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How to Use this Guide

The Continuing Education Accreditation Standards and Policies Guide is intended to be a resource manual for prospective planners—physicians, nurses, pharmacists—and their staff. It is focused primarily on communicating the accreditation standards Duke Health adheres to, as directed by our accrediting body, Joint Accreditation.

Secondly it serves to apprise these planners and external educational partners, Joint Providers, of the policies put into place related to formalized processes that need to be followed.

Both of these areas are reflected in detail in this guide. Please use the guide as your primary resource tool for understanding accreditation and Duke Health’s policies pertaining thereto.
Accreditation Standards

ABOUT JOINT ACCREDITATION

Duke has always placed a strong emphasis on continuing education (CE) as a way to improve provider performance and thereby offer the best patient care. In recent years, the focus of CE has shifted from educating the individual healthcare provider to advocating for a team-based approach. While these practices are already common at Duke, the organization lacked a formal, regulated process to guide and oversee cross-department educational endeavors.

The Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) started developing a joint accreditation process in 1998 but only began awarding this recognition to organizations in 2010.

In 2012, Duke Health, Duke Health System Department of Clinical Education and Professional Development, received Joint Accreditation (JA), representing both an affirmation of Duke’s continuing education efforts and a renewed commitment to quality improvement. Duke Health System Department of Clinical Education and Professional Development is now only one of a few academic medical centers in the nation to receive Joint Accreditation.

Through the joint accreditation mechanism, Duke is accredited to provide continuing education credit for medicine, nursing, and pharmacy using one set of accreditation standards.

We now abide by the accreditation criteria set forth by the American Nurses Credentialing Center (ANCC), the Accreditation Council for Pharmacy Education (ACPE), and the Accreditation Council for Continuing Medical Education (ACCME), as well as ACCME Standards for Commercial Support℠.

The following are formal accreditation statements that are required to be communicated to all learners for continuing educational activities in which Duke is the accredited provider. These statements may not be altered in any way:

**Joint Accreditation Statement**

In support of improving patient care, the Duke University Health System Department of Clinical Education and Professional Development is accredited by the American Nurses Credentialing Center (ANCC), the Accreditation Council for Pharmacy Education (ACPE), and the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing education to the healthcare team.
Education Credits

Category 1
Duke University Health System Department of Clinical Education and Professional Development designates this activity for a maximum of ______ [insert # of credits] AMA PRA Category 1 Credits™. Physicians should claim only credit commensurate with the extent of their participation in the activity.

Nursing CE
Duke University Health System Department of Clinical Education and Professional Development designates this activity for a maximum of ____ [insert # of credits] credit hours for nurses. Nurses should claim only credit commensurate with the extent of their participation in this activity.

Pharmacy
Duke University Health System Department of Clinical Education and Professional Development designates this knowledge-based activity for ____ [insert # of credits] ACPE credit hours. Universal Activity Numbers: xxx-xx-xxxxx
PLANNING TEAM-BASED EDUCATION

Joint Accreditation is a set of criteria and standards for education that is designed for the team by the team. This type of education is known as Interprofessional Education (IPE) or Team-Based Education. It is a step away from single discipline-centric education.

When planning the activity, it is best to try and incorporate these principles into the activity.

Questions to Address for the Planning Process

1. **Support the Mission Statement of Duke Health System Clinical Education and Professional Development’s Interprofessional Education and Identify Target Audience**

   The Mission Statement is a written statement which includes the purpose, content areas, target audience, type of activities provided, and expected results of the program.

   a. **Question:** In what specific ways does this activity support the Mission Statement?

   b. **Question:** Who will comprise the target audience? The identification of the desired target audience provides an initial framework for educational planning and the context for the activity/series.

2. **Analyze Practice Gaps**

   Professional practice gaps are the variations or differences in the practice patterns when compared to current evidence, standards of care or clinical guidelines that are designed to provide quality of care to patients.

   a. **Question:** What specific professional practice gaps can be identified as the ones which will be addressed through the IPE activity?

   b. **Question:** Which health care professionals should participate in identifying the practice gaps? For IPE activities, identifying practice gaps involve profession-specific and interprofessional shared, pooled gap analysis.

   c. **Question:** Is it possible to obtain and utilize clinical performance data of individual team members and care teams to identify practice gaps? Clinical performance data of individual team members and care teams are utilized identifying practice gaps.

3. **Identify Barriers**

   Barriers to changing practice patterns may contribute to the practice gaps. Barriers include limited knowledge and skills, beliefs and attitudes of health professionals, role expectations, and organizational factors such as lack of equipment or transport.

   a. **Question:** Which topic-specific, profession-specific, and interprofessional barriers to ideal practice pertain to and should be utilized to develop this activity?

   b. **Question:** How can these identified barriers be included as part of the content along with information and practical strategies for overcoming the barriers?
4. Articulate Goals/Objectives

Articulating the educational goals and objectives involve identifying the competency areas to be addressed through the IPE activity and incorporating into the IPE activity the educational needs of knowledge, competence, or performance that underlie the professional practice gaps of the target audience.

a. **Question:** Are the learning objectives written so as to describe changes in individual and/or team-based practice performance? **Use strong and measurable verbs** when writing objectives.

b. **Question:** Are the learning objectives written so that the education outcomes can be measured?

c. **Question:** Are there learning objectives which pertain to profession-specific and interprofessional competency development and physician core competencies, as well as knowledge outcomes?

5. Design Educational Interventions

Educational formats chosen for activities must be appropriate for the setting, objectives and desired results of the activities. The educational activities are developed in the context of IPE learning theories and IPE teaching/learning methods/formats.

a. **Question:** Which IPE learning theories, e.g. self-reflection, experiential, and identity theory, are being used to guide the teaching/learning for this activity?

b. **Question:** Which teaching/learning methods/formats, e.g. interactive and workplace, are being used to support learning “about, from, and with” other health professionals?

6. Evaluate Outcomes

Evaluating outcomes involves analyzing individual behavioral changes, improved team function, and improved team process and clinical outcomes achieved as a result of the activity.

a. **Question:** How are individual behavioral changes to be measured relative to the learning objectives?

b. **Question:** How are improvements in team function, team process, and clinical outcomes to be measured relative to the learning objectives?

**CONTENT VALIDATION**

Validating educational content is crucial to establishing independence and fair balance in service to patient care and public health outcomes.

Duke Health adheres to specific criteria as it relates to designing and implementing educational activities around valid content that “matches the healthcare team's current or potential scope of professional activities.” The Duke University Health System Department of Clinical Education and Professional Development, the accredited provider, must ensure that all content designated for continuing education credits is valid, accordingly.
Acceptable Content

The definition of acceptable content pursuant to Joint Accreditation standards:

“Continuing education consists of educational activities, which serve to maintain, develop or increase the knowledge, skills and professional performance, and relationships that a healthcare professional uses to provide services for patients, the public or the profession. The content of CE is that body of knowledge and skills generally recognized and accepted by the profession as within the basic healthcare sciences, the discipline of healthcare, and the provision of health care to the public.”

The CE activity will comply with Joint accreditation’s Content Validation criteria (JAC1/JAC9):

• All recommendations involving clinical medicine in a CE activity must be based on evidence that is accepted within the professions of medicine, nursing, and pharmacy as adequate justification for their indications and contra-indications in the care of patients.

• All scientific research referred to, reported or used in 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 that promote recommendations, treatment, or manners of practicing medicine, nursing, or pharmacy that are not within the definition of CE or, are known to have risks or dangers that outweigh the benefits or, are known to be ineffective in the treatment of patients will not be certified for credit.

• Presentations and CE activity materials must give a balanced view of therapeutic options; use of generic names will contribute to this impartiality. If the CE educational materials or content includes trade names, where available, trade names from several companies must be used.

• Faculty (speaker or presenter), 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); and 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.

• All such content validation, fair balance, and independence requirements are included in an official letter to faculty, including activity directors and co-directors, faculty committee planners, speakers, and moderators.

• Ultimate responsibility for the rigor, independence, and fair balance of educational content lies with the Activity Director and/or Co-Director of record.

Independence

• Each activity designated for credit will be in compliance with the Joint Accreditation criteria and ACCME’s Standards for Commercial Support of Continuing Medical Education.

• Final authority for all areas relating to Joint Accreditation criteria and ACCME’s Standards for Commercial Support of Continuing Medical Education will be retained by the Duke University Health System Department of
Clinical Education and Professional Development and its administrative units.

- All faculty, meeting, and marketing logistics are to be appropriately handled by Duke employees or their designee(s). Representatives from a commercial interest cannot provide meeting planning or faculty coordination functions.
- Information on the identity of learners at CE activities is considered to be the confidential property of Duke. Information on learners will only be released to third parties when learners have prospectively signed a document authorizing this release of information.
- At the discretion of Duke, anonymous evaluation summaries of the supported activity may be shared with industry representatives.

Review areas

The following are specific areas of review applicable to all content, including slide decks, text-based monographs, outlines of videographic material, and all other educational formats.

- Scientific rigor/treatment recommendations: Recommendations involving clinical medicine in a CE activity are based on evidence that is accepted within the profession of medicine as adequate justification for their indications and contraindications in the care of patients. Scientific research referred to, reported or used in CE in support or justification of a patient care recommendation conforms to the generally accepted standards of experimental design, data collection and analysis.
- Learning objectives: The content addresses learning objectives as approved in the Joint Accreditation application and are measurable.
- Bias: All bias towards a product, procedure, device or therapy is avoided.
- Fair balance: All applicable products, devices, or therapies is addressed to ensure fair and equal balance.
AGREEMENT/DISCLOSURE/ATTESTATION (ADA)

Joint Accreditation requires Duke Health to identify and resolve conflicts of interest for all individuals responsible for the development, management, presentation, and/or evaluation of a CE activity. In order to fulfill this requirement, Duke Health can only designate credits for a CE activity when all involved individuals have completed a disclosure form. The disclosure report must be active during the time period of the activity.

**Purpose:**
To assure fair and unbiased presentation of valuable educational materials and to comply with the ACCME Standards for Commercial Support.

**Who:**
Planning committee members, speakers, presenters, moderators, Activity Directors, authors, etc. Disclosures must include relevant financial relationships of spouses and partners with commercial interest. Commercial interest are defined as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

**How Often:**
Annually or within 30 days of terminating or acquiring a new relevant financial relationship.

CONFLICTS OF INTEREST RESOLUTION

All CE-designated activities must be developed free from the control of a commercial interest and be balanced, objective, and scientifically rigorous.

**Definition of Conflict of Interest (COI):**
A conflict of interest exists when individuals in a position to control the content of a CE activity have a relevant personal financial relationship with a commercial interest that benefits the individual and may ultimately bias the content being presented. The following factors serve as part of the foundation for potential COI:

- A financial relationship (in any amount) with a commercial interest occurring within the past 12 months and
- The opportunity to affect the content of CE about the products or services of that commercial interest.

When the individual’s interests are aligned with those of a commercial interest the interests of the provider are in ‘conflict’ with the interests of the public. The interests of the people controlling CE must always be aligned with what is in the best interests of the public.
**Definition of a Commercial Interest**

A commercial interest is defined as “any entity producing, marketing, re-selling, or distributing healthcare goods or services consumed by, or used on, patients.”

Duke Health is responsible for creating a mechanism to identify, manage, and resolve all conflicts of interests for all individuals involved in the planning and implementation of a Joint Accredited activity.

We incorporate the following strategies as part of the overall planning process of CE activities:

- Monitor the execution of CE activities to validate the presence/absence of commercial bias and the consistent application of the standards of quality education for physicians, nurses, pharmacists, and other healthcare professionals.

- Seek feedback from the learners on the effectiveness of all activities through an activity evaluation.

**Procedures for Identifying, Managing, and Resolving Conflicts of Interest**

All individuals in a position to control the content of a CE activity (planning committee members, speakers, authors, etc.) are required to complete a disclosure and attestation form in which they disclose their financial relationships as well as attest that any and all clinical recommendations made for patient care will be based on the best available evidence, that a balanced view of therapeutic options will be given, and that the content will be developed in accordance with Joint Accreditation criteria.

Duke Health implements primary and secondary COI resolution methods for all CE-designated activities; the primary resolution method is implemented for all individuals in a position to control the content of a CE activity. The secondary resolution methods are implemented for all individuals who have identified financial relationships with commercial interests through the primary resolution method.

**Primary COI Resolution Method for All Activity Types:**

Completion of the disclosure and attestation form as described above. In addition, learners will have the opportunity to identify any perceived commercial bias through the course evaluation.
Secondary COI Resolution Method Options by Activity Type:

Directly Provided, Live Courses (including regularly scheduled series [RSS])¹:
- Course Director(s) prospectively review the content and complete a "Resolution of Conflict of Interest" form stating the action taken to resolve the COI; completed forms must be returned to DUKE HEALTH, or
- The speaker(s) prospectively provide slides to DUKE HEALTH for review prior to presenting; content is revised as needed according to the results of the review.

Directly Provided, Enduring Materials (i.e., print, Internet-based):
- All content will be prospectively reviewed and approved by Duke Health prior to the release of the activity; content will be revised as needed according to the results of the review.

Jointly Provided Activities (Duke designates CE credits with outside entity):
- All content will be prospectively reviewed and approved by Duke Health, the Duke faculty member, AND/or an independent content validation reviewer prior to the release of the activity; content will be revised as needed according to the results of the review.

Note: if the activity involves a moderator who has identified conflicts of interest and has no identifiable content to be reviewed, then the resolution method for that moderator consists of completion of the disclosure and attestation form as well as completion of the course evaluation by the activity learners.

¹ Because presentations given as part of RSSs primarily consist of case discussions, presentation of clinical research findings, morbidity and mortality discussions, tumor boards, etc. the secondary resolution method will be utilized at the CEPD office's discretion.
<table>
<thead>
<tr>
<th>Reported COI</th>
<th>Prescribed Prospective Action for Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Level 1</em>: No financial relationships.</td>
<td>• No action required; designation letter provides guidelines for content development</td>
</tr>
<tr>
<td><em>Level 1A</em>: Financial relationships with commercial interests but not related to content.</td>
<td>• No action required; designation letter provides guidelines for content development</td>
</tr>
<tr>
<td><em>Level 2</em>: Individual has financial relationships with one or more commercial interests and related to content.</td>
<td>• Course director reviews content and disclosure report of individual, resolves conflict and signs COI resolution form stating action taken</td>
</tr>
<tr>
<td><em>Level 2A</em>: Individual has financial relationships with one or more commercial interests, including relationships with commercial supporter(s) of CE activity.</td>
<td>• Course director reviews content and disclosure report of individual, resolves conflict and signs COI resolution form stating action taken</td>
</tr>
</tbody>
</table>
| *Level 3*: Individual has financial relationships with one or more commercial interests, including relationships with commercial supporter(s) of CE activity. | • Duke Health reviews content and makes edits as needed  
• Course director reviews content and completes COI resolution form stating action taken  
• Duke Health may identify an independent content reviewer to conduct a secondary review, if necessary |
| *Level 4*: Individual is employed by a commercial interest and related to content. | • Course director reviews content and disclosure report of individual, resolves conflict and signs COI resolution form stating action taken |
Timing of the Identification, Management, and Resolution of Conflicts of Interest

Course Director(s) and Planning Committee Member(s):

- Completion of the disclosure and attestation before submission of the Joint Accreditation application. Application will not be reviewed until disclosure is completed.
- Financial relationship(s) is reviewed by CE staff:
  - No COI identified: no action will be taken and planning process can continue.
  - COI is identified: Duke Health staff will determine how topics and faculty were determined and obtain evidence that the topics represent a balanced, evidenced-based medicine approach.

Faculty/Speaker/Moderator/Author:

- Completion of the disclosure and attestation no less than 30 days prior to the date of the presentation.
- Financial relationship(s) is reviewed by Duke Health staff:
  - No COI is identified: no action will be taken and the individual can proceed with developing content.
  - COI is identified: CE staff will determine the appropriate secondary resolution method as described above.

Situations Where Conflict of Interest cannot be Effectively Resolved

While Duke Health strives to be flexible, accessible and helpful in the development and implementation of CE-designated activities, there are some situations where adequate resolution of COI may not be feasible. In these situations, CE designation will not be provided. Examples of these situations include:

- Requests for CE designation of the content after the majority of the planning for the CE activity has occurred with faculty and/or content selections already determined;
- Short planning timeframes that don’t permit adequate planning and implementation of required Joint Accreditation and Duke Health policies;
- Inappropriate processes in educational planning and/or financial management that are not consistent with Joint Accreditation and/or Duke Health policies.

COMMERCIAL SUPPORT

The Duke University Health System Department of Clinical Education and Professional Development—the Accredited Provider—is committed to presenting CE activities that promote improvements or quality in healthcare and are independent of the control of commercial interests.

Commercial Support Requests Submitted by Departments

- Duke University Departments may submit grant requests directly to commercial supporters.
- No Duke faculty, including Activity Directors/Co-Directors, may sign any grant letter of agreements.
- Duke Health is responsible for the review and signing of all CE grant letter of agreements; the Duke Department is responsible for prospectively submitting grant letter of...
agreements for commercial support to Duke Health for review and approval. This includes cases of online acceptances.

The Commercial Interest, the Accredited Provider, and the Educational Partner(s) agree to abide by all requirements of the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Continuing Medical Education.

The activity must be for scientific and educational purposes only and will not promote any specific proprietary business interest of the Commercial Interest.

The Accredited Provider is responsible for all decisions regarding the identification of educational needs, determination of learning objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content of the CE, selection of education methods, selection of target audience, evaluation of the activity, and marketing of the activity.

The Accredited Provider and the Commercial Interest must agree that the Commercial Support provided has not been determined in a manner which takes into account the volume or value of any referrals, financial relationship(s) or other business arrangement(s) otherwise existing between the parties for which payment may be made, in whole or in part, under any Federal or state health care program, including, without limitation, Medicare or Medicaid. The provided funds or portions of the provided funds may be reportable in compliance with the Physician Payments Sunshine Act.

Duke Health accepts usage of a commercial supporter's standard letter of agreement template. Alternatively, Duke Health has an internally developed Letter of Agreement that may be used, should commercial supporters agree to its usage.

**APPROPRIATE MANAGEMENT OF ASSOCIATED COMMERCIAL PROMOTION**

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 CE activities.

- Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support). Exhibitors should sign Duke’s **Hold Harmless Form**.
- Exhibit fees shall be approved by Duke for each activity and will be standard for that activity; potential exhibitors shall have equal access to purchasing exhibit space (first come-first serve).
- All exhibitors must be in a room or area separate from the educational activity and the exhibits must not interfere or in any way compete with the learning experience prior to, during, or immediately after the CE activity.
- All exhibitors will be required to sign a Hold Harmless Form.
- Exhibitors may not receive sign-in lists or rosters without the prior approval of the accredited provider.
Acknowledgement of Support

Learners must be notified of educational grants provided in support of an educational activity. This acknowledgement may be in the form of a save-the-date announcement or brochure if known prior to the activity date. Learners—at the time of the course—must be notified of educational grants in syllabi or other educational material (slide decks).

“This activity is supported by unrestricted medical education grants from Pfizer.”

Without fully executed educational grants, acknowledgement in no form may be made.

Duke Health will not utilize a commercial interest as the agent providing a CE activity to learners; e.g., distribution of self-study CE activities or arranging for electronic access to CE activities.

Any abstracts, slides, or other handouts cannot contain logos, slogans, trade names or product-group messaging of a commercial interest.

Safeguards against Commercial Bias

It is important to recognize that bias perceived by learners may be the result of subtle emphasis by a speaker during a presentation.

The content or format of CE activities and related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. All financial relationships of individuals involved with the development and implementation of the activity content will be disclosed to learners prior to the activity.

When preparing your material, speakers, presenters, moderators should adhere to the following guidelines:

- Avoid all bias towards a product, procedure, device or therapy.
- All applicable products, devices or therapies should be addressed in your presentation to ensure fair and equal balance.
- Classes of drugs and devices should be used rather than individual agents whenever possible.
- Do not refer to trade names of any products unless all products’ trade names are used.
- Neither generic nor trade names of products should be in the title of a slide.
- No product logos should be included in the educational materials (slides, abstracts, handouts, etc.).
MATERIALS USED TO ADVERTISE AND PROMOTE EDUCATION

An important aspect of promoting accredited education is public announcement. Often, such announcements to internal or external audiences may include Website pages, email/fax blasts, flyers, save-the-date cards, and brochures.

Materials that include specific information about credit designation, number of credits, or use of “CE” are required to be reviewed and approved by Duke Health in advance of the printing and dissemination of the materials. (Announcements or displays that do not feature use of any accredited information do not require review and approval.)

As posting and distributing educational announcements are vital to generating adequate audiences, it is important that adequate review time be provided to the Duke Health staff.

When Credits are Designated
If credits for your program have been designated and you've received a designation letter, you may add the exact number of credits designated to your advertising materials.

When Credits Have Not Been Designated
Advertising for educational activities may be posted or disseminated prior to an official receipt of credit designation by the Duke Health staff. In these cases, it is permissible to still advertise the activity provided there is no mention of credits or credits pending.

Educational Content
All promotional endeavors related to accredited education should place educational content as the priority of all messaging. Accredited information, such as the number of credits designated, should precede educational content in all advertising.

Product Promotion/Messaging
According to ACCME’s Standards for Commercial Support, Standard #4, all content and advertising materials must be free of commercial marketing or product messaging, including supporter logos, tag lines, and slogans.

Required Elements for Advertisements
The Accreditation Council for Continuing Medical Education (ACCME) and the American Medical Association (AMA), and Joint Accreditation to name a few, require that advertising of accredited education
contain certain elements that all potential learners must receive. For information on specific required elements that all advertising materials should contain, refer to the Required Elements for Advertisements and Syllabi Required Elements of Joint Accreditation.

HIPAA COMPLIANCE
In response to growing concerns about keeping health information private, Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The legislation includes a privacy rule that creates national standards to protect individuals' personal health information. HIPAA allows healthcare providers to utilize patient information, without authorization, in teaching activities involving Duke faculty, staff, and medical trainees. When other individuals may be present at a conference (for example, college students visiting for a day or physicians and nurses from a private practice) patient authorization must be obtained OR information de-identified.

The items considered to be identifiers by the federal government and therefore to be removed are extensive—basically anything that could tie the medical information to an individual—including, but not limited to name, address, social security and medical record number, picture of face, any date associated with the individual (admission, discharge, birth, death), and implanted device serial numbers.

Whenever possible, de-identify information to be presented at conferences.
For additional information, visit https://www.dukemedicine.org/patients-and-visitors/hipaa.

JOINT PROVIDERSHIPS
CE activities are planned and implemented in accordance with the criteria of Joint Accreditation and the ACCME Standards for Commercial Support. Duke is committed to providing relevant educational activities for practitioners to promote improvements or quality in health care that are independent of the control of commercial interests. As part of this commitment, Duke Health does not jointly provide CE activities with commercial interests. That is, a commercial interest cannot take the role of non-accredited partner in a Joint Providership relationship.

ACCME defines a commercial interest as any entity producing, marketing, re-selling, or
distributing healthcare goods or services consumed by, or used on, patients.

**Educational Partner Attestation**

All potential Joint Provider relationships will be examined on their individual merits.

It is the responsibility of Duke Health to ensure that all non-accredited organizations with which we collaborate are not commercial interests or owned or controlled by a commercial interest.

Duke Health reserves the right to refuse to enter into a joint providership agreement for any reason whatsoever, regardless of that organization’s willingness to comply with this policy.

- Duke Health may request company references before entering into a project with a new company. Duke Health requires information regarding any parent companies.
- If any affiliate (sister company) or subsidiary of the organization is involved in providing commercial or other company-directed activities for a commercial interest, a corporate firewall must be in place to maintain independence in the development of content and implementation of CE activities. Verification that the organization has guidelines and firewalls in place to provide for separation of CE and promotional staff (e.g., independent, non-overlapping management, distinct and separate staff responsible for the development of educational content, separate physical locations, different telephone and fax numbers and Internet domains for e-mail addresses, individual computer networks, etc.) is required.

- Joint Providers must abide by Joint Accreditation criteria.
- Jointly provided activities must be consistent with Duke’s mission and purpose statements.
- The responsibilities and roles of the Joint Provider will be clearly delineated in a Joint Providership Agreement between the Joint Provider and Duke.
- Duke has the right to withdraw from any activity if the Joint Provider fails to meet its obligations as described in the Joint Providership Agreement or fails to comply with CE Policies and the Joint Accreditation Criteria.

**Category 1:**

A Duke physician must be involved with the project. This can be in the form of a course director, content reviewer, author, presenter, chair, etc.

Duke does not get involved with negotiating the honoraria for the Duke physician—this must be done directly with the Duke physician.

**Pharmacy:**

A Duke pharmacist must be involved with the project. This can be in the form of a content reviewer, author, presenter, chair, etc. The role must be negotiated with Duke as well as the pharmacist.

Duke does not get involved with negotiating the honoraria for the Duke pharmacist – this must be done directly with the Duke pharmacist.
Nurse CE:
A Duke nurse must be involved with the project. This can be in the form of a content reviewer, author, presenter, chair, etc. Duke does not get involved with negotiating the honoraria for the Duke nurse — this must be done directly with the Duke nurse.

Activity Operations
- All educational grants and agreements associated with funded activities must be reviewed and approved by Duke Legal via Duke Health’s office prior. All such agreements will be prospectively entered into Duke’s Sponsored Projects System (SPS) by the Duke department.
- All effort on funded activities may not proceed unless and until the following are fully executed and received:
  - Fully Executed unrestricted educational grants (allow up to four (4) working weeks for Duke Legal review, without substantial changes required by Duke Legal)
  - Fully Executed Joint Providership Agreement (see above; allow up to five (5) working weeks for Duke Legal review and internal review, without substantial changes made by Partner)
  - Signed and Dated Budget
- Duke Health must review and approve all educational materials (content and marketing materials) associated with the activity prior to their release; once these materials have been reviewed and approved by Duke Health, no further changes to materials can be made.
- IRB protocols submitted by Duke Health in support of a jointly provided activity remain the sole province and oversight of Duke Health.

- All activities operationalized with external partners will be monitored via an onsite evaluation, performed by Duke Health staff. This allows us to document adherence to accreditation standards and criteria.

Grant Proposal Submissions
- A *minimum* turn-around time of 10 business days per Letter of Agreement is required for review and approval.
- Plan on a minimum timeframe of 3 months from grant proposal review and submission.
- A projected budget will be submitted for each CE activity to Duke Health for review and approval. Duke Health will review the projected budget to ensure that adequate resources have been devoted to the development of an activity consistent with meeting the activity’s objectives. CEPD will withdraw from an activity if resources are inadequate for the development of a high quality educational product or activity.
- Any and all funds solicited on behalf of a CE activity must be received by Duke Health.
- Duke Health will not contract with third-party vendors.

Faculty Payment and Travel Reimbursement
- Honoraria amounts shall be based on fair market value with the realization that the amounts will vary with the specialty, subspecialty, speaker qualifications, length and number of presentation(s), nature of the conference, preparation time, and travel time.
- No individual involved in a CE activity may receive payment directly from a commercial interest for honoraria, travel, or out-of-pocket expenses.
• Reimbursement or prepayment of travel expenses for faculty (speaker, presenter, moderator, panel member) of Duke CE-designated activities must be in compliance with Duke’s Travel policy—coach airfare, ground transportation, food and beverage while traveling, overnight accommodations, and gratuities—and the ACCME Standards for Commercial Support of CME.

• All physician payments, travel reimbursements, and certain other qualified transfers of value are subject to be reported to manufacturers of drugs, devices, biological, or medical supplies, who may in turn report such payments to CMS (Sunshine Law).

REGULARLY SCHEDULED SERIES (RSS)
Joint Accreditation requires to describe and verify it has a system in place to monitor regularly scheduled series (RSSs) for compliance with the above guidelines. Joint Accreditation expects that each session of each RSS series be planned and implemented with the intention of being in compliance. The information in this document is intended to provide guidance for faculty and staff who plan and execute RSSs.

• All RSSs are expected to be planned, implemented, and evaluated in compliance with the ACCME Essentials, Policies, and Standards for Commercial Support, and pertinent Duke Health Policies. All RSS sessions are expected to meet the ACCME definition of an RSS and the AMA definition of continuing medical education (see “Definitions”).

• The emphasis Duke Health’s RSS oversight is a system of audit and review that will ensure there is documented compliance with all pertinent ACCME Elements, Policies, and Standards for Commercial Support, and Duke Health Policies. Duke Health staff will perform regular documentation audits as well as periodic, random, on-site evaluation visits to document compliance. A summary report of the audit findings and on-site evaluation visits will be kept in each RSS file.

• Academic units and/or regional institutions that plan and execute RSS's are required to provide the necessary resources and staffing needed to carry-out regularly scheduled CE conferences and to fully comply with Joint Accreditation criteria.

• RSS activity directors and their departments are required to participate in a planning process that links identified needs, objectives, and educational format to desired results. A Duke physician serve should serve as the Activity Director. As such, it is expected that the individuals responsible for RSSs will take part in an annual planning cycle that documents these connections. Also, global learning objectives for an RSS series will be prepared and communicated to learners.

• RSS planners must obtain signed grant letters of agreement from any commercial supporter(s). All such agreements will be prospectively entered into Duke's Sponsored Projects System (SPS). If commercial support is obtained, activity directors, or their designee, must communicate the existence of that support to the participants PRIOR to the activity session.

• Random, unannounced on-site evaluations of RSSs by a Duke Health staff member may occur throughout the approval period.

• Following an audit by Duke Health to confirm compliance with Joint Accreditation and Duke Health Policies, Duke Health will ensure that records of attendance and/or participation
are entered into our system. Credit for sessions found to be noncompliant will not be issued; Duke Health will notify the RSS activity director and staff support person of this action. Noncompliance will be addressed with consultation and education with the activity director and staff support personnel for the RSS. In the event credit is not designated for an RSS activity session or series due to the department’s noncompliance, Duke Health fees will not be refunded to the department.

Duke Health will maintain participant credit records for six years. Duke providers can access transcripts via https://ja.dh.duke.edu or by contacting the Accreditation Office (919) 477-2644.
ENDURING MATERIALS

Educational content that endures (archived Webinars, CD-ROM, podcasts, monographs, DVDs, and other activities housed on a Website) for one year or more must include certain required information for the prospective learner. (Activities in which two or more professions have designated credit may endure for a period of (2) years.)

There are requirements that enduring materials must meet. In instances where content is endured for subsequent years, content must be reviewed for relevancy and accuracy by the Activity Director. This review date must be included on all CE information provided to the learner. The following are additional requirements:

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<th>Dates and Duration:</th>
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<tbody>
<tr>
<td>- Release Date</td>
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<tr>
<td>- End Date</td>
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<tr>
<td>- Latest Review Date (as applicable)</td>
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<tr>
<td>- Estimated Time To Complete</td>
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Note: estimated time to complete is determined by a Duke Health pilot study.

Example:
- Release Date: October 16, 2016
- Estimated Time to Complete: 2 hours
- End date: October 15, 2017

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<th>Assessment</th>
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Learners must achieve a minimum performance level to measure achievement in meeting the educational goals of the activity. Usually this is in the form of a post-test but can be cases studies related to patient management or an “application of new concepts in response to simulated problems.”
Policies

**FACULTY PAYMENT AND TRAVEL REIMBURSEMENT**

As a Joint Accredited (JA) provider of continuing education (CE), the Duke University Health System (DUHS) is required to have a working policy that dictates the provision of payments to faculty in relation to their participation in the planning, implementation and evaluation of CE activities.

Under the DUHS jointly accredited provider status, Duke Health has the ability to designate JA credit for CE activities (A) within the enterprises that constitute “Duke Health”; and (B) external to Duke. As such, the following policy sets parameters around payments allowed for faculty who participate in the types of activities as described above. This policy also applies to Duke Health activities that do not offer accredited content.

- No individual involved in a CE activity may receive payment directly from a commercial interest for honoraria, travel, or out-of-pocket expenses.
- All faculty payments, travel reimbursements, and certain other qualified transfers of value are subject to be reported to manufacturers of drugs, devices, biological, or medical supplies, who may in turn report such payments to CMS.

**A. FACULTY PAYMENT FOR CE ACTIVITIES INTERNAL TO THE DUKE UNIVERSITY HEALTH SYSTEM**

1. We are frequently approached by Duke medical departments and subdivisions to designate credit for CE activities that are planned, organized, and implemented by those particular groups (e.g., Regularly Scheduled Series).

2. Duke faculty participation in Regularly Scheduled Series (RSS), live courses and/or the development of enduring content on behalf of their department is considered part of routine faculty duties; therefore, no supplementary payment will be provided. However, the clinical departments may compensate faculty for their participation in these CE activities in accordance with their department’s faculty compensation plan and subject to the Duke University School of Medicine Extraordinary Pay Policy at the approval of the credit designator and in accordance with the payment limitations stated in Section D below.

**SOCIAL EVENTS, FACULTY DINNERS, MEALS, AND GIFTS**

In the event there are social events or meals at CE activities, they cannot compete with or take precedence over the educational event(s) and should comply with the American Medical Association’s Guidelines on Gifts to Physicians: E-8.061 (http://www.ama-assn.org/).
CONTINUING EDUCATION ACCREDITATION STANDARDS AND POLICIES GUIDE

GUIDELINES FOR SPEAKERS

Duke faculty who serve as presenters for continuing education may receive honoraria and reimbursements for activities provided by Duke Health System, whether these activities are directly provided or jointly provided (with educational partners). Faculty will be asked to attest that work done for a CE activity will be performed outside of normal Duke-paid activities.

Standard coach airfare; one night’s stay at a hotel, including tax; ground transportation; and one day’s per diem are standard reimbursement items.

Content Validation

Recommendations involving clinical medicine in a 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. Scientific research referred to, reported or used in CE in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection and analysis.

Safeguards against Commercial Bias

The content or format of CE activities and related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest. All financial relationships of individuals involved with the development and implementation of the activity content will be disclosed to learners prior to the activity. Via this disclosure, we will determine whether there is a conflict of interest related to your role in the activity. If a conflict of interest is found, we will disclose to all learners how we resolved the conflict.

When preparing your material, please adhere to the following guidelines:

- Avoid all bias towards a product, procedure, device or therapeutic option.
- All applicable products, devices or therapies should be addressed in your presentation to ensure fair and equal balance.
- Classes of drugs and devices should be used rather than individual agents whenever possible.
- Do not refer to trade names of any products unless all products’ trade names are used.
- Neither generic nor trade names of products should be in the title of a slide.
- No product logos should be included in the educational materials (slides, handouts, etc.).

Unapproved Use Disclosure

CE faculty (speakers) are required to disclose to the attendees when products or procedures being discussed are off-label, unlabeled, experimental, and/or investigational (not FDA approved) and 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. Please notify us in writing (prior to the
activity) if you will be discussing any off-label products or procedures.

Measurements of Effectiveness
Duke Health will seek feedback from the learners on the effectiveness of a CE activity through an activity evaluation.

Educational Materials
☐ All slides must be HIPAA compliant, comply with copyright regulations, and be balanced, objective, and scientifically rigorous.

☐ Remove all patient identifiers from laboratory studies, x-rays, imaging studies, slides OR obtain written permission from the patient to use his/her information as part of your presentation.

☐ Do not use identifiable photographs of patients unless written patient permission has been granted.

☐ At a minimum, proper attribution should be included on tables, figures, algorithms, material copied and pasted from web sites, etc. (the source of the cited material can be properly acknowledged in a footnote on the slide).

Audio/Video Recording
Should any CE-designated activity be recorded, faculty may choose to grant permission to be recorded as a part of the activity by completing an audio-visual release form.

Enduring Material
According to the AMA, faculty are required to provide a minimum of three (3) post-test questions with answers for all enduring materials developed for a CE-designated activity or other approved method for evaluation of learner acquisition and application of knowledge. Learners will be required to achieve a passing score of 80% or successful completion as identified by planners to receive a certificate.

INTERNET POLICY
• CE-designated activities only appear on Websites identified as appropriate — they cannot be posted on a pharmaceutical or medical device manufacturer's Website.

• Links from Duke Websites to the Websites of pharmaceutical and medical device manufacturers are permitted before or after the educational content of a directly or jointly provided activity, but shall not be embedded in the educational content of the CE activity. The learner must be clearly notified that s/he is leaving the educational Website.

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

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

• Internet CE activities shall include a mechanism for the learner to contact Duke Health if there are any questions about the Internet CE activity. A contact for technical issues is also required.
CONTINUING EDUCATION ACCREDITATION STANDARDS AND POLICIES GUIDE

- Internet CE 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 Duke Health.
- Duke University Health System 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 CE activity on the Internet.

“SUNSHINE” POLICY (OPEN PAYMENTS)

**Physician Payments Sunshine Act**

Open Payments was established by the Centers for Medicare and Medicaid Services (CMS) to create greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals. The program requires that certain payments and other transfers of value (TOV) made to U.S.-based physicians (Doctor of Medicine, Osteopathy, Dentistry, Dental Surgery, Podiatry, Optometry, or Chiropractic Medicine) and teaching hospitals be reported annually to CMS.

Part of the Affordable Care Act (ACA), this Federal policy regulates TOVs to ensure transparency of relationships between physicians, teaching hospitals, and manufacturers. Transfers of value include fees, lodging, meals, snacks and travel provided directly or indirectly to physicians and fellows who are licensed in the United States as well as teaching hospitals (Covered Recipients).

Certain CE-designated activities may be supported by educational grants from companies considered to be applicable manufacturers. Meals provided as part of these activities may need to be reported to CMS as a transfer of value. In these cases, regulations dictate that physicians’ medical license numbers and National Provider Identifier (NPI) numbers may need to be provided to Duke Health for reporting purposes.

(Physicians may also choose to opt out from receiving a TOV via a signed form filed with Duke Health.)

**Open Payments FAQs Concerning CE Activities**

**What information needs to be reported to you if I, as a Covered Recipient, accept an indirect payment (via an Accredited Provider, e.g.) or direct payment (a value of $10 or more paid directly to Covered Recipient, e.g.) from a manufacturer?**

You will be requested to provide your full name and address, specialty, medical license number (state) and your national provider identifier, the amount, date, and type of the transfer of value (consultation fees, e.g.) and form of payment (cash, stock, e.g.). Note that there are exceptions to what qualifies as a direct payment. For example, product samples and educational materials that directly benefit patients are not reportable.

**Do Nurses, Pharmacists, Physicians Assistants or other individuals in attendance at educational activities need to report transfers of value?**

No, only Covered Recipients are required to report transfers of value. Such reported data may be found on the CMS Website.

**I am offering a buffet style meal for over 50 attendees, and I know the names of all attendees receiving the meal. Do I report transfers of value for this?**


If the Accredited Provider has the ability to identify all attendees receiving the buffet, the transfer of value to attendees who are Covered Recipients must be reported. The only exception is where a large buffet meal, snacks or coffee is provided to all conference attendees and where it would be difficult to establish the identity of the attendees, who partook in the meal or snack. This exception does not apply to meals provided to select attendees at a conference where the identity of the attendees can be established.

Who actually reports transfers of values to CMS?

The manufacturer is required to report transfers of values for all direct or indirect payments made to Covered Recipients. However, the Accredited Provider may be required to provide transfers of value information to the manufacturer related to CE activities.

Do all manufacturers provide food and beverages for educational activities they support?

No, many manufacturers no longer support food and beverages as part of CE activities due to the Sunshine Act.

Is there a distinction of what food and beverages are transfers of value and what are not?

Yes, there are. Buffet meals, snacks, coffee and soft drinks may not have to be reported because such participants may not be able to be identified (as to those who accepted these offerings and those who did not). However, all other meals, such as box meals, are reportable.

As a CE planner, does the Sunshine Act concern me or just Covered Recipients?

If your CE activity includes physician attendees, speakers who are physicians, and is supported financially by a manufacturer, then the Sunshine Act impacts you as a planner.

For more FAQs on Open Payments, please refer to the CMS Website, Policy and Medicine Website, and the AMA’s Sunshine Act Toolkit.
Definitions

**Activity Director:** The member in charge of planning, implementing, and evaluating the CE activity and who is responsible for collaborating with Duke Health to ensure compliance.

**Commercial Interest:** Any proprietary entity producing healthcare goods or services, with the exemption of non-profit or government organizations and non-healthcare related companies.

**Commercial Support:** Financial, or in-kind, contributions given by a commercial interest, which are used to pay all or part of the costs of a CE activity.

**Conflict of Interest:** Circumstances create a conflict of interest when an individual has an opportunity to affect CE content about products or services of a commercial interest with which he/she has a financial relationship. The ACCME considers financial relationships to create actual conflicts of interest in CME when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of CME about the products or services of that commercial interest.

**Continuing Education (CE):** Educational activities that serve to maintain, develop, or increase the knowledge, skills, professional performance, and relationships a physician uses to provide services for patients, the public, or the profession. The content of CE 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. (Sources: ACCME and AMA).

**Exhibit Fee:** A fee paid by a commercial interest to display and promote its products. Exhibit fees are considered a business transaction (e.g., they are not considered "commercial support").

**Faculty:** An individual speaking at or giving a presentation at a CE activity.

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

Personal financial relationships: ‘contracted research’ includes research funding where the institution gets the grant and manages the funds and the person is the principal or named investigator on the grant.

Financial relationships with commercial interests: when a person divests himself of a relationship it is immediately not relevant to conflicts of interest but it must be disclosed to the learners for 12 months.

Relevant financial relationships: financial relationships in any amount occurring within the past 12 months that create a conflict of interest...
ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship.

Interprofessional Education (IPE): Education that is designed, planned and implemented for the benefit of all members of the healthcare team, emphasizing a collaborative care approach.

Joint Accreditation: Multiple accreditation in liaison with the Accrediting Council for Continuing Medical Education (ACCME), American Nurses Credentialing Center (ANCC), the Accreditation Council for Pharmacy Education (ACPE).

Joint Provider: A non-ACCME accredited organization that plans and presents a CE activity in partnership with an ACCME-accredited organization.

Learner: An individual in attendance at a CE activity.

Moderator: The individual moderating or hosting the CE activity (introduces the presenters, facilitates question & answer and/or panel discussions, etc.).

Provider: The accredited provider responsible for designating an activity for continuing education credit and, therefore, responsible for ensuring compliance with the Joint Accreditation criteria.
Regulatory Agencies

Accreditation Council for Continuing Medical Education (ACCME), http://accme.org/

- Centers for Medicare and Medicaid Services (Open Payments), http://www.cms.gov/openpayments/
- Joint Accreditation, http://jointaccreditation.org/
- Pharmaceutical Research and Manufacturers of America (PhRMA) Code, http://www.phrma.org/
- Stark Law, http://starklaw.org/