduled conferences such as grand rounds, tumor boards, review courses, etc; regional, national, international symposia and conferences, teleconferences, and enduring materials (e.g., online learning, monographs, CD-ROMs, etc.).

4. The expected results of the CME Mission is to provide a lifetime of learning that:
   - measures changes in competence, performance and/or patient outcomes through continuous assessment of learner participant;
   - enhances our healthcare professionals and physician participants’ knowledge and skill set to improve patient care.

Approved, April 2009
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AMA Definition of Continuing Medical Education

“Continuing Medical Education consists of educational activities that serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships a physician uses to provide services for patients, the public, or the profession. CME represents that body of knowledge and skills generally recognized and accepted by the profession as within the basic medical sciences, the discipline of clinical medicine, and the provision of health care to the public.”

*American Medical Association (AMA)*

ACCME Essential Areas of Accreditation for Sponsors

The OCME must follow the Essentials set forth by ACCME in order to comply with the ACCME Standards. Below are the Updated Criteria for compliance with ACCME’s Accreditation Elements.

<table>
<thead>
<tr>
<th>THE ACCME’S ESSENTIAL AREAS AND THEIR ELEMENTS</th>
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<tbody>
<tr>
<td>ESSENTIAL AREA 1: PURPOSE AND MISSION</td>
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<tr>
<td>ESSENTIAL AREA 2: EDUCATIONAL PLANNING</td>
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<td>ESSENTIAL AREA 3: EVALUATION AND IMPROVEMENT</td>
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</table>

NOTE: The ACCME’s policies for disclosure and commercial support are articulated in (1) *The Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, as adopted by the ACCME in September 2004, and (2) The ACCME policies applicable to commercial support and disclosure. All materials can be found on [www.accme.org](http://www.accme.org).
### UPDATED CRITERIA FOR COMPLIANCE WITH ACCME’S ACCREDITATION ELEMENTS

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level 1 Provider</th>
<th>Level 2 Provider</th>
<th>Level 3 Provider</th>
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<tbody>
<tr>
<td>1. The provider has a CME mission statement that includes all of the</td>
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<td>☑</td>
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<td>basic components (CME purpose, content areas, target audience, type</td>
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<td>of activities, expected results) with expected results articulated</td>
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<tr>
<td>in terms of changes in competence, performance, or patient outcomes</td>
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<td>that will be the result of the program.</td>
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<td>2. The provider incorporates into CME activities the educational</td>
<td>☑ 2.1</td>
<td>☑ 2.2</td>
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<tr>
<td>needs (knowledge, competence, or performance) that underlie the</td>
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<td>professional practice gaps of their own learners.</td>
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<td>3. The provider generates activities/educational interventions that</td>
<td>☑ 2.1</td>
<td>☑ 2.2</td>
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<tr>
<td>are designed to change competence, performance, or patient outcomes</td>
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<tr>
<td>as described in its mission statement.</td>
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<td>4. The provider generates activities/educational interventions on</td>
<td>☑ 2.1</td>
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<tr>
<td>content that matches the learners’ current or potential scope of</td>
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<td>professional activities.</td>
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<tr>
<td>5. The provider chooses educational formats for activities/interventions</td>
<td>☑ 2.1</td>
<td>☑ 2.2</td>
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<tr>
<td>that are appropriate for the setting, objectives and desired results</td>
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<tr>
<td>of the activity.</td>
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<tr>
<td>6. The provider develops activities/educational interventions in the</td>
<td>☑ 2.1</td>
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<tr>
<td>context of desirable physician attributes (e.g., IOM competencies,</td>
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<tr>
<td>ACCME Competencies).</td>
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<tr>
<td>7. The provider develops activities/educational interventions</td>
<td>☑ SCS</td>
<td>☑ SCS</td>
<td>☑ SCS</td>
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<tr>
<td>independent of commercial interests (SCS 1, 2 and 3).</td>
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<tr>
<td>8. The provider appropriately manages commercial support (if</td>
<td>☑ SCS</td>
<td>☑ SCS</td>
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<td>applicable, SCS 3).</td>
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<td>9. The provider maintains a separation of promotion from education</td>
<td>☑ SCS</td>
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<td>(SCS 4).</td>
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<td>10. The provider actively promotes improvements in health care and</td>
<td>☑ SCS</td>
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<td>NOT proprietary interests of a commercial interest (SCS 6).</td>
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<tr>
<td>11. The provider analyzes changes in learners (competence,</td>
<td>☑ 2.4</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
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<tr>
<td>performance, or patient outcomes) achieved as a result of the</td>
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<tr>
<td>overall program’s activities/educational interventions,</td>
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<tr>
<td>12. The provider gathers data and information and conducts a program-</td>
<td>☑ 2.4</td>
<td>☑ 2.5</td>
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<tr>
<td>based analysis on the degree to which the CME mission of the</td>
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<tr>
<td>provider has been met through the conduct of CME activities/educational</td>
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<tr>
<td>interventions.</td>
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<tr>
<td>13. The provider identifies, plans and implements the needed or desired</td>
<td>☑ 2.4</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
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<tr>
<td>changes in the overall program (e.g., planners, teachers, infrastructure,</td>
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<tr>
<td>methods, resources, facilities, interventions) that are required to</td>
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<td>improve on ability to meet the CME mission.</td>
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<tr>
<td>14. The provider demonstrates that identified program changes or</td>
<td>☑ 2.4</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
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<tr>
<td>improvements, that are required to improve on the provider’s ability</td>
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<tr>
<td>to meet the CME mission, are underway or completed.</td>
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<tr>
<td>15. The provider demonstrates that the impacts of program</td>
<td>☑ 2.4</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
</tr>
<tr>
<td>improvements, that are required to improve on the provider’s ability</td>
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<tr>
<td>to meet the CME mission, are measured.</td>
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<tr>
<td>16. The provider operates in a manner that integrates CME into the</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
<td>☑ 2.7</td>
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<tr>
<td>process for improving professional practice.</td>
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<tr>
<td>17. The provider utilizes non-education strategies to enhance change as</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
<td>☑ 2.7</td>
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<tr>
<td>an adjacent to its activities/educational interventions (e.g.,</td>
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<td>reminders, patient feedback).</td>
<td></td>
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<tr>
<td>18. The provider identifies factors outside the provider’s control that</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
<td>☑ 2.7</td>
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<tr>
<td>impact on patient outcomes.</td>
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<tr>
<td>19. The provider implements educational strategies to remove, overcome</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
<td>☑ 2.7</td>
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<tr>
<td>or address barriers to physician change.</td>
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<tr>
<td>20. The provider builds bridges with other stakeholders through</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
<td>☑ 2.7</td>
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<tr>
<td>collaboration and cooperation.</td>
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<tr>
<td>21. The provider participates within an institutional or system framework</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
<td>☑ 2.7</td>
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<tr>
<td>for quality improvement.</td>
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<tr>
<td>22. The provider is positioned to influence the scope and content of</td>
<td>☑ 2.5</td>
<td>☑ 2.6</td>
<td>☑ 2.7</td>
</tr>
<tr>
<td>activities/educational interventions.</td>
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</tbody>
</table>
Regularly Scheduled Series Policy and Procedure

To be in compliance with the ACCME, all Activity Directors must comply with the mission of the OCME at SUNY Downstate Medical Center and the AMA’s definition of CME. Approval for category 1 certification depends on the following:

1. Regularly Scheduled Series (RSS): “The daily, weekly, or monthly CME activities of ACCME accredited providers that are primarily planned by and presented to the institution’s professional staff. These activities are often known as “Grand Rounds,” “Tumor Boards,” or “Morbidity/Mortality Conferences.” (Source: ACCME) RSS Activity Directors must be involved in the planning stages of the CME activity for which category 1 certification is being requested. The planning process consists of linking identified needs, objectives, and educational format to desired results. See Activity Development Worksheet on page 34.

2. The planned activity must conform to the AMA’s definition of CME, “CME consists of educational activities that serve to maintain, develop, or increase the knowledge, skills and professional performance and relationships a physician uses to provide services for patients, the public, or the profession.” The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. Presentations and activity materials must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational materials or content includes trade names, where available, trade names from several companies should be used, not just trade names from a single company

3. Certification Request Forms (CRFs) submitted for AMA PRA Category 1 Credit™ will not be considered for approval without all required forms and documentation. The following is required:
   a) Completed and signed CME Application Form
   b) Signed RSS Policy and Procedure (for new activity directors)
   c) Planning Minutes
   d) Global Objectives (for the activity as a whole)
   e) Needs Statement with supporting documentation
   f) Disclosures
   g) Preliminary Budget Form
   h) A sample flyer
   i) A sample evaluation form (if not using OCME form)
   j) Certification Request fee

4. Supporting documentation of your needs assessment and professional practice gaps must be part of the planning process and attached to the application and forwarded to the OCME. Reference to your needs assessment must be included in your planning minutes.

5. Planning of the CME activity may take place yearly or every other year. However, a planning process must be used to identify the professional practice gaps and needs assessment for the activity and linkage to the objectives and desired results.
Regularly Scheduled Series Policy and Procedure (cont’d)

6. The global educational objectives for the RSS must be stated. The objectives should relate to the need and tell participants what they will learn by attending the program. Global objectives pertain to the CME activity as a whole, which would be the objectives indicated on your application. You are required to obtain from each of your presenters, their session objectives. This means that each of your flyers will have different objectives. Do not use global objectives for each session held.

7. The target audience must be defined and stated.

8. Disclosure - All individuals who are in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest within the past 12 months. This includes, but is not limited to: activity medical directors, planning committee members, expert/peer reviewers, authors, faculty/speaker/presenters, moderators, panel members, and administrative support staff. Any individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, faculty/speaker/presenter, or an author of CME programs, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of an activity. Products or procedures being discussed that are off-label, unlabeled, experimental, and/or investigational and not FDA approved must be disclosed, including any limitations on the information that is presented, such as data that are preliminary or that represent ongoing research, interim analyses, and/or unsupported opinion.

9. A Budget Plan must be filled out and returned with the Certification Request Form. All anticipated income and expenses, including the OCME fee must be disclosed. A Final Budget Form must be filled out two weeks following the end of the activity.

10. Commercial Support
   a. A Commercial Support Form must be filled out if a commercial organization provides funding of any kind to the activity. The form must be signed by the company representative, the Activity Director, and the Director of the OCME.

   b. All commercial support funds are to be paid directly to the OCME or to the department presenting the activity with the OCME’s approval. Speakers, or any related expenses for the program, may NOT be paid directly by commercial companies. This includes travel, honoraria, gifts, etc. Please refer to the OCME’s Policy for Commercial Support.

11. All CME activities requesting category 1 certification must be evaluated.

12. Any audio or video of a program for later distribution must be approved by the OCME. Additional fees may apply.
Regularly Scheduled Series Policy and Procedure (cont’d)

13. The Activity Director must assure that the activity is HIPAA Compliant and agree to obtain all necessary copyright permission(s) for any portion of the CME activity materials that are not original works.

14. Program Announcement
   a. Brochures and announcement materials must have the statement of need, educational objectives and the intended audience.
   b. You may not indicate in the brochure or flyer that you have applied for credit or state the number of credits applied for until the OCME has issued an approval.
   c. The OCME at SUNY Downstate Medical Center, as the accredited provider, must be prominently displayed as the SPONSOR on the front of the brochure or flyer and your department as the PRESENTER of the activity.
   d. The educational format and course outline must be defined in the brochure.
   e. Registration fee and location of the activity must be present.
   f. Acknowledgement of any type of support by commercial companies must be identified in the brochure, and/or your flyer.
   g. Your flyer must indicate any disclosure information the speaker may have and any off-label usage.
   h. The Final Draft of the brochure must be reviewed and approved by the OCME before printing.
   i. The following Accreditation and Disclaimer Statements must appear on all distributed CME activity brochures and flyers. If you are planning a jointly-sponsored activity, please refer to page32 of this guide for the proper accreditation statement.

Accreditation Statement
The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

Designation Statement
The SUNY Downstate Medical Center designates this educational activity for a maximum of (insert # of credits) AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Disclosure Statement
SUNY Downstate Medical Center Office of CME (OCME) and its affiliates are committed to providing educational activities that are objective, balanced and as free of bias as possible. The OCME has established policies that will identify and resolve all conflicts of interest prior to this educational activity. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, and unlabeled/unapproved uses of drugs and devices. Detailed disclosures will be made verbally and/or in writing during the program.
Regularly Scheduled Conference Policy and Procedure (cont’d)

Americans with Disabilities Act (ADA) Statement
Special Needs: In accordance with the Americans with Disabilities Act (ADA), SUNY Downstate Medical Center seeks to make this conference accessible to all. If you have a disability which might require special accommodations, please contact... or e-mail your needs to:

15. At the end of each month, we require the following: flyers; schedules; attendance; disclosures (1 per academic year - per presenter), evaluations, program handouts (which validates content); and fully executed commercial support letters of agreement (if applicable). Timely submission ensures compliance and approval.

16. The fee for the RSS is $250 per academic year. CME credit will be given as of the date the application is received by the OCME. Jointly sponsored RSS’s are accredited at a higher fee. Contact the OCME for more information.

17. CME credit will not be awarded for sessions found to be non-compliant. OCME fees will not be refunded to the department due to the department’s non-compliance.

18. At the conclusion of the activity, all final documentation, including a final budget form and an outcome summary of the activity must be forwarded to the OCME.

19. Transcripts of physicians’ CME credits will be prepared by the OCME by request only. Request forms may be obtained from the OCME website. A $20 fee will be charged for each academic year requested.

20. The RSS Policy and Procedure must be signed by the program Activity Director, and submitted with the CRF. Remember: Only 1 form per department is required.
Live Annual Conference/Symposia Policy and Procedure

To be in compliance with the ACCME, all Activity Directors must comply with the mission of the Office of CME at SUNY Downstate Medical Center and the AMA’s definition of CME. Approval for category 1 certification depends on the following conditions:

1. The OCME must be involved in the initial planning stages of the CME activity for which category 1 certification is being requested.

2. The planned activity must conform to the AMA’s definition of CME, “CME consists of educational activities that serve to maintain, develop, or increase the knowledge, skills and professional performance and relationships a physician uses to provide services for patients, the public, or the profession.” The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. Presentations and activity materials must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational materials or content includes trade names, where available, trade names from several companies should be used, not just trade names from a single company.

3. Certification Request Forms submitted for AMA PRA Category 1 Credit™ must be submitted with the following, required documentation:
   a) Completed and signed CME Application Form
   b) Signed Live Activity/Symposia Policy and Procedure
   c) Needs assessment with supporting documentation
   d) Educational Objectives
   e) Preliminary Budget Form
   f) Draft of brochure
   g) Disclosures for all those involved with content and planning
   h) Copies of any commercial support grant requests made (if applicable)
   i) Abstracts of speakers’ presentations*
   j) Certification Request fee

   * may be forwarded as it becomes available

4. Several weeks before the start of the program, you will need to forward the following:
   a) Sample evaluation form
   b) Disclosures with attestations for all speakers
   c) Faculty Disclosure Summary listing all financial relationships, including off-label usage
   d) Fully executed Commercial Support Letters of Agreement (if applicable)
   e) Final copy of brochure with commercial support acknowledgements (if applicable) (6 copies must be submitted)
Live Annual Conference/Symposia Policy and Procedure (cont’d)

5. After the completion of the program, the following documents must be forwarded to the OCME:
   a) Attendance
   b) Outcome Summary
   c) Final Budget including summary of commercial support funds (if applicable)

Failure to submit required documentation may result in denial of AMA PRA Category 1 Credit™ status of your CME activity.

Documentation of needs assessment must be part of planning and attached to the application and sent to our office.

6. The professional practice gaps and educational objectives must be stated. The objectives should relate to the need and tell participants what they will learn by attending the program. See Activity Development Worksheet on page 34.

7. The planning of the activity must be documented in the form of minutes, including schedule of topics, speakers and format.

8. The target audience must be defined and stated.

9. Disclosure - All individuals who are in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest within the past 12months. This includes, but is not limited to: activity medical directors, planning committee members, expert/peer reviewers, authors, faculty/speaker/presenters, moderators, panel members, and administrative support staff. Any individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, faculty/speaker/presenter, or an author of CME programs, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of an activity. Products or procedures being discussed that are off-label, unlabeled, experimental, and/or investigational and not FDA approved must be disclosed. This includes any limitations on the information that is presented, such as data that are preliminary or that represent ongoing research, interim analyses, and/or unsupported opinion.

10. A Budget Plan must be filled out and returned with the application. All anticipated income and expenses, including the OCME fee, must be disclosed. A Final Budget Form must be filled out two weeks following the end of the activity.

11. Commercial Support - See OCME Policy for Commercial Support
   a. A Commercial Support Form must be filled out if a commercial organization provides funding of any sort to the program. The form must be signed by the company representative, the Activity Director, and the Director of the OCME.

Jointly sponsored programs see page 26
Live Annual Conference/Symposia Policy and Procedure (cont’d)

b. All commercial support funds are to be paid directly to the OCME or to the department sponsoring the program. Speakers may NOT be paid directly by commercial companies for any related expenses to the program. This includes travel, honoraria, etc.

12. All CME activities requesting category 1 certification must be evaluated.

13. Any audio or video of the program for later distribution must be approved by the OCME. Additional fees will be applied.

14. The Activity Director must ensure that the activity is HIPAA Compliant and agree to obtain all necessary copyright permission(s) for any portion of the CME activity materials that are not original works.

15. Program Announcement
   a. Brochures and announcement materials must have the statement of need, educational objectives and the intended physician audience.
   b. You may not indicate on the brochure or flyer that you have applied for certification or state the number of certifications applied for until the OCME has issued an approval.
   c. The OCME at Downstate Medical Center, as the accredited provider, must be prominently displayed as the SPONSOR on the front of the brochure or flyer and your department as the PRESENTER of the activity.
   d. The educational format and course outline must be defined in the brochure.
   e. Registration fee and location of the activity must be present.
   f. Acknowledgement of any type of support by commercial companies must be listed in the activity announcement and brochure.
   g. The Final Draft of the brochure must be reviewed and approved by the OCME before printing.
   h. The following Statements must appear on all distributed CME activity brochures and flyers.

Accreditation Statement
The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

SUNY Downstate Medical Center designates this [learning format] for a maximum of [number of credits] AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The learning format listed in the Credit Designation Statement must be one of the following AMA approved learning formats:
1. Live activity                      2. Enduring material
3. Journal-based CME activity       4. Test-item writing activity
5. Manuscript review activity       6. PI CME activity
7. Internet point-of-care activity  

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Permission to copy all or a portion of this Guide must be obtained from the Office of CME,
Fifth Edition, Revised Winter 2010
Live Annual Conference/Symposia Policy and Procedure (cont’d)

Disclosure Statement
SUNY Downstate Medical Center Office of CME (OCME) and its affiliates are committed to providing educational activities that are objective, balanced and as free of bias as possible. The OCME has established policies that will identify and resolve all conflicts of interest prior to this educational activity. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, and unlabeled/unapproved uses of drugs and devices. Detailed disclosures will be made verbally and/or in writing during the program.

Americans with Disabilities Act (ADA) Statement
Special Needs: In accordance with the Americans with Disabilities Act, SUNY Downstate Medical Center seeks to make this conference accessible to all. If you have a disability which might require special accommodations, please contact... or e-mail your needs to:...

16. At the conclusion of the activity, Certificates of Attendance will be mailed to activity participants listed on the attendance sheets by the OCME for a fee of $20 per certificate.

17. The fee for a live annual conference is $1500. Jointly sponsored conferences are accredited at a higher fee. Contact the OCME for more information. The application must be received by the OCME twelve (12) weeks prior to the start of the activity. ANY Certification Request Form received less than thirty (30) days before the conference begins will NOT be accepted. Additional administrative fees will be applied if conference management services are requested from the OCME.

18. The Live Annual Conference/Symposia Policy and Procedure must be signed by the program Activity Director, and submitted with the CRF, when applying for AMA PRA Category 1 Credit™.
Policy for Industry Support

This policy will apply to continuing educational programs (grand rounds series, annual conferences and symposia) accredited by the Office of Continuing Medical Education (OCME) at SUNY Downstate Medical Center and our affiliated partners.

The OCME policy is to comply with the Industry Policy of the State University of New York. It is the policy of the OCME that industry grants for continuing medical education must comply with the Standards for Commercial Support of the Accreditation Council for Continuing Medical Education (ACCME) and be executed by the Office of CME.

The Office of CME at the State University of New York will comply with the Ethics in Government Act set forth by the State University of New York, HTTP://WWW.SUNY.EDU/INTERNALCONTROLS/NYSETHICS.CFM and Conflict of Interest Policy set by SUNY Downstate.

All CME activity directors must comply with the Industry Support Policy of the OCME. The ACCME believes that independence from commercial interests will help ensure that CME is free of commercial bias and, therefore would be in the best interest of the public. As a result, the OCME, CME affiliates and joint-sponsors will comply with the Standards of Commercial Support and follow these procedures:

1. The OCME will monitor all activities to ensure that they are free from the control of commercial interests. SUNY Downstate OCME does not allow commercial interests to play any role in providing access to CME activities.

2. CME Activity Directors and planning committee members are responsible for identifying professional practice gaps and needs; determining their educational objectives, selecting content, faculty, teaching methods, and evaluation methods for their activities.

3. All planning committee members will provide full disclosure. In addition, all annual conferences are reviewed by a CME sub-committee.

4. Approval of the activity is dependent upon ensuring that the educational needs have been identified, objectives have been determined, that the content is valid and serves the best interest of the public, and that there is no influence from a commercial interest.

5. Commercial support shall be provided with the knowledge, consent, and written approval of the Office of Continuing Medical Education (OCME) and shall be in the form of an educational grant. All General Sponsorship is considered commercial support. No other payment from a commercial interest shall be given to the Activity Director, planning committee members, faculty (speakers or presenters), authors, joint sponsor, or any others involved with the supported CME activity.

6. Content without commercial bias
   Each CME Activity Director signs a policy and procedure statement attesting that their activity promotes improvements or quality in health care and is not in the proprietary interest of a
commercial interest, that the content is balanced and that they will comply with the mission of the SUNY Office of CME. CME certified activities will be free from control of commercial interests in both planning, and implementation. The use of peer and content review to ensure data validity is encouraged. A balanced view of therapeutics should be included in content, and disclosure should be made to participants regarding the source and type of evidence use for content.

7. Disclosure of relationships to participants
All individuals who are involved with the content of an educational activity are required to disclose all relevant financial relationships in any amount occurring within the past 12 months related both to content and to commercial supporters of the activity including:
- The name of the individual
- The name of the commercial interest(s)
- The nature of the relationship the individual has with each commercial interest.
- Any individual who does not disclose relevant financial relationships will be disqualified from participating in the planning and implementation of educational activities.
- All relationships and source of support whether in-kind or otherwise must be disclosed in a text format (print, slide, online) to participants prior to the presentation of the content of the activity; if no relationship exists, this must be disclosed in the same manner.
- The source and type of evidence for key teaching points must be made clear to participants
- The OCME will monitor all activities to identify and resolve all conflicts of interest prior to the educational activity being delivered to learners.

8. A commercial interest cannot take the role of non-accredited partner in a jointly sponsored activity.

9. Commercial Support Letter of Agreement (LOA) must be completed and signed by both the Activity Director and company representative for each commercial support occurrence. All letters of agreement requires the signature of the accredited provider. This SUNY OCME form may be duplicated and used for each commercial support occurrence. Letter of Agreement Forms from Pharmaceutical companies may also be used. Devices on loan from commercial companies also require an LOA.

   a. Grants made payable to: SUNY - Office of CME. The OCME will process all disbursements to the appropriate parties via the Research Foundation of SUNY. Please have the pharmaceutical representative contact the OCME for additional information. An administrative fee will be charged. If commercial support is awarded to the Office of CME, proceeds will remain in the CME account unless notified or return to the grantor as indicated by the grantor’s agreement. Company/department or division is responsible for all deficits in the account. In addition, a 20% fee of the total grant amount is charge to administer all grants. Funds will be dispersed after the activity takes place.

10. Grants made payable to the Clinical Departments (SUNY and Affiliates). With “full knowledge and approval” of the OCME, the clinical departments at SUNY and at our affiliates may make all disbursements. Signature of the Director of CME must be on all Letters of Agreement. A record must be kept of all disbursements and entered on your Final Budget form, which will be submitted to the OCME at the conclusion of the activity.
11. At no time should the commercial supporter pay an honorarium or other disbursements directly. This includes catering expenses or social events associated with the activity. No commercial support payment will be provided for tuition to CME program, lodging, or other course expenses to participants or their guests.

12. Reimbursements: For honorariums, reimbursements of travel, and catering expenses from a commercial source, you must provide the OCME with a W9 for the recipient, original receipts, and a letter/invoice requesting payment.

13. CME Application Form - On page 3 of the application, you will find a section to indicate whether or not commercial funds will be used. In this section, you must indicate whether the activity will be funded all or in part by departmental funds, commercial support, etc. Please do not put “N/A”, as this is not acceptable.

14. Preliminary Budget Form is to be submitted with your CME Certification Request form. The estimated costs for your activity, which includes your estimated commercial support funds, and the names of your supporters, must be included on the form.

15. Final Budget Form is to be submitted when your CME activity has concluded. The final reconciliation will outline total costs, which includes departmental or divisional funds, income from participant fees, and funding from commercial companies. It includes a breakdown of expenses, and a record of disbursements made from commercial support funding. Unused funds are returned as applicable. Final budget information is essential to the completion and compliance of your CME activity.

16. Sponsorship: “SUNY Downstate Medical Center” is the sponsor of all CME activities accredited by the ACCME; not the pharmaceutical company and not the Hospital. Therefore, when you read the Letter of Agreement, the word “sponsor” refers to SUNY Downstate.

17. Signature: All Letters of Agreement must be signed by the Office of CME at Downstate where “Provider” or “Sponsor” is indicated before the activity takes place.
Exhibit policy

Exhibit fees are considered a business transaction – they are not considered commercial support. However, it is the policy of the OCME that all exhibits, ads, or promotion are kept separate from the CME activity.

1. All exhibitors must sign the Exhibitor Agreement
2. Exhibitors must respect and adhere to the terms of the Agreement.
3. For exhibits, all exhibitors must be in a room or area separate from the educational activity, and the exhibits must not interfere or compete with the learning experience.
   a. Arrangements for exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
   b. Educational materials such as slides, abstracts, and handouts must not contain any advertising or trade names, when they are part of a CME activity.
   c. If a presentation must mention a trade name, it must be for more than one company. Otherwise, generic names must be used.
Honorarium and Reimbursement Policy

Honorarium and Reimbursement Policy

- An honorarium for a presenter lies within the discretion of the activity director and/or planning committee.
- Criteria for determining an honorarium will include the individual’s background, the level of honoraria for the discipline, time and development considerations and available funding. In addition to providing an honorarium, it is expected that travel, meals, and lodging for faculty will be reimbursed.
- The OCME may authorize direct payment to individual faculty members for participating in CME activities but may also delegate this responsibility to one of its educational partners.
- Honoraria are not provided to SUNY Downstate Medical Center faculty, as teaching is considered an essential component of the faculty appointment. A Downstate faculty member may receive an honorarium for his/her participation in CME activities with outside affiliates and other institutions.
- Honoraria and/or out-of-pocket expenses for all faculty, planners, teachers, authors and staff are subject to CME Committee review, and must comply with SUNY Downstate Medical Center policies on reimbursement.
- A letter should be sent to the guest faculty confirming topic, objectives of the presentation, faculty responsibility (time commitment and planned deliverables) and payment terms. The OCME should be carbon copied. Faculty should sign and return copy of letter for file.

Method of Payments

- For all payments, the OCME must be provided with original receipts and a signed W9 for all vendors, staff, personnel, faculty, etc.

- For reimbursement of travel and catering expenses, the OCME must be provided with a signed W9 for the recipient, original receipts and a letter/invoice requesting payment on letterhead stationary (use of payment sample cover below).

- For catering reimbursements, an attendance sheet will also be required. Payment information such as names and addresses must be legible.

- Payments can also be provided by an educational partner approved by the OCME for reimbursements made directly to a faculty member. All payments take about 4-6 weeks to be processed.

At no time may an honorarium be paid directly by a commercial interest to a speaker or Activity Director or planning committee member. All funds from a commercial interest must be received and managed by the OCME. If the honorarium is to be transferred to a gift account, then the faculty is responsible for providing an account number to the OCME staff.
### SAMPLE MEMO OF REQUEST FOR PAYMENT

<table>
<thead>
<tr>
<th>On Institutional stationary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
</tr>
<tr>
<td>To: Staff name, Office of CME</td>
</tr>
<tr>
<td>Reference: Name of CME Program Grant name/ID</td>
</tr>
<tr>
<td>Remit to: name/address of vendor, tax ID #</td>
</tr>
<tr>
<td>Invoice Number:</td>
</tr>
<tr>
<td>PO Number:</td>
</tr>
<tr>
<td>Description:</td>
</tr>
<tr>
<td>Invoice Amount to be paid:</td>
</tr>
</tbody>
</table>
Disclosure Policy

The ACCME and the AMA Standards and Guidelines require that individuals attending continuing medical education activities be aware of relationships with commercial companies that could potentially affect the information presented. In keeping with these regulations, you are required to do the following:

1. The disclosure form must be filled out completely.

2. All speakers including individuals who are in a position to control the content of an educational activity must disclose all relevant financial relationships with any commercial interest to the OCME. This includes Activity Directors, planning committee members, peer reviewers, faculty/presenters/speakers, moderators, panel members, and administrative support staff. This information must include the following:
   a. Name of individual
   b. Name of commercial interest
   c. Nature of the relationship with each commercial interest

3. Scheduled speakers and planners are expected to disclose to the audience, verbally or in writing, any apparent conflict of interest related to the content of the program that they might have. By completing the disclosure, they agree to abide by this policy and attest that their content is unbiased, scientifically balanced and based on the best available evidence and best practices in medicine. In addition, faculty will provide evidence that supports their recommendations, if required.

4. Two or more speakers may not sign the same disclosure form.

5. A disclosure form must be signed before a speaker makes his or her presentation.

6. Relationships with a commercial company must be indicated on the disclosure form. (Both the company’s name and the relationship with that company must be indicated on the disclosure form.)

7. Any discussion of off-label, experimental or investigational use of drugs or devices must be indicated on the disclosure form.

8. If a speaker has no relationship with a commercial company or will not discuss off-label drugs or device usage, he or she must indicate that on the disclosure form.

9. A disclosure form must be completed whether or not a commercial company is supporting the CME activity.

10. Disclosure of information must be distributed to all learners prior to the activity taking place, along with evaluations, and other handout materials. Disclosure information should be included on flyers (for RSS) and Disclosure Summaries (for annual conferences). The disclosure summary includes speakers and planners disclosures about their financial relationships (if any), and is given to all audiences/learners. For RSS, planner disclosures may be displayed at the activity location.
Conflict of Interest Resolution Policy

The ACCME considers financial relationships create actual conflicts of interest in CME, when individuals have both financial relationships 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 increasing the value of the financial relationship with the commercial interest creates an incentive to influence the content of CME – an incentive to insert commercial bias. Commercial bias is prohibited in CME. (ACCME)

All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, and unlabeled/unapproved uses of drugs and devices. Detailed disclosures must be made verbally and/or in writing during each program.

To resolve conflicts of interest, the OCME has several options:

1. All RSS and annual conference presentations are to be reviewed by Activity Directors, before the activity occurs. If a conflict does not exist, no action will be taken. If a conflict exists, the Activity Directors will ask the presenter to refrain from making recommendations on topics in which conflicts exist, and to base recommendations on peer review data.

2. All conference abstracts will be reviewed by a sub-committee of CME Advisory Board Members.

3. If a conflict arises during a presentation, the Activity Director or appointed moderator will ask questions or make comments to counter the commercial bias.

4. After each activity, program evaluations will be reviewed for any perceived commercial bias. If there is no bias, no action will be taken. If over 5% of the audience perceives bias, the OCME will discuss the issue with the participant and Activity Director to avoid future incidents.
Additional and supplemental mechanisms to resolve conflicts of interest include:

1. An individual without a conflict of interest replaces the conflicted individual.
2. The conflicted individual renounces the relationship(s) with the commercial interest(s).
3. The scope of the conflicted individual’s role is restricted (the individual will not determine content or make recommendations for clinical practice limiting their role to review and discussions on epidemiology, pathophysiology, mechanisms of actions, etc.).
4. The conflicted individual attests in writing that the recommendations he/she will make for clinical practice will be based upon data derived from multiple, randomized clinical trials or meta-analyses and will disclose this to the learners.
5. The CME materials (presentation, monograph, etc.) prepared by the conflicted individual will be peer reviewed for content validation and fair balance and modified accordingly, if necessary.

Off-Label Use Disclosure

1. Faculty (speakers/presenters), Activity Directors, and moderators are required to disclose to the learners:
   - When products or procedures being discussed are off-label, unlabeled, experimental, and/or investigational (not FDA approved).
   - Any limitations on the information that is presented, such as data that are preliminary that represent ongoing research, interim analyses, and/or unsupported opinion.
Content Validation Policy

The OCME accepts and promote the ACCME’s three value statements with respect to content validity:

1. “All the recommendations involving clinical medicine in a CME activity must be based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients.”

2. “All scientific research referred to, reported or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.”

3. Activities will not be certified by the OCME “if they present activities that promote:

   a. Recommendations, treatment or manners of practicing medicine that are not within the definition of CME, or are
   
   b. Known to have risks or dangers that outweigh the benefits or are
   
   c. Known to be ineffective in the treatment of patients”. 
Joint Sponsorship Policy

Joint sponsorship occurs when a non-accredited provider wants to partner with the OCME to produce a CME activity, excluding our CME affiliates. A commercial interest, defined as any proprietary entity producing health care goods or services, with the exception of non-profit or government organizations and non-health care related companies, cannot take the role of non-accredited partner in a joint sponsorship relationship.

1. The appropriate accreditation statement must inform the learner of the joint sponsorship relationship between Downstate and the non-accredited provider, which includes all printed materials. (See Accreditation and Disclaimer Statements Section)

2. Jointly sponsored activities must be consistent with the OCME’s mission statement. The OCME must review and approve all materials associated with the activity prior to their circulation.

3. A commercial interest cannot take the role of non-accredited partner in a jointly sponsored activity. As per ACCME policy, “To maintain CME as independent from commercial interests, control of identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content of the CME, selection of educational methods, and evaluation of the activity cannot be in the hands of a commercial interest”. (ACCME® Accreditation Policies)

4. The responsibilities of the joint sponsor will be clearly defined in a letter of agreement between the joint sponsor and the OCME. The OCME has the right to withdraw from any activity if the joint sponsor fails to meet its obligations as described in the letter of agreement or fails to comply with the OCME’s policies and procedures.

5. The joint sponsor must submit a projected budget for each CME activity to the OCME for review and approval. The OCME will review the projected budget to ensure that adequate resources have been allotted to the development of an activity consistent with meeting the activity’s objectives. All funds requested for a CME activity must either be received by the OCME or delivered to the joint sponsor, upon written authorization from the OCME.

6. At the discretion of the OCME and with written authorization, the joint sponsor may solicit funds under the direction of the OCME, but may not make any representations or commitments to commercial supporters as to educational content, choice of speakers, learning objectives, marketing, and/or evaluation.

7. Commercial support shall be provided with the knowledge, consent, and written approval of the OCME and shall be in the form of an educational grant. (Provision of equipment for skills-based learning activities is permitted, but still requires a written letter of agreement.) No other payment from a commercial interest shall be given to the Activity Director, planning committee members, faculty (speaker or presenter), authors, joint sponsors, or any others involved with the supported CME activity.

8. The OCME will charge fees for services. These fees will be mutually agreed upon and clearly defined in the letter of agreement between the joint sponsor and the OCME.
Internet CME Policy

Live or enduring material activities that are provided via the Internet are considered to be “Internet CME.” Internet CME must comply with all ACCME Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies. However, there are special requirements for Internet CME because of the nature of the activities:

1. **Activity Location:** CME activities cannot be placed on a pharmaceutical or device manufacturers’ product website.

2. **Links to Product Websites:** With clear notification that the learner is leaving the educational website, links from the website of an ACCME accredited provider to pharmaceutical and device manufacturers’ product websites are permitted before or after the educational content of a CME activity, but shall not be embedded in the educational content of a CME activity.

3. **Advertising:** Advertising of any type is prohibited within the educational content of CME activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads. For computer based CME activities, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleaved between computer ‘windows’ or screens of the CME content.

4. **Hardware/Software Requirements:** The accredited provider must indicate, at the start of each Internet CME activity, the hardware and software required for the learner to participate.

5. **Provider Contact Information:** The accredited provider must have a mechanism in place for the learner to be able to contact the provider if there are questions about the Internet CME activity.

6. **Policy on Privacy and Confidentiality:** The accredited provider must have, adhere to, and inform the learner about its policy on privacy and confidentiality that relates to the CME activities it provides on the Internet.

7. **Copyright:** The accredited provider must be able to document that it owns the copyright for, or has received permissions for use of, or is otherwise permitted to use copyrighted materials within a CME activity on the Internet.
Enduring Materials Policy

The AMA describe enduring material as such “An enduring material is a certified CME activity that endures over a specified time. These include print, audio, video and Internet materials, such as monographs, podcasts, CD-ROMs, DVDs, archived webinars, as well as other web-based activities”.

Enduring materials must comply with all ACCME Essential Areas and Elements (including the Standards for Commercial Support) and Accreditation Policies.

The following must be communicated to participants prior to starting the educational activity:

1. Principal faculty and their credentials;
2. Medium or combination of media used;
3. Method of physician participation in the learning process;
4. Estimated time to complete the educational activity (same as number of designated credit hours);
5. Dates of original release and most recent review or update; and
6. Termination date (date after which enduring material is no longer certified for credit).

The enduring material cannot be certified for credit for subsequent years without review on the part of the OCME to ensure that the content is still up-to-date and accurate. An additional fee will be charged for renewal.

To comply with the Standards for Commercial Support:

1. There must be no product specific advertising in enduring materials;
2. Commercial support must be acknowledged in the enduring material;
3. This acknowledgement must be placed only at the beginning of an enduring material;
4. The institutional acknowledgement may state the name, mission, and areas of clinical involvement of the company or institution, and may include corporate logos and slogans, if they are not product promotional in nature;
5. No brand names or product-group messages may be used in the acknowledgement, even if they are not related to the topic of the enduring material;
6. Commercial interests may not enlist assistance to provide or distribute enduring materials to learners.
7. Post-Tests and evaluation are required.
8. The OCME, at SUNY Downstate Medical Center, is the certifying agent.
9. The OCME will review and approve all printed material and the CD-ROM prior to final production and distribution to the target audience.
10. The Communication Company or activity director is responsible for creative development, editorial development, and production of reference materials, letterhead, mailing and postage.
11. The Activity Director takes responsibility for the content and scientific integrity of the monograph.

To be certified for AMA PRA Category 1 Credit™, an enduring material activity must:

• Meet all AMA core requirements for certifying an activity.
• Provide clear instructions to the learner on how to successfully complete the activity.
• Provide an assessment of the learner that measures achievement of the educational purpose and/or objective(s) of the activity with an established minimum performance level; examples include, but are not limited to, patient-management case studies, a post-test, and/or application of new concepts in response to simulated problems.

• Communicate to the participants the minimum performance level that must be demonstrated in the assessment in order to successfully complete the activity for AMA PRA Category 1 Credit™.

• Provide access to appropriate bibliographic sources to allow for further study.

Designating and awarding credit for participation in an enduring material

• Credit designation for each enduring material must be determined by a mechanism developed by the accredited CME provider to establish a good faith estimate of the amount of time a physician will take to complete the activity to achieve its purpose and/or learning objectives (e.g. the average time it takes a small sample group of the target audience to complete the material); credit is designated in 15 minute or 0.25 credit increments; accredited CME providers must round to the nearest quarter hour.

• Credit should be awarded only to physicians who meet at least the minimum performance level on the assessment as established by the accredited CME provider.
Journal CME Policy

A Journal-based CME activity includes the reading of an article (or adapted formats for special needs), a provider stipulated/learner directed phase (that may include reflection, discussion, or debate about the material contained in the article(s)) and a requirement for the completion by the learner of a pre-determined set of questions or tasks relating to the content of the material as part of the learning process. The educational content of Journal CME must be within the ACCME’s Definition of CME (ACCME).

According to the AMA, a “journal-based CME activity is a certified CME activity in which an article, within a peer-reviewed, professional journal, is certified for AMA PRA Category 1 Credit™ prior to publication of the journal.

To be certified for AMA PRA Category 1 Credit™, a journal-based CME activity must:

- Meet all AMA core requirements for certifying an activity.
- Be a peer-reviewed article.
- Provide an assessment of the learner that measures achievement of the educational purpose and/or objective(s) of the activity with an established minimum performance level; this may include, but is not limited to, patient-management case studies, a post-test and/ or application of new concepts in response to simulated problems.
- Communicate to the participants the minimum performance level that must be demonstrated in the assessment in order to successfully complete the activity for AMA PRA Category 1 Credit™.

Designating and awarding credit for participation in a journal-based CME activity

- Accredited CME providers should designate individual articles for one (1) AMA PRA Category 1 Credit™.
- Credit should be awarded only to physicians who meet at least the minimum performance level on the assessment as established by the accredited CME provider.

The Office of CME at Downstate requires that all Journal CME & Journal Clubs activities meet the following criteria:

1. Evidence of learner participation in the activity must be forwarded to the OCME.

2. The learner should not encounter advertising within the pages of the article or within the pages of the related questions or evaluation materials.

3. Copies of articles reviewed must be forwarded to the OCME with monthly documentation.
Promotional and Syllabi Policy

The following guidelines must be strictly adhered to regarding the promotion of CME activities:

1. For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.

2. For computer based, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer ‘windows’ or screens of the CME content.

3. For audio and video recording, advertisements and promotional materials will not be included within the CME. There will be no ‘commercial breaks’ in between the educational material.

4. For live, face-to-face CME, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

5. For exhibits, all exhibitors must be in a room or area separate from the educational activity, and the exhibits must not interfere or compete with the learning experience.
   a. Arrangements for exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
   b. Educational materials such as slides, abstracts, and handouts must not contain any advertising or trade names, when they are part of a CME activity.
   c. If a presentation must mention a trade name, it must be for more than one company. Otherwise, generic names must be used.
   d. Exhibit fees shall be set by the OCME for each activity and will be standard for that activity. Potential exhibitors shall have equal access to purchasing exhibit space. Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support).

This policy is relevant to printed materials (e.g. syllabi, brochures, etc.), Internet CME, enduring materials, and live CME activities.
Accreditation and Disclaimer Statements

The following accreditation, disclaimer and ADA statements must be included in all CME brochures, flyers, and enduring materials:

Accreditation & Designation Statements

1.) Directly Sponsored Activities

The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

SUNY Downstate Medical Center designates this [learning format] for a maximum of [number of credits]AMA PRA Category 1 Credit™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The learning format listed in the Credit Designation Statement must be one of the following AMA approved learning formats:
1. Live activity
2. Enduring material
3. Journal-based CME activity
4. Test-item writing activity
5. Manuscript review activity
6. PI CME activity
7. Internet point-of-care activity

2.) Jointly Sponsored Activities

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of SUNY Downstate Medical Center, and the (name of joint sponsor). The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

SUNY Downstate Medical Center designates this (learning format) activity for a maximum of ____ AMA PRA Category 1 credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

3.) Disclosure Statement (Must be included with both statements)

SUNY Downstate Medical Center’s Office of Continuing Medical Education (OCME) and its affiliates are committed to providing educational activities that are objective, balanced, and as free of bias as possible. The OCME has established policies that will identify and resolve all conflicts of interest prior to this educational activity. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, and unlabeled/unapproved uses of drugs and devices. Detailed disclosures will be made verbally and/or in writing during the program.

Please remember that AMA PRA Category 1 Credit(s)™ must always be italicized.
Americans with Disabilities Act (ADA) Statement

The following ADA statement must be included on all brochures, and enduring materials:

In accordance with the Americans with Disabilities Act, (Name of Your Institution) seeks to make this conference accessible to all. If you have a disability, which might require special accommodations, please contact _____________ at _____________ or e-mail your needs to _____________.

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If you have any questions, please contact us (718 270-2422)
ACTIVITY DEVELOPMENT WORKSHEET

- All steps should be taken independently of commercial interest.
- Everyone who is in a position to control content must disclose all relevant financial relationships with a commercial interest to the provider.
- The provider (OCME) appropriately manages commercial support (if applicable).
- Maintain a separation of promotion from education.
- Disclosure must be made to the learners of relevant financial relationships and any commercial support for the CME activity.
- The activity promotes improvements or quality in healthcare and not proprietary interests of a commercial supporter.

1. What is the quality or professional practice gap to be addressed? (C2) ACCME adapted the Agency for Healthcare Research and Quality definition of a gap in the quality of patient-care where the gap is the “difference between health care processes or outcomes observed in practice, and those potentially achievable on the basis of current professional knowledge”. When there is a gap between what the professional is doing or accomplishing compared to what is “achievable on the basis of current professional knowledge” there is a professional practice gap.

2. What needs can or should be addressed to close this gap? Is it a gap in physician knowledge, competence, or performance? Are the needs related to the IOM, ACGME or other competencies? How were the needs identified? (C2,3,6 &7)

3. What is the physician target audience? Based on the physician target audience and the gap that is being addressed, what is the right content to cover? How does the content relate to the scope of practice of the physician target audience? Should the content also relate to specific patient groups? Should it contain content outside the clinical topic? (C2,4)

4. What are the potential or real barriers facing these physicians if this need/gap is to be addressed? What educational strategies will be used to remove, overcome or address barriers to physician change? Are there non-educational strategies that are currently being used that address this issue? If no, what kinds of non-educational strategies could be used to address this issue? (C18,19, 20)

5. Based on the need/gap the activity is addressing, what are the desired results of the activity? Said differently, “What is the activity designed to change?” (C3)

6. Based on the desired results of the activity, what are the objectives of the activity? Note: Your objectives can support the attainment of the desired result. (C3, 4, 10) “At the end of this activity, participant will provide better patient care through an increased ability to…..
   Describe
   Explain
   Demonstrate
   Contrast, etc.
7. Are there other initiatives within my institution working on this issue? Are there other organizations we could partner with that are working on this issue?

8. In what ways could we include these internal or external groups in our CME activity to help us address or remove barriers as identified in question 3?

9. Who are the right faculty to cover this content? (C3, 4)

10. Based on the previous steps, what is the right format to use for the activity? What type of activity will it be (Live, Enduring Material, Internet, Other). What will be the educational design of the activity (e.g. presentation, case studies, round table, and simulation)? (Remember to consider adult learning principles and the physician learning and change process.) (C3, 5)

11. What type(s) of evaluation method(s) will you use to know if the activity was effective at meeting the need and creating change in competence, performance, or patient outcomes? (C11)

12. How will you determine whether the activity meets the CME mission of the provider? Outcomes summary should be completed to determine if the activity meets the mission (C12):
   
   measures changes in competence, performance and/or patient outcomes through continuous assessment of learner participant;
   
   enhances our healthcare professionals and physician participants’ knowledge and skill set to improve patient care

Describe your CME Activity:

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Outcomes Assessment Methodology

SUNY Downstate Medical Center Office of Continuing Medical Education (OCME) assesses the outcomes of its educational activities. **What we are trying to assess is whether learning took place. Did the activity have an impact on the learner's, competence and performance or patient outcomes?** You may elect to create your own evaluation, however keep in mind that the main point is to assess the educational objectives of the session (s) presented.

The ACCME asks that we, the provider, demonstrate that the activities we accredit are designed to change competence, performance or patient outcomes. A change in competence is addressed by covering issues being presented; the post test assesses the knowledge acquired. For performance, changes can be noted from the baseline to an increase in the learner’s performance from what was presented at the meeting. Quality improvement projects are a great way to assess performance. As far as outcomes, chart reviews and community health statistics are some of the ways to assess learning.

The types of techniques used to assess the outcomes of educational activities will depend on the educational format of the CME activity and the level of outcomes you are seeking. The Office of CME uses the Moore’s Level 1 to 7 in developing its outcomes-based evaluations.

Moore’s outcome level areas are as follows:

- **Level 1** Participation
- **Level 2** Satisfaction
- **Level 3A** Learning: Declarative Knowledge (Knows)
- **Level 3B** Learning: Procedural Knowledge (Knows How)
- **Level 4** Learning: Competence (Shows How)
- **Level 5** Performance (Does)
- **Level 6** Patient Health
- **Level 7** Community Health

The OCME requests that all CME activities be measured for Levels 1, 2 and 3 --- asking participants reason for participation in the activity, rating their level of satisfaction with the activity, and the degree to which they believe the learning objectives were met. Participants of CME activities are asked to rate the impact of the presentation based on knowledge, competence, performance or patient outcomes (Level 4 measurement).

**Measurement of the objectives starts by asking participants the following:** “At the conclusion of this activity, participants will be able to ….”or “At the end of this activity, participants will provide better patient care through an increased ability to…..Describe, Explain, Demonstrate, Contrast, etc. This process demonstrates whether or not the objectives were achieved.

**Pre-and post-tests** - Activity participants complete multiple choice questions concerning activity content before and immediately after a CME activity. This method provides the CME staff with immediate feedback regarding the learning that has occurred (L3b). However it does not assess retention of content that can affect performance. Pre- and post-tests can be used in conjunction with live meetings, printed enduring materials and Internet-based CME activities.

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Fifth Edition, Revised Winter 2010
Commitment to Change - The OCME evaluation template asks participants of all activity formats if they plan any changes due to the knowledge they have gained from participating. (L4).
Post activity surveys - Post activity surveys go further in measuring change by focusing Level 5 outcomes (performance-based changes). Participants are asked, at the conclusion of a CME activity, to list changes that they intend to make as a result of the activity. The OCME will e-mail attendees within one to three months of the CME activity and ask participants if they have implemented the changes they intended to make and if not, what the barriers are that they have encountered.

Although the rate of return is low because of the self-reporting of the process, the OCME (something missing here) However, in the absence of actual observation of a physician’s performance in practice, this information serves as a surrogate marker that, according to Lockyer’s research, is indicative of actual change.

Case based assessment - Competence questions will be in the form of case-based vignettes to demonstrate the degree to which participants show they can apply what they have learned in the educational setting. The cases and questions can be presented before and after the CME activity to measure learning.

Performance Improvement Initiatives - The Office of CME can assist individual physicians or groups who wish to participate in performance improvement activities. Following the AMA’s guidelines on awarding *AMA PRA Category 1 Credit™* for performance improvement, the OCME staff will work with physicians to undertake practice-based performance improvement initiatives. Performance improvement activities will lead to Level 5 outcomes assessment data.

Summary
Currently the OCME measures for Moore’s Level 6 and 7 through our Brooklyn Community Health Report which can be accessed at http://www.downstate.edu/bhr/

The OCME will continue to incorporate formative assessment processes into its activities that will provide participants with opportunities for practice and feedback.

References:


# Sample - Regularly Scheduled Conference Evaluation Form

Thank you for participating in this CME activity. The Office of Continuing Medical Education would like to know if this was a valuable learning experience for you, and would appreciate your responses to the following questions.

**Title of Activity:** __________  
**Date:** __________

## 1. Presenter:

To what extent was the presenter knowledgeable, organized and effective in his/her presentation?  

<table>
<thead>
<tr>
<th>1=Poor</th>
<th>2=Below Average</th>
<th>3=Average</th>
<th>4=Above Average</th>
<th>5=Outstanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>__________</td>
<td>__________</td>
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<td>__________</td>
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</table>

## 2. How might the format of this activity be improved in order to be most appropriate for the content presented (select all that apply)?

- Format was appropriate, no changes needed  
- Add a hands-on instructional component  
- Include more case-based presentations  
- Schedule more time for Q and A  
- Increase interactivity with attendees  
- Other, describe  
- Add breakouts for subtopics

## 3. Please rate the projected impact of the presentation objectives on:

<table>
<thead>
<tr>
<th>Knowledge, Competence, Performance, Patient Outcomes</th>
<th>Not Applicable</th>
<th>No Impact</th>
<th>Moderate Impact</th>
<th>High Impact</th>
</tr>
</thead>
<tbody>
<tr>
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<td>__________</td>
<td>__________</td>
<td>__________</td>
<td>__________</td>
</tr>
</tbody>
</table>

## 4. Did you have the opportunity to discuss practice-relevant issues with the speakers?

- YES  
- NO

## 5. How will you change your practice as a result of attending this activity (select all that apply)?

- Create/revise protocols, policies, and/or procedures  
- Change the management and/or treatment of my patients  
- This activity validated my current practice  
- I will not make any changes to my practice  
- Other, please specify:

## 6. Was there any apparent conflict of interest shown by the speaker(s)? If yes, please explain

- YES  
- NO

## 7. Was the meeting room conducive to learning?

- YES  
- NO

## General Comments:

**E-mail address to participate in an outcome-measured post-evaluation activity:**

<table>
<thead>
<tr>
<th>Specialty:</th>
<th>MD/DO</th>
<th>RN</th>
<th>PA</th>
<th>Student</th>
<th>Other health professional</th>
</tr>
</thead>
<tbody>
<tr>
<td>__________</td>
<td>__________</td>
<td>__________</td>
<td>__________</td>
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<td>__________</td>
</tr>
</tbody>
</table>
Sample - Annual Conference/Symposium Evaluation Form

CONFERENCE/SYMPOSIUM EVALUATION FORM

Thank you for participating in this CME activity. The Office of Continuing Medical Education would like to know if this was a valuable learning experience for you, and would appreciate your responses to the following questions.

Title of Activity ______ Date ______

1. Presenter: ______
To what extent was the presenter knowledgeable, organized and effective in his/her presentation?

<table>
<thead>
<tr>
<th>1=Poor</th>
<th>2=Below Average</th>
<th>3=Average</th>
<th>4=Above Average</th>
<th>5=Outstanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

2. Please check all that applied

- to develop clinical skills
- to develop interpretive and diagnostic skills
- to acquire new information on the subject
- to review the subject
- to meet CME requirements

3. How might the format of this activity be improved in order to be most appropriate for the content presented? select all that apply

- Format was appropriate, no changes needed
- Add a hands-on instructional component
- Include more case-based presentations
- Schedule more time for Q and A
- Increase interactivity with attendees
- Other, describe
- Add breakout sessions for subtopics

4. Please rate the overall aspects of this educational activity on the basis of:

<table>
<thead>
<tr>
<th>1=Poor</th>
<th>2=Below Average</th>
<th>3=Average</th>
<th>4=Above Average</th>
<th>5=Outstanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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</tbody>
</table>

Educational content
Relevance to practice
Quality of presenters
Selection of topics
Overall quality of activity
# CONFERENCE/SYMPOSIUM EVALUATION FORM

5. Did you have the opportunity to discuss practice-relevant issues with the speakers?  
   - YES ☐  
   - NO ☐

6. How will you change your practice as a result of attending this activity? Select all that apply:
   - [ ] Create/revise protocols, policies, and/or procedures
   - [ ] Change the management and/or treatment of my patients
   - [ ] Other, please specify: ___
   - [ ] This activity validated my current practice
   - [ ] I will not make any changes to my practice

7. Any perceived barriers in making changes identified?  
   - YES ☐  
   - NO ☐

   If yes, please indicate: [ ]

8. Has this activity met your identified needs and professional practice gaps?  
   - YES ☐  
   - NO ☐

9. Please rate the overall impact of this activity objectives on:

<table>
<thead>
<tr>
<th>Knowledge Competence Performance Patient outcomes</th>
<th>Not Applicable</th>
<th>No Impact</th>
<th>Moderate Impact</th>
<th>High Impact</th>
</tr>
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<tr>
<td>☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐</td>
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</table>

10. Was there any apparent conflict of interest shown by the speaker(s)? If yes, please explain below:  
    - YES ☐  
    - NO ☐

11. Were the meeting rooms conducive to learning?  
    - YES ☐  
    - NO ☐

General Comments:

E-mail address to participate in an outcome-measured post evaluation activity:

<table>
<thead>
<tr>
<th>Specialty</th>
<th>MD/DO</th>
<th>RN</th>
<th>PA</th>
<th>Student</th>
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Mar.10
ACCME Standards for Commercial Support

Please review the following ACCME Standards for Commercial Support carefully, so that you are knowledgeable of all the required guidelines. This information is essential to everyone involved in planning CME activities, but especially important to those who routinely request grants in support of their CME activities. Also review the Industry Support Policy on page 17 of this guide.

Accreditation Council for Continuing Medical Education (ACCME)
STANDARDS FOR COMMERCIAL SUPPORT
Standards to Ensure Independence in CME Activities

PREAMBLE
The purpose of continuing medical education (CME) is to enhance the physician’s ability to care for patients. It is the responsibility of the accredited provider of a CME activity to assure that the activity is designed primarily for that purpose. Accredited providers often receive financial and other support from non-accredited commercial organizations. Such support can contribute significantly to the quality of CME activities. The purpose of these Standards is to describe appropriate behavior of accredited providers in planning, designing, implementing, and evaluating certified CME activities for which commercial support is received.

STANDARD 1: Independence
1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a “commercial interest” as any proprietary entity producing health care goods or services, with the exemption of non-profit or government organizations and non-health care related companies.
   a) Identification of CME needs;
   b) Determination of educational objectives;
   c) Selection and 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.
1.2 A commercial interest cannot take the role of non-accredited partner in a joint sponsorship relationship.

STANDARD 2: Resolution of Personal Conflicts of Interest
2.1 The provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines “‘relevant’ financial relationships” as financial relationships in any amount occurring within the past 12 months that create a conflict of interest.
2.2 An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.
2.3 The provider must have implemented a mechanism to identify and resolve all conflicts of interest prior to the education activity being delivered to learners.

STANDARD 3: Appropriate Use of Commercial Support
3.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.
3.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as conditions of contributing funds or services.

3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider.

Written agreement documenting terms of support

3.4 The terms, conditions, and purposes of the commercial support must be documented in a written agreement between the commercial supporter that includes the provider and its educational partner(s). The agreement must include the provider, even if the support is given directly to the provider’s educational partner or a joint sponsor.

3.5 The written agreement must specify the commercial interest that is the source of commercial support.

3.6 Both the commercial supporter and the provider must sign the written agreement between the commercial supporter and the provider.

Expenditures for an individual providing CME

3.7 The provider must have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.

3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider’s written policies and procedures.

3.9 No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

3.10 If teachers or authors are listed on the agenda as facilitating or conducting a presentation of session, but participate in the remainder of an educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their teacher or author role only.

Expenditures for learners

3.11 Social events or meals at CME activities cannot compete with or take precedence over the educational events.

3.12 The provider may not use commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Accountability

3.13 The provider must be able to produce accurate documentation detailing the receipt and expenditure of the commercial support.

STANDARD 4: Appropriate Management of Associated Commercial Promotion

4.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.

4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

* For print, advertisements and promotional materials will not be interleaved within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content, as long as these materials are not related to the CME content they face, and are not paid for by the commercial supporters of the CME activity.
• For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer ‘windows’ or screens of the CME content.

• For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no ‘commercial breaks.’

• For **live, face-to-face CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of Commercial Interests to engage in sales or promotional activities while in the space or place of the CME activity.

4.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product-promotion material or product-specific advertisement.

4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

**STANDARD 5: Content and Format without Commercial Bias**

5.1 The content or format of a CME activity or its related materials must promote improvements or quality in health care and not a specific proprietary business interest or a commercial interest.

5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

**STANDARD 6: Disclosures Relevant to Potential Commercial Bias Relevant financial relationships of those with control over CME content.**

6.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

• the name of the individual;
• the name of the commercial interest(s);
• the nature of the relationship the person has with each commercial interest.

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

**Commercial support for the CME activity**

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is ‘in-kind’ the nature of the support must be disclosed to learners.

6.4 ‘Disclosure’ must never include the use of a trade name or a product-group message.

**Time of disclosure**

6.5 A provider must disclose the above information to learners prior to the beginning of the educational activity.
## Sample - Commercial Support Letter of Agreement

### COMMERCIAL SUPPORT LETTER OF AGREEMENT

This Letter of Agreement, entered into this ______ day of ______, 200____ by and among SUNY Downstate Medical Center acting for and on behalf of the Educational Partner named below (if applicable); and the Commercial Interest named below, witnesses the following:

**Date of Activity:**

**Location of Activity:**

**Commercial Company name:**

**Support Amount:**

**GRANT MADE PAYABLE TO:**

- [ ] OCME
- [ ] Downstate Clinical Department
- [ ] Educational Partner

### GENERAL CONDITIONS (BASED ON ACCME STANDARDS)

#### STANDARD 1: Independence

1.1 A CME provider must ensure that the following decisions were made free of the control of a commercial interest. The ACCME defines a “commercial interest” as any proprietary entity producing health care goods or services, with the exception of non-profit or government organizations and non-health care related companies. (a) Identification of CME needs: the Commercial Interest may not be the agent providing the CME activity to the learners.

#### STANDARD 2: Appropriate Use of Commercial Support

2.1 The provider must make all decisions regarding the disposition and disbursement of commercial support.

2.2 A provider cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from education matters, including content, from a commercial interest as conditions of commercial interest as conditions of contributing funds or services contributing funds or services. 3.3 All commercial support associated with a CME activity must be given with the full knowledge and approval of the provider. 3.8 The provider, the joint sponsor, or designated educational partner must pay directly any teacher or author honoraria or reimbursement of out-of-pocket expenses in compliance with the provider’s written policies and procedures. No other payment shall be given to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.

#### STANDARD 3: Appropriate Management of Associated Commercial Promotion

3.1 Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities. 4.2 Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.

3.3 Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message. 4.4 Print or electronic information distributed about the non-CME elements of a CME activity that are not directly related to the transfer of education to the learners, such as schedules and content descriptions may include product promotion content descriptions, may include product promotion material or product-specific advertisement material or product-specific advertisement. 4.5 A provider cannot use a commercial interest as the agent providing a CME activity to learners, e.g., distribution of self-study CME activities or arranging for electronic access to CME activities.

#### STANDARD 4: Content and Format without Commercial Bias

4.1 The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. 5.2 Presentations must give a balanced view of therapeutic options. Use of generic names will contribute to this impartiality. If the CME educational material or content includes trade names, where available trade names from several companies should be used, not just trade names from a single company.

#### STANDARD 5: Disclosures Relevant to Potential Commercial Bias

5.1 An individual must disclose to learners any relevant financial relationship(s), to include the following information:

- The name of the individual
- The name of the commercial interest(s)
- The nature of the relationship the person has with each commercial interest

6.2 For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.

6.3 The source of all support from commercial interests must be disclosed to learners. When commercial support is “in-kind” the nature of the support must be disclosed to learners. 6.4 “Disclosure” must never include the use...
of a trade name or a product-group message. A provider must disclose the above information to learners prior to the beginning of the educational activity.

The Commercial Supporter agrees to abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education.

The Accredited Provider agrees to:

- abide by all requirements of the ACCME Standards for Commercial Support of Continuing Medical Education;
- acknowledge educational support from the commercial company in program brochures, syllabi and other program materials; and upon request, furnish the commercial supporter with a report concerning the expenditure of funds provided.

<table>
<thead>
<tr>
<th>Accredited Provider:</th>
<th>SUNY Downstate Medical Center</th>
<th>Tax ID Number: 14-1368361</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact Person</td>
<td></td>
<td></td>
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<tr>
<td>E-mail Address</td>
<td></td>
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<tr>
<td>Phone Number &amp; Fax Number</td>
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</table>

<table>
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<tr>
<th>Educational Partner (Facility/Dept):</th>
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<tbody>
<tr>
<td>Contact Person</td>
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<tr>
<td>E-mail Address</td>
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<tr>
<td>Phone Number &amp; Fax Number</td>
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</tbody>
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<tr>
<th>Commercial Interest:</th>
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<tbody>
<tr>
<td>Contact Person</td>
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<tr>
<td>E-mail Address</td>
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<tr>
<td>Phone Number &amp; Fax Number</td>
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</table>

**AGREED:**

<table>
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<tr>
<th>Accredited Provider:</th>
<th>Educational Partner (if applicable):</th>
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<tr>
<td>Signature/Date</td>
<td>Signature/Date</td>
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<tr>
<td>Edeline Mitton, MEd, CPP</td>
<td>Print Name:</td>
</tr>
<tr>
<td>Director, OCME</td>
<td>Title:</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Commercial Interest:</th>
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<tbody>
<tr>
<td>Signature/Date</td>
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</table>
Faculty Information

Based on your educational needs, decide who will best be able to provide the information that meets those needs. Choose speakers who not only have the requisite store of information, but also have the ability to relate to your target audience. Provide your speakers with the course objectives, and any background data you feel are important.

1) Speaker’s Letter
To be sent to speaker’s along with Disclosure Form, before your meeting takes place. You are welcome to use our sample letter, which may be found on our website, but you may also use your own.

2) Flyer (For RSCs)
A flyer must be used to inform participants of topic, speakers, target audience, educational objectives, commercial support acknowledgement (if applicable), and disclosure information for all speakers for all regularly scheduled conferences.

3) Disclosure Summary
When presenting a program with multiple speakers (e.g. conference, seminar etc.), and there are many disclosures to be made, the Disclosure Summary is to be used. You may include it in your syllabi or it may be given out with other handouts. **

Please note: Verbal disclosure is always required, but documented disclosure is mandatory. Non-documented disclosure information means non-compliance to ACCME guidelines, which means you will not receive AMA PRA Category 1 Credit™ for your activity.
Sample Disclosure Form

CME DISCLOSURE FORM

ANYONE INVOLVED WITH THE CONTENT OF THE CME ACTIVITY MUST SIGN THIS FORM
(Dept. chairs, committee members, residents, fellows, nurses, presenters, etc.)

I understand that SUNY Downstate Medical Center endorses the Guidelines of the American Medical Association and the Standards of the Accreditation Council for Continuing Medical Education. Therefore, faculty or anyone involved with the presentation content for a CME activity must disclose to participants the presence of any relationships with commercial companies (healthcare related).

Significant financial relationships include receiving (from a company) research grants, consultancies, honorarium and travel, or other benefits or having self-managed equity in a company. Individuals with substantive conflicts of interest cannot plan or speak. Faculty are also expected to openly disclose any off-label, experimental, or investigational use of drugs or devices discussed in their presentation. Financial relationships of your spouse or partner, which you are aware of, for this purpose, are considered yours.

An individual who refuses to disclose relevant financial relationships will be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity (ACCME Standard 2.5).

<table>
<thead>
<tr>
<th>Activity Title</th>
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<tbody>
<tr>
<td>Title of Presentation</td>
<td></td>
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<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Check one:</td>
<td>Faculty</td>
</tr>
<tr>
<td>Name</td>
<td></td>
</tr>
<tr>
<td>Degree and Credentials</td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Organization</td>
<td></td>
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<tr>
<td>Address</td>
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<tr>
<td>City/State/Zip</td>
<td></td>
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<tr>
<td>Phone</td>
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<tr>
<td>Email</td>
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DISCLOSURE OF FINANCIAL RELATIONSHIPS

1. Within the past twelve months, I and/or my spouse/significant other have received support from or had a relationship with any of the following commercial interests (indicate all that apply). Disclosure should include relationships in any amount.

<table>
<thead>
<tr>
<th>[ ] No</th>
<th>[ ] Yes, (if you provide complete information)</th>
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<tbody>
<tr>
<td>Commercial Interest</td>
<td>Speakers bureau</td>
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* not including stocks owned in a managed portfolio

Please describe any additional relevant disclosure below:

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2. I will discuss a drug or medical device that has not been approved by the FDA.

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<tr>
<th>No</th>
<th>Yes</th>
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<td>(Describe)</td>
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</table>

3. I will be using slides, scripts, or other teaching material that were provided from a commercial source.

<table>
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<th>No</th>
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<td>(Describe)</td>
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4. Content Validation/Resolution of Conflicts of Interest

I attest to the following:

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<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tr>
<td>You</td>
<td>No</td>
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<td></td>
<td>I understand that the information presented to the learner must be unbiased, scientifically balanced, and based on best available evidence and best practices in medicine. I agree to present all reasonable clinical alternatives when making practice recommendations. I attest that relationships with commercial interests will not influence or bias my presentation and/or planning of the CME activity.</td>
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<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tr>
<td>You</td>
<td>No</td>
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<tr>
<td></td>
<td>All scientific research referred to, reported, or used in support or justification of patient care recommendations will conform to the generally accepted standards of experimental design, data collection, and analysis.</td>
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<th>Yes</th>
<th>No</th>
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<tr>
<td>You</td>
<td>No</td>
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<tr>
<td></td>
<td>I attest that I will not accept any payment or reimbursement for this presentation directly from any commercial interest. I understand that all payments and reimbursements must be made by the accredited provider or authorized educational partner.</td>
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I agree to:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<td></td>
<td>Avoid the use of trade names in my presentation. If I determine that it is important to clarify via the use of trade names, trade names from all available companies should be included, not just trade names from a single company.</td>
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<th>Yes</th>
<th>No</th>
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<td>If requested, provide appropriate peer-reviewed journal references which support clinical or practice recommendations. I understand that my CME presentation may be evaluated by participants for fair balance (e.g. degree of commercial bias) and that ensuring materials (if applicable) will be peer-reviewed for fair balance and validation of content and may be edited accordingly.</td>
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<th>Yes</th>
<th>No</th>
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<td></td>
<td>Disclose to the program audience when products/services are not labeled for the use under discussion or when the products are still under investigation.</td>
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<th>Yes</th>
<th>No</th>
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<td>Comply with patient confidentiality requirements as outlined in the Health Insurance Portability and Accountability Act (HIPAA).</td>
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<th>Yes</th>
<th>No</th>
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<tr>
<td></td>
<td>Obtain the necessary copyright permission(s) if any portion of my CME activity materials that I prepare is not my original work or for which I do not hold the copyright.</td>
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5. Abstract of Presentation – Brief description of your presentation


6. Learning Objectives –
List at least 3 expected learning outcomes in terms of knowledge, skills, attitudes and professional practice.
What will the participant be able to do after viewing your presentation?


You may email your CV and/or Slide presentation to cme@downstate.edu

Signature _____________________________ Date _____________
Sample Flyer

SUNY Downstate Medical Center
Department of Pediatrics
2002-2003 Practicing Pediatricians Lecture Series

July 6, 2007

Topic: “Vaccination Update”

Date and Time: Thursday – 9:00 A.M. – 10:00 A.M.

Location: Lecture Hall 1-A, Education Building

Presenter(s): Kenneth Bromberg, M.D.
Division of Infectious Diseases
Department of Pediatrics
SUNY Downstate Medical Center

Target Audience: General Pediatricians, Family Practitioners, and General Practitioners in private practice in Brooklyn and Western Queens

Objectives: At the conclusion of this activity the participants will be able to:
1) Integrate state-of-the-art knowledge of topics discussed in the lectures into their own diagnoses and treatments of their patients.
2) Formulate for the topics discussed appropriate criteria for referral of children with complex health problems to pediatric sub-specialties.
3) In each lecture and in the whole series, attendees will be encouraged to develop ongoing, working relationships with our medical school community.

Off Label Drugs/Device Usage: None

Disclosures: None reported

Commercial Support: Pfizer Pharmaceuticals

Accreditation Statement
The State University of New York (SUNY) Downstate Medical Center is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Designation Statement
SUNY Downstate Medical Center designates this live activity for a maximum of ___ AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Disclosure Statement
SUNY Downstate Medical Center Office of CME (OCME) and its affiliates are committed to providing educational activities that are objective, balanced and as free of bias as possible. The OCME has established policies that will identify and resolve all conflicts of interest prior to this educational activity. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, and unlabeled/unapproved uses of drugs and devices. Detailed disclosures will be made verbally and/or in writing during the program.
Sample disclosure summary

Conference title

Disclosure Statement
SUNY Downstate Medical Center Office of CME (OCME) and its affiliates are committed to providing educational activities that are objective, balanced and as free of bias as possible. The OCME has established policies in place that will identify and resolve all conflicts of interest prior to this educational activity. All participating faculty are expected to disclose to the audience, verbally or in writing, any commercial relationships that might be perceived as a real or apparent conflict of interest related to the content of their presentations, and unlabeled/unapproved uses of drugs and devices. Detailed disclosures will be made verbally and/or in writing during the program.

Faculties and their relationships

<table>
<thead>
<tr>
<th>Faculty</th>
<th>Disclosures</th>
<th>Nature of Relationship</th>
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The faculty listed below will refer to the following off-label drug or a device that has not been approved by the FDA: list all items that will be referred and their use

<table>
<thead>
<tr>
<th>Faculty</th>
<th>Disclaimer</th>
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Meeting Management/Checklist

The success of your CME activity will depend largely on making sure that you have covered all aspects of your meeting. Ensure that:

- Meeting area is clean and properly prepared
- Lighting is adequate
- AV needs are met (including Biomedical assistance, if required), and that speakers can operate equipment
- Marketing Needs – website, social networks, e-mail, Podcast, etc
- Catering arrangements have been confirmed, and food will be set up in a timely manner, as requested
- Hotel/transportation for speakers has been arranged and confirmed
- Proper faculty/speaker disclosures and commercial support statements are made
- Program objectives are clearly stated to participants at the start of the meeting
- Registration/Attendance Records are accurate and legible
- Program evaluations are completed and collected
- Completed needs assessment forms, if applicable, are collected.
Final Documentation

The following documentation is required at the conclusion of your activity:

- **Outcome Summary**
  A summary of the year’s activity, including number of attendees, and improvements, or changes to be made for the following year’s activity. Also may be used as a needs assessment tool.

- **Final Budget**
  Final budget is the total expenses for your activity for the year, including commercial support. If commercial support is received, you must show how the grant was dispersed e.g. Name of payee receiving support (speaker, caterer, etc.), amount of payment, reason for payment and the company providing the grant. For those clinical departments making payments directly to the speaker(s), copies of the checks should be forwarded with your budget form.

- **Summary of Expenses for Commercial Support (if applicable)**
  If you request a large number of grants, it may be necessary for you to submit a separate summary of those expenses. The format should be the same as previously indicated for the Final Budget Form. For the clinical departments making payments directly to the speaker(s), copies of the checks

- **Attendance Roster**
  All final attendance must be submitted no later than thirty (30) days after the completion of your activity. The later you submit your final attendance roster, the later your faculty will receive their requested transcripts for the academic year.
Can the OCME help you with your activity?

The following are just some of the services provided by the OCME that are available to assist you with any aspect of developing your CME activity. If you wish, we can plan the entire activity. A current fee schedule may be provided upon request. Please remember that if you wish to utilize any of these services, you must contact the OCME at least six (6) months prior to the activity date.

Document Coordination
- Preparation of Credit Request and accompanying forms
- Forwarding and collecting Commercial Support forms
- Forwarding and collecting Disclosure forms

Marketing
- Preparation of brochure
- “Save the Date” cards (includes design, proofing, coordinating printing, etc).
- Coordination of photography, journal ads, and greeters can be arrange
- Web presence, e-mails

Mailings
- Preparation and mailing of “Save the Date” cards
- Preparation and mailing of activity brochure
- Obtaining and preparing mailing labels

From Our Biomedical Communications Department
- Designing of brochures, flyers, posters, and banners
- Preparation of prints, transparencies, and slides
- Photography

From Our Audio-Visual Department
- AV projectionist
- Teleconferencing services
- Videotaping services

Other Services
- Room reservations at DMC or hotel reservations
- Transportation arrangements
- Catering arrangements
- Registration and payment assistance (online registration available)
- Abstract submission and review

We hope this CME Activity Development Guide, and the services we can provide will assist you in the preparation of your CME activity. As always, the OCME is available to answer your questions.
References & Sources

American Medical Association - www.ama-assn.org

Accreditation Council for Continuing Medical Education - www.accme.org