DEPARTMENT OF CONTINUING MEDICAL EDUCATION POLICIES

Beaumont Health, hereinafter referred to as Beaumont, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) and the American Osteopathic Association (AOA) to sponsor continuing medical education (CME) for physicians and the American Psychological Association (APA) to sponsor continuing education (CE) for psychologists. The CME department is the administrative unit responsible for ensuring compliance with the ACCME <u>Criteria</u>, <u>Policies</u>, and <u>Standards for Commercial</u> <u>Support (SCS)</u>, the AOA <u>Accreditation Requirements for Category 1-A Sponsors</u>, the APA <u>Standards</u>, <u>Criteria</u>, and <u>Policies</u> as well as other regulations and laws as they relate to the provision of CME/CE.

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Validity of the Content of CME/CE

Policy Overview

CME/CE activities provided by accredited providers (i.e., Beaumont) are used for the purpose of increasing healthcare provider competence (knowledge/skills) and performance in order to improve patient outcomes, and to assist providers with approval of hospital privileges, maintenance of licensure and maintenance of specialty board recertification. Continuing medical education should not be utilized as a mechanism to induce referrals to the hospital or health system.

The review and validation of the content of continuing medical education activities is critical to assuring the public and learners that (1) content is based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients, and (2) that all scientific research referred to, reported or used in CME/CE in support or justification of a patient care recommendation conforms to the generally accepted standards of experimental design, data collection and analysis.

General Definition of Acceptable Content

The Accreditation Council for Continuing Medical Education (ACCME) defines continuing medical education as consisting of "educational activities which serve to maintain, develop, or increase the knowledge, skills, and professional performance and relationships that a physician uses to provide services for patients, the public, or the profession. The content of CME is 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."

The American Osteopathic Association (AOA) defines CME as content *"to enhance the physician's ability to care for patients."*

The American Psychological Association (APA) defines continuing education (CE) in psychology as an "ongoing process consisting of formal learning activities that (1) are relevant to psychological practice, education and science; (2) enable psychologists to keep pace with the most current scientific evidence regarding assessment, intervention, and education as well as important legal, statutory, or regulatory issues ; and (3) allow psychologists to maintain, develop, and increase competencies in order to improve services to the public and enhance contributions to the profession. Continuing education builds upon a completed doctoral program in psychology. It is not a substitute for the basic academic education and training needed for entry to the field of psychology, nor should it be the primary vehicle for career changes from one APA-recognized specialty area (e.g., clinical, counseling, school psychology) to another."

Validating the Content of CME/CE Activities

Accredited providers must take steps to assure its learners and the public that the content of certified activities is accurate and reliable. Therefore, the following principles shall apply to the process of validating CME/CE content:

 All recommendations involving clinical medicine in a CME/CE 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.

Continuing Medical Education Department Policy Statements

- All scientific research referred to, reported or used in CME/CE in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.
- Activities cannot be presented that promote:
 - Recommendations, treatment or manners of practicing medicine that are not within the definition of CME/CE, or are
 - Known to have risks or dangers that outweigh the benefits or are
 - Known to be ineffective in the treatment of patients

Independence in the Review of Content

Because the validation of CME/CE content is often used as a mechanism to resolve conflict of interest for teachers, managers, planners or reviewers, the process should be independent from the influence of the activity planners and faculty. Therefore, an independent source of content validation should be utilized to review content and either approve it or recommend changes to the content. The process of reviewing and making changes should be documented to demonstrate adherence to the policy. Independent sources of review include the following:

- The reviewer should be a healthcare provider with knowledge of the specialty area being reviewed. The reviewer should have a copy of this policy and a copy of the *Standards for Commercial Support* to fully grasp their responsibilities as the reviewer.
- Members of the CME/CE Committee that do not have conflicts of interest
- Individually-contracted reviewers with the above qualifications
- The activity's faculty or director would **not** be appropriate for content review because they are not independent of the activity.

Areas of Content Review

Five areas of review should occur for each content module reviewed, as follows:

- Review for Fair Balance—Is the content balanced among various options available for treatment and not biased toward a particular product or manufacturer? Pros and cons should be analyzed and reflected in the content, and the content should be based on a need related to physician competence, practice performance improvement, or increased quality in patient care rather than on a product.
- 2. **Patient Treatment Recommendations**—Are the patient treatment recommendations contained in the content evidence-based? Are the treatment recommendations appropriate for the target audience? Do the patient treatment recommendations contribute to overall improvement in patient care?
- 3. **Scientific Validity**—Do scientific studies cited in this activity conform to standards accepted by the scientific community?
- 4. **Learning Objectives**—Does the educational content support the learning objectives of the activity? Are the objectives stated in terms of performance-in-practice and are they actionable and measurable?
- 5. **Omission and Commission**—Do any slides or materials need to be deleted? Are there any studies, data, or best evidence that is missing?

A standardized Content Review Form shall be utilized by each reviewer covering the above categories of review.

Communication of Content Validity Policies

The CME director or designee will be responsible for providing clear directives to faculty on content validity policies and procedures. The principle method of communication is the Faculty Letter, which shall include information on the Definition of CME/CE, evidence-based content, fair balance and scientific objectivity. Additionally, the Conflict of Interest Disclosure Form may also reinforce these requirements.

Maintenance of Documentation

The CME director or designee shall ensure the files for each activity include documentation that a content review was completed, the recommendations made by the reviewer, and evidence that any necessary changes requested by the reviewer were implemented.



Identification and Resolution of Conflicts of Interest

Beaumont abides by the current Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support.

Identification

For an educational activity, all individuals involved in control of the content must disclose relationships with a commercial interest if the relationship is financial, occurred within the past 12 months and is relevant to the content.

A commercial interest is defined as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. Providers of clinical service directly to patients are not considered to be commercial interests - unless the provider of clinical service is owned, or controlled by, an ACCME-defined commercial interest.¹

Financial relationships are those relationships, in any amount, in which the individual benefits by receiving salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.

Financial benefits are usually associated with roles, such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, or other activities for which remuneration is received.

Relationships of the person involved in the CME/CE activity also include financial relationships of a spouse or partner. Both the presence and absence of financial interests must be disclosed to the audience for all individuals involved with the content of the activity. In addition, faculty must disclose any off-label use of product(s) discussed. A Conflict of Interest Disclosure Declaration must be completed by:

- 1. CME/CE Committee members or other reviewers of content annually
- 2. each individual involved in the planning at the initiation of the planning process
- 3. each speaker/presenter, moderator, panel member, author prior to the presentation
- 4. members of a panel, if not participating in the activity elsewhere

Should a potential conflict of interest of anyone involved with the content of the activity be identified from the Disclosure Declaration, this conflict must be resolved according to the <u>Resolution of Conflict of Interest Policy</u>.

The prospective audience must be made aware of any affiliation/financial interest a speaker may have (after material to be presented is reviewed and any conflict resolved) as well as the off-label use of a product that the speaker may be discussing in the presentation. In addition, any affiliation/financial interest of a planning committee member, CME Course Director, member of panel or moderator must be disclosed to the audience. This must be accomplished by an acknowledgement in the notice of the meeting, handout material or the syllabus. Participants of enduring materials must be informed of the financial relationships prior to accessing the educational activity.

¹ Accreditation Council for Continuing Medical Education. <u>http://www.accme.org</u>

Resolution

The CME Department will review all disclosure declarations for course directors and planning members prior to an educational activity receiving approval for credit; disclosure declarations for speakers, presenters, moderators, panelists, authors will be reviewed prior to the activity occurring.

In the event the CME Department finds the potential for a conflict of interest of anyone in control of the content of a CME/CE-approved educational activity (including speakers, planning committee members, course directors/moderators, panel participants and CME/CE Committee members/reviewers of content), one or more of the following actions will be initiated to allow for resolution to occur. Actions will depend on the way in which the content for the activity will be developed and will meet the goal of managing conflict in a way that is in the best interest of the public and those attending the CME/CE-certified activity.

Resolution of Conflict of Interest Actions:

CME/CE Committee Members and Reviewers of Content:

- 1. Complete the CME/CE conflict of interest disclosure declaration annually or as changes to financial relationships occur (whichever comes first).
- 2. Content will only be reviewed by committee members and reviewers who have no relevant financial relationships related to the content under review.

CME/CE Course Directors and Planning Committee Members:

- Complete the CME/CE conflict of interest disclosure declaration prior to submission of the activity CME/CE application. Applications will not be reviewed until disclosure is completed by all course directors and planners. CME staff will review all completed conflict of interest disclosure declaration forms and identify the best course of action.
- 2. If no conflict is identified, then no additional action is required prior to CME/CE approval of the activity.
- 3. If a conflict is identified:
 - Require course directors and planners to complete the Conflict of Interest Resolution Form prior to the activity being reviewed and approved for CME/CE credit.
 - b) CME staff will review the resolution and attestation form in addition to all planning documents, identified speakers, and topics to ensure that speakers and topics represent a balanced, evidence-based medicine approach.
- 4. If CME staff and/or committee reviewers feel the conflict(s) are unable to be resolved then another faculty member with no relevant conflicts may be identified to assist with the planning to ensure independence, the course director or planning member may be required to be replaced by planners with no relevant conflicts, or the application for CME/CE credit may be denied.

CME/CE Moderators and Panel Members:

- 1. Complete the CME/CE conflict of interest disclosure declaration prior to the CME/CE activity start date. CME staff will review all completed conflict of interest disclosure declaration forms and identify the best course of action.
- 2. If no conflict is identified, then no additional action is required prior to CME/CE approval of the activity.



- 3. If a conflict is identified and there is no physical content (i.e., presentation slides) to be reviewed:
 - a) Require the moderator/planner to complete the Conflict of Interest Resolution Form at least one (1) week prior to the activity start date.
 - b) CME staff as well as committee reviewers will determine how topics and speakers were determined and obtain evidence that the topics represent a balanced, evidence-based medicine approach.
- 4. If a conflict is identified and there is physical content available to be reviewed:
 - a) Require the moderator/planner to submit content for review and resolution by CME staff and committee members.
- 5. If CME staff and/or committee reviewers feel the conflict(s) are unable to be resolved, the moderator/panelist will not be allowed to continue in the role or CME/CE credit will be eliminated from their involvement.

Speakers/Presenters/Authors:

- 1. Complete the CME/CE conflict of interest disclosure declaration prior to the CME/CE activity start date. CME staff will review all completed conflict of interest disclosure declaration forms and identify the best course of action.
- 2. If no conflict is identified, then no additional action is required prior to CME/CE approval of the activity.
- 3. If a conflict is identified, provide the CME Department with a copy of the slides/content to be presented at least two (2) weeks prior to the CME/CE activity start date.
 - a) The presentation content will be peer reviewed by CME/CE committee member or by an independent specialist who is familiar with the content.
 - b) If a conflict of interest or bias is detected within the content, the speaker/presenter/author is expected to modify the content, the content will be modified by CME/CE staff/committee member, or the speaker may be replaced.
- 4. If CME staff and/or committee reviewers feel the conflict(s) are unable to be adequately resolved, CME/CE credit(s) will be eliminated from the affected presentation(s).

Situations where Conflict of Interest cannot be Effectively Resolved:

Beaumont CME strives to ensure independence from commercial interests in the planning, development, implementation, and evaluation of CME/CE-certified activities. As a result, there are some situations where adequate resolution of conflicts of interests may not be feasible. In these situations, CME/CE credits will not be provided to individual presentations and/or entire activities. Examples of these situations, include, but are not limited to:

- Short planning timeframes that do not permit adequate planning and implementation of required ACCME, AOA, or APA standards, criteria, and policies and Beaumont CME policies and procedures;
- Requests for CME/CE certification for content that is already fully developed;
- Inappropriate processes in educational planning and/or management that are not consistent with ACCME, AOA, APA and/or Beaumont CME policies and procedures; and
- Individuals, regardless of their role in the activity, who are employed by an ACCMEdefined commercial interest AND the content they are involved with planning and/or presenting is related to the business lines or products of that employer.



Commercial Support

All funds received in support of an educational activity from a commercial interest² must be in the form of an educational grant. Full disclosure for use of these funds must be provided to the CME Department of Beaumont. All expenses incurred will be directly paid by the provider (Beaumont).

Independence

The educational activity shall be planned and the content controlled by the provider, including identification of the need/gap in practice and competency(ies) to be addressed, objectives, selection of speakers, educational methods and evaluation; the commercial interest shall have no involvement or influence over the activity. Requests for "technical review" of the content of the CME/CE activity by the commercial interest(s) will not be accepted.

Indirect support of educational activities for speakers' honoraria, travel/lodging expenses, per diem expenses and attendee food may be given by commercial entities in the form of educational grants to Beaumont. The money may be designated for particular educational activities within a department or division, but industry can have no control over the choice of speakers or the contents of their presentations.

Beaumont will not utilize a commercial interest as the agent providing a CME/CE activity to learners; e.g., distribution of self-study CME/CE activities or arranging for electronic access to CME/CE activities. Distribution of CME/CE activity brochures by representatives of a commercial interest may be allowed by Beaumont if said distribution is not the sole marketing method, commercial interest has signed a grant agreement in support of the activity, AND Beaumont CME/CE has sent a formal request letter to the commercial interest requesting this assistance.

Industry representatives, if invited, may attend CME/CE-approved activities discreetly for their own education, but may not interact with attendees in any way that might be interpreted as marketing nor may they participate in the discussion.

Information on the identity of learners at CME/CE activities is considered to be the confidential property of Beaumont. Information on learners will only be released to third parties when learners have prospectively authorized this release of information.

Management of Funds

Beaumont controls all aspects of the management of funds from a commercial interest. The commercial interest shall not pay directly for any expenses associated with the activity to avoid undue influence by the company into the content of the material presented. No pharmaceutical samples or gifts of any kind will be allowed in connection with CME/CE activities.

A Commercial Support Grant Letter of Agreement must be completed and signed by the designated representative of the commercial interest and the CME Department Director. This agreement specifies the terms and conditions and indicates that the sole responsibility for the content lies with Beaumont. An agreement will be completed for both educational grants and in-kind funds (if applicable).

²ACCME defines a commercial interest as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The ACCME does not consider providers of clinical service directly to patients to be commercial interests.



Acknowledgement

Acknowledgement of educational grants to the audience may be made in the brochure or announcement of the meeting, if known at the time of printing, but <u>must</u> be included in the syllabus or handout material that is distributed at the time of the meeting. Participants of enduring materials must be informed of the commercial support prior to accessing the educational activity.

Acknowledgement of educational grants cannot occur until a fully executed grant letter of agreement is in place and should read as follows: *"This activity is supported by (an) educational grant(s) from [Name of company(ies)]."* Disclosure of commercial support may include the name, mission, and areas of clinical involvement, but **must never include corporate logos**, **slogans, trade names or product-group messages** of an ACCME-defined commercial interest.

Educational materials that are part of a CME/CE activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, trade name or a product-group message of an ACCME-defined commercial interest.



Promotional Materials and Exhibits

The provision of exhibits at educational activities may serve to complement or enhance the activities' value. At the discretion of the course director, commercial exhibitors may be invited to display materials relevant to the subject of the meeting. Beaumont Health reserves the right to deny the request of service to any company that may be in conflict with the interests of our organization.

The CME/CE activity consists of all functions associated with an activity designated for AMA PRA Category 1 Credit[™], AOA credit, and/or APA credit including all peripheral functions such as refreshments and displays. Any function that is present because of the CME/CE activity in the same location as the activity must be considered part of the CME/CE activity. Therefore, all peripheral functions are regulated by CME/CE guidelines.

Exhibitors

An exhibitor is defined as a company that has purchased a display booth as an advertisement/promotional opportunity. Commercial exhibits and advertisements are promotional functions. Therefore, the monies are not considered to be "commercial support."

Exhibitors cannot influence the planning of an activity, interfere with the presentation, or require that the exhibit be a condition for commercial support. Beaumont Health is responsible for control and selection of the planning committee, presenters and moderators for the CME/CE activity.

Beaumont Health reserves the right to deny the request of service to any company that may be in conflict with the interests of our organization.

Funds

Exhibit fees shall be set by the department for each activity and approved by the CME/CE Department prior to solicitation.

- Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support).
- All exhibitors must be charged a fee; fees shall not be waived for any exhibitors
- Different fee amounts can be set based on amount of space (i.e., 3' table vs. 6' table), organization type (i.e. for-profit vs. not-for-profit). All fee options must be made available to all exhibitors.
- Exhibit fees may include registrations for up to two (2) representatives per company; additional representatives shall be paid for according to the set registration fees for the activity.
- All monies must be paid with the full knowledge and approval of the Beaumont CME/CE Department. No other funds from the company will be paid to the activity administrator, speaker or others involved with the activity. Exhibitor income requires an exhibitor agreement to document the terms, conditions and purposes of the contribution. All funds must adhere to the <u>ACCME Standards for Commercial Support</u>.

Placement

All exhibitors must be in a room or area separate from the education and the exhibits must not interfere or in any way compete with the learning experience prior to, during, or immediately after the activity. CME/CE participants must not be compelled to visit exhibits.

Advertisements and promotional materials may not be displayed or distributed in the educational space at any time. No product advertisements will be permitted in the same room or obligatory path of the educational activity. Exhibit placement must not be a condition of support for the CME/CE activity.

Special acknowledgement of exhibitors in activity materials is not required, but is permissible. Acknowledgement of exhibitors may state the name, mission, and areas of clinical involvement of an ACCME/CE-defined commercial interest but **may not include corporate logos and/or slogans.**

Commercial interest representatives may attend CME/CE activities at the discretion of Beaumont for the direct purpose of the representatives' own education; however, they may not engage in sales or marketing activities while in the space or place of the educational activity.

Information on the identity of learners at CME/CE activities is the confidential property of Beaumont. Information on learners will only be released to third parties when learners have prospectively authorized this release of information.

Exhibits must be in compliance with ACCME Standards for Commercial Support. Checks should be made payable to Beaumont. A record of all payments must be kept. No more than two company representatives for each exhibit will ordinarily be permitted. Space may be a limiting factor.

Promotional Materials

Product-promotion material or product-specific advertisement of any type is prohibited in or during CME/CE 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/CE.

Beaumont does not permit subtle advertising in conjunction with CME/CE-certified activities by having book bags, pens, or other accoutrement that bears the name of the manufacturer and/or its products. Educational materials that are part of a CME/CE activity, such as slides, abstracts and handouts, cannot contain any advertising, corporate logo, slogan, trade name or a product-group message.

- For **print**, advertisements and promotional materials will not be interleafed within the pages of the CME/CE content, including meeting syllabi.
- For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME/CE content and not interleafed between computer 'windows' or screens of the CME/CE content.
- For **audio and video recording**, advertisements and promotional materials will not be included within the CME/CE. There will be no 'commercial breaks.'
- For **live**, **face-to-face CME/CE**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME/CE activity. Learners shall not be forced to interact with exhibitors and/or promotional activities. Commercial Interests are not allowed to engage in sales or promotional activities while in the space or place of the CME/CE activity.



Advertising and Promotion of CME/CE Activities

Brochures and other promotional materials (including websites and email announcements) are an important aspect for the success of a CME/CE event.

Only Limited Promotion Permitted Before Approval of Formal Application.

With the exception of a "save the date" notice, which includes only title, date and location (with no mention of CME/CE credit or CME/CE credit "pending"), no promotion of a CME/CE-certified activity or mention of CME/CE credits may occur until the application for credit has been formally approved.

All Promotional Material Must Be Approved by the Beaumont Department of CME.

Before printing, distribution or posting, all promotional materials must be reviewed and approved by the Beaumont Department of CME. CME/CE staff will make all efforts to review these materials as quickly as possible. However, the materials will be reviewed on a first come, first served basis; if the materials contain CME/CE related information, approval will not be granted until the activity is formally approved for CME/CE credits. It is highly recommended that materials be submitted to the Department of CME no less than two weeks prior to the printing deadline. To reduce editing costs, it is recommended that the Department of CME be included in the design process of all marketing materials.

If advance authorization is not obtained from the Department of CME and there is an error in, or omission of, any of the required elements of the printed promotional materials, the Department of CME may require the materials to be reprinted and disseminated with the corrections at the department's expense. *This includes printed brochures, flyers, announcements (U.S. mailed or emailed), "save the date" cards and/or posting to websites.* Send proposed text and/or preliminary draft materials to your assigned CME/CE coordinator for review and approval; see Appendix A.

Required Elements for CME/CE Promotional Materials.

Promotional items must be produced in accordance with all American Medical Association (AMA), Accreditation Council for Continuing Medical Education (ACCME), American Osteopathic Association (AOA), American Psychological Association (APA) and other CME/CE guidelines, and must be approved by the Department of CME in advance. AMA, ACCME, and APA guidelines require specific information be conveyed to all *potential* participants of an activity.

Freedom from Commercial Marketing or Product Messaging.

All Beaumont continuing medical education (CME/CE) syllabi, brochures, course web sites, lecture slides, etc. must be entirely free of commercial marketing or product messaging such as logos and slogans.

No Promotion by Commercial Interests.

Beaumont CME/CE activities are not permitted to be marketed on commercial web sites or marketed by commercial entities because it could be misunderstood to imply a relationship that does not exist.

Emphasis on Educational Content.

The primary focus of Beaumont CME/CE-related marketing should be on the educational content. All education-related information should be presented in the front pages of the material.



Appendix A: Required Elements for CME/CE Promotional Materials

This page contains all of the required and recommended elements for your CME/CE promotional materials. The Beaumont Department of CME will work directly off this checklist when reviewing your materials. If a required element is missing, the promotional piece will be returned to you without approval.

All promotional materials must be reviewed and approved by the Department of CME prior to printing or posting. All promotional materials certified for CME/CE credits by Beaumont require the following elements unless otherwise stated (see Advertisement Required Elements):

Providership Statement	(on cover of brochure of	r home page of website)
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- Title, Date and Location of Activity (on cover of brochure or home page of website)
- ☐ Learning Objectives (must match what was included on the CME/CE application; if the objectives have changed since receiving approval, you must notify the CME department of the changes).
- Activity Overview/Statement of Need
- Intended Target Audience
- ☐ Faculty Planning Committee and Presenters with Credentials (Beaumont faculty with OUWB appointments must list both titles. The first mention of OUWB must be spelled out as Oakland University William Beaumont (OUWB) School of Medicine; subsequent mentions can be listed as OUWB School of Medicine. The faculty members department must be included with their title (i.e., Assistant Professor of Medicine, OUWB School of Medicine).
- Activity Agenda with Times, Topics and Speakers
- Cancellation and Refund Statements (The CME Department automatically charges a \$25 cancellation fee for meetings that have a registration fee managed by CME. This cancellation fee is retained by the CME Department).
- Accreditation Statement
- Credit Designation Statement
- Facility and/or Hotel Accommodation Information (recommended)
- Registration Form



Meals, Social Events, and Gifts

Modest meals and social events may accompany a CME/CE activity, but commercial "sponsorship" is prohibited, and commercial employees may not attend except as paid registrants of the CME/CE activity.³ Any meals or social events provided in connection with a CME/CE activity shall not compete for time or space with or take precedence over the educational event. Gifts must not be provided to conference attendees, but may be provided to conference planners or speakers in lieu of an honorarium. Gifts must be modest (<\$100 per person) and should be educational in nature, especially if being paid for using funds from commercial interests. All gifts must be prospectively approved by the Department of CME.

Activity Participants' Meals

Meals provided for activity participants during the course of a CME/CE activity are allowed for the purpose of promoting interaction and exchange between faculty and learners as long as they are modest in scale (less than \$100 per person) so as not to take precedence over the educational event. Additionally, they must be appropriate for the educational setting in which the activity takes place and be open to all participants of the CME/CE activity. These meals may be paid for either through tuition revenue, educational grants, or promotional funds (i.e., exhibit fees) received from commercial interests. If meals will be paid for using educational grants or promotional funds from commercial interests, there must be more than 50 physicians in attendance and the meal must be a buffet meal, snack, soft drink, or coffee made available to all participants in order to comply with reporting requirements of the Physician Payment Sunshine Act. If fewer than 50 physicians are in attendance, meals must be paid for from alternate income sources.

Faculty Appreciation Meals

The Department of CME allows faculty dinners, either through tuition or commercial support income, which are generally held in appreciation for faculty participation in a course or other form of CME/CE activity (in lieu of honoraria payments). Additionally, faculty dinners constitute a legitimate business meal expense if course business is discussed during the dinner, which may take place immediately before, immediately after, or during a multi-day educational event.

Business meals related to CME/CE activities are intended for the faculty teaching a particular educational event. There has to be a specific business purpose for non-activity faculty to participate in a meal. If other invited individuals are providing guidance or feedback, or are serving as advisers, the business purpose for their presence must be stated.

Commercial support funds may not be used for faculty appreciation or business meals that include individuals other than course faculty or staff working on the activity. Travel and incidental expenses (individual airfare, lodging, ground transportation, and meals other than described above) for any family member/travel companion are not allowed as a course expense under any circumstance.

³ Exhibit /display fees may include registration for up to 2 company representatives. Additional representatives must pay the posted registration fee.



Social Events

Social events must not compete for time or space with or take precedence over the educational event. The social event should not be made a major highlight of the promotional brochure. Spouses, partners, children or guests of faculty or participants may not attend the social event unless a separate fee is charged.

Gifts to Healthcare Providers

Gifts of any type distributed to attendees of educational activities by commercial interests give the appearance of creating a conflict of interest. No gifts are to be given by commercial interests to conference attendees, speakers, or planning members before, during or after the event.

Gifts or compensation may not be accepted for simply attending a CME/CE or other activity or conference, including the defraying of costs (that is, if the individual is not speaking or otherwise actively participating or presenting at the event).

Gifts may be given to planning members and/or speakers of CME/CE events, but must be modest (<\$100 per person) and should be educational in nature. Gifts can be purchased using registration fees or department funds only; funds from educational grant or promotional exhibits cannot be used toward the gift purchase (Physician Payment Sunshine Act); all gifts must be purchased by Beaumont. All gifts must be prospectively approved by the Department of CME.



Payment of Honoraria and Reimbursement

Honoraria and out-of-pocket expenses incurred by faculty will be reimbursed directly by Beaumont or its representative. No other payment from any other source shall be given to the director of the activity, planning committee members, teachers or authors, joint provider, or any others involved with the supported activity. The honoraria guidelines must be consistent with the fair market value in the Midwest region of the country and at Beaumont.

The following factors should be considered when determining the amount paid to faculty:

- (1) The expertise (university affiliated, nationally known, local, etc.)
- (2) Published works in the field of medicine
- (3) Research in specialty areas
- (4) The length of presentation or role in activity (one-hour, half-day, whole day, etc.)
- (5) The need for and value of the content of the presentation.

Amounts being paid will be reviewed by the Corporate CME Department to assure that:

- (1) the honoraria being paid are commensurate with the value of the faculty role;
- (2) the procedure for payment is consistent with ACCME policy and Standards for Commercial Support as well as AOA and APA accreditation requirements;
- (3) payment is consistent within the institution;
- (4) out of pocket expense reimbursement may include: (A) coach airfare, (B) hotel accommodations, (C) food and beverage while traveling, (D) ground transportation, (E) gratuities.

If faculty facilitate or conduct a presentation or session for a portion of an education event, but then participate in the remainder of the educational event as a learner, their expenses can be reimbursed and honoraria can be paid for their faculty role only.

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/CE activity. The provider may use commercial support to pay for travel, lodging, honoraria, or personal expenses for faculty, bona fide employees and volunteers of the provider, joint sponsor or educational partner.

Regardless of type of activity, any single honorarium in excess of \$3,000 MUST be approved by the CME Department.

Expenses of individuals who serve as employees in facilitating an event may be paid for their time and have their expenses covered.

Educational event faculty who are also employees of Beaumont Health may receive an honorarium for their involvement. However, this honorarium must be disclosed by the individual on his/her annual Beaumont Health institutional conflict of interest disclosure.



Non-Employed Physicians

All non-Beaumont physicians who attend or participate as learners in activities certified for CME/CE credit by Beaumont in any manner shall be required to pay an applicable registration fee in an amount equal to the fair market value⁴ of the activity.

Such fee shall be inclusive of any food, materials, or other goods, items, or services provided by Beaumont at the CME/CE-certified activity.

Beaumont shall not reimburse any non-Beaumont physician for any registration fees, meals, lodging, travel expenses, or any other out-of-pocket costs related to such non-Beaumont physician's attendance at a Beaumont CME/CE activity.

Exceptions:

The reimbursement limitations set forth above shall not apply to any non-Beaumont physicians who are planning members, speakers or presenters at the CME/CE-certified activity and may receive reimbursement in accordance with applicable policies of Beaumont for their planner or speaker role.

Beaumont will not be required to charge a registration fee to non-Beaumont physicians for any CME/CE-certified activity for which the primary purpose is compliance training.⁵

Beaumont will not be required to charge a registration fee for attendance or participation in a CME/CE-certified activity that is wholly funded by a third party where such support is intended to be used to reduce or eliminate the cost of a registration fee (i.e., educational grants).

Beaumont will not be required to charge a registration fee if the education is less than 1 ½ hours in duration, occurs within one of the health system's hospitals, is offered to all medical staff members or those practicing in the same specialty, and relates to the provision of, or is designed to facilitate the delivery of medical services within the health system (i.e., grand rounds, tumor boards, cases conferences, etcetera).

⁴ The fair market value to be used to be compliant with this policy is \$25.00 per CME/CE credit, effective for all CME/CE activities approved on or after January 1, 2013.

⁵ For purposes of this policy, compliance training refers to training regarding the basic elements of a compliance program, such as establishing policies and procedures, training of staff, internal monitoring, or reporting; specific training regarding the requirements of the Federal and State health care programs (for example, billing, coding, reasonable and necessary services, documentation, or unlawful referral arrangements); or training regarding other Federal , State, or local laws, regulations, or rules governing the conduct of the party for whom the training is provided.



Regularly Scheduled Series (RSS)

A regularly scheduled series (RSS) is defined as the daily, weekly or monthly CME/CE activities that are primarily planned by and presented to the institution's professional staff. (Source: ACCME).

All RSS are expected to be planned, implemented, and evaluated in compliance with the ACCME Essentials, Policies, Standards for Commercial Support, and pertinent Beaumont CME/CE Policies and Procedures. All RSS sessions are expected to meet the definitions of an RSS and continuing medical education*.

Following an audit to confirm compliance with ACCME Essentials, Policies, Standards and CME/CE Policies and Procedures, the CME Department will assure that records of attendance and/or participation are entered into the database. Non-compliance will be addressed through department consultation and education. Upon the third compliance violation, CME/CE credit may be withdrawn; the CME Department will notify the RSS course director of this action.

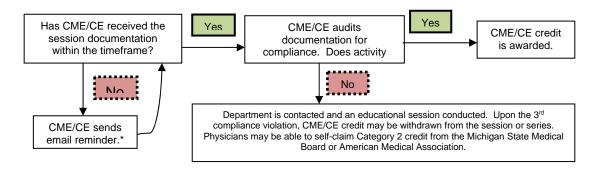
Survey Requirements

All planners of regularly scheduled series should survey their audience annually for suggestions or comments for improvement and to identify from the physicians' perspective where they perceive there is a need or gap in their patient care.

RSS Monitoring and Improvement Plan

All RSS (grand rounds, tumor boards, M&M, journal club, case conference, etc.) meeting documentation must be received by the CME/CE department **no later than three (3) days prior to the meeting date**. If documentation is not received within this time frame, an appropriate intervention will take place as identified below.

- 1st Intervention: communication/education session with department coordinator(s)
- 2nd Intervention: communication/education session with department coordinator(s) and course director(s)
- 3rd Intervention: Withdrawal of CME/CE credits from applicable meeting session(s)
- 4th Intervention: Withdrawal of CME/CE credits from applicable meeting session(s) as well as all remaining meeting sessions in the series through the remainder of the approval period (December 31)



Random, unannounced, on-site evaluations of RSS sessions by a CME/CE staff member may occur throughout the approval period.



Joint/Co-Providership

- 1. A commercial interest cannot take the role of non-accredited partner in a joint-providership relationship.
- 2. Jointly/co-provided activities must be consistent with Beaumont's CME/CE mission and purpose statements.
- 3. A clinical faculty member from Beaumont should be involved with the project and should review and approve the proposed activity prior to grant submission.
- 4. The CME Department must review and approve all materials associated with the activity prior to their release (including grant submissions); once these materials have been reviewed and approved, no further changes can be made without notifying the Beaumont CME Department.
- 5. The responsibilities and role of the joint/co-provider will be clearly delineated in an agreement between the joint/co-provider and Beaumont Department of CME.
- 6. All potential joint/co-providership relationships will be examined on their individual merits. Although all CME/CE activities joint/co-provided with Beaumont must comply with this policy, the CME Department reserves the right to refuse to enter into a joint/co-providership agreement for any reason whatsoever, regardless of that organization's willingness to comply with this policy.
- 7. Beaumont will charge fees for its CME/CE services. These fees and the terms for its payment will be mutually agreed upon and delineated in the aforementioned agreement between Beaumont Department of CME and the joint/co-provider.

The Beaumont CME Department must be involved before any major planning occurs with the project (i.e., speakers invited, content developed, etcetera). Beaumont will not be involved if a proposal is submitted for funding prior to contacting Beaumont Department of CME. If changes are made to a proposal (including budget) after Beaumont CME has given approval, the proposal must be resubmitted for review and approval.



Enduring Materials

CME/CE-certified activities sponsored by Beaumont shall only appear on websites identified by the CME Department as appropriate – they cannot be posted on the website of a commercial interest. Links from CME/CE-approved websites to the websites of commercial interests are permitted before or after the educational content of a CME/CE-sponsored activity, but shall not be embedded in the educational content. The learner must be clearly notified that s/he is leaving the educational website.

Beaumont prohibits advertising of any type within the educational content of CME/CE activities on the Internet including, but not limited to, banner ads, subliminal ads, and pop-up window ads.

At the start of each CME/CE-sponsored Internet activity, the hardware and software required for the learner to participate shall be delineated.

CME/CE-sponsored Internet activities shall include a mechanism for the learner to contact Beaumont Department of CME if there are any questions about the Internet CME/CE activity. A contact for technical issues is also required.

CME/CE-sponsored Internet activities must have, adhere to, and inform the learner about the site's policy on privacy and confidentiality and said policy must be approved by the CME/CE Department.

The CME Department must be able to document that it owns the copyright for, or has received permission for use of, or is otherwise permitted to use copyrighted materials within a CME/CE activity on the Internet.

Content should only be approved for one (1) year initially; CME/CE credit can be extended annually for up to 3 years as long as all content is reviewed each year and verified as accurate ('date of review' must be updated and expiration date changed on the website each year).

Because there is no direct interaction between the provider and/or faculty and the learner, the provider must communicate the following information to participants so that they are *aware of this information* **prior to starting** the educational activity:

- 1. Dates of original release and most recent review or update
- 2. Termination date (date after which enduring material is no longer certified for credit)
- 3. Estimated time to complete the educational activity
- 4. Disclosure of financial relationships
- 5. Disclosure of commercial support (if applicable)

The following additional information must be communicated to participants, but can be done so through pop-ups, links, tabs, etc.

- 1. Method of participation in the learning process
- 2. Principal faculty and their credentials
- 3. Medium or combination of media used
- 4. Accreditation and credit designation statements
- 5. Learning objectives
- 6. Any other information deemed necessary

AMA Policies for Enduring Materials

An enduring material is a certified CME/CE 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. To be certified for *AMA PRA Category 1 Credit*TM, 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 posttest, 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.
- Credit designation for each enduring material must be determined by a mechanism developed by the accredited CME/CE 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/CE 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/CE provider.



Emergencies/Disasters

The following procedures must be followed in the event that an educational activity may need to be cancelled, the date changed or the meeting venue changed due to:

- 1. Inclement weather
- 2. A problem arising with the facility at which the activity is to be held
- 3. A natural disaster

<u>Inclement Weather:</u> On the brochure or announcement of a conference that is to be held when weather may be a factor, the potential attendees need to be informed of a phone number they may contact prior to the conference if there is doubt as to whether the conference will be held, postponed or cancelled.

<u>Facility Problem/Natural Disaster:</u> If an activity is to be held at a location outside of the hospital (hotel, conference center, resort, etc.) and the facility is unable to host the activity, either because of a natural disaster or a problem within the facility itself, an attempt should be made by the Department to secure the facility's help in finding another similar location.

Department Responsibilities:

To the best of their ability, it is the responsibility of the Department staff to assure that all registrants, the faculty and anyone else involved are informed of a cancellation, postponement, change of venue or date in as expeditious a manner as possible. The first method of contact should be via telephone, followed up (if there is time) by a written confirmation of the change/cancellation.

If a conference is cancelled, the Department is required to refund any registration fees that have been received as soon as possible and to assure that monetary settlement with the planned facility is carried out in the hospital's best interest.



Grievance Policy

If a grievance occurs regarding a Beaumont CME event, the grievance must be submitted in writing to the Department of Continuing Medical Education at 26901 Beaumont Boulevard, CME 433-BSC, Southfield, MI 48033. All grievances will receive an initial response in writing within thirty (30) days of receipt.

The Director of CME will review all grievances and resolve if possible. If no resolution is possible, the Director will then pass the information on to the event planning committee and/or Continuing Medical Education / Continuing Psychology Education Committee for resolution.

To submit a written grievance, please send to:

Brooke J. Taylor, MPH, CHCP, FACEHP Director, Continuing Medical Education Beaumont Health, CME Department 26901 Beaumont Boulevard, CME 433-BSC Southfield, MI 48033 brooke.taylor@beaumont.edu