

# CENTERS FOR MEDICARE & MEDICAID SERVICES CONTINUING EDUCATION (CMSCE) POLICIES

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## **CMSCE Advance Disclosure of Relevant Financial Relationships and Resolution of Conflicts of Interest Policy**

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) that all individuals involved in presenting or developing content will disclose all relevant proprietary or third party commercial relationships in advance of the activity and that learners are advised in advance of the presence or absence of any relevant financial relationships. It is also the policy of CMSCE that content be free of bias due to conflicts of interest.

**Purpose:** Individuals who participate in continuing education experiences, activities, or programs have the right to know:

- The commercial interests an instructor may have in a product, instrument, device, service, or material that is mentioned as part of the learning activity, and that
- The content is free of any bias due to conflict of interest.

**Responsibilities:** Activity Developers (ADs) are responsible for implementing this policy and the CMSCE for monitoring.

### **Process/Procedures:**

1. All content creators/presenters (all subject matter experts, speakers, presenters, content writers and those with the ability to affect content) will complete the **Form CMSCE-3: Disclosure & Attestation**, indicating agreement with “I have disclosed to the Centers for Medicare & Medicaid Services (CMS) all relevant financial relationships. If I am a presenter for a lecture/didactic session, I will also disclose these relationships to learners (verbally, through a slide, etc.), so they may form their own opinions as to possible bias in either exposition or conclusion. I am aware that CMS will disclose this information to learners through additional means and, where evaluation forms are used, ask participants to indicate their opinions regarding possible bias.” (This form also includes definitions of essential terms such as “relevant financial interest” and “conflict of interest” so that these definitions are clearly provided to the content creator/presenter.)
2. The AD will ensure compliance with the above and will indicate compliance by reviewing all of the **Form CMSCE-3: Disclosure & Attestation** submitted using the **Disclosure and Attestation Checklist**, and submitting the results of that review on the **Form CMSCE-4: Design & Development**.
3. The AD will disqualify any individual who refuses to disclose relevant financial relationships from being a planning committee member, a teacher, or an author, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the activity.
4. In the event that there is a relevant conflict of interest involving an individual involved in the CE Activity development, the AD will work with that individual in an effort to resolve the conflict of interest. CMSCE considers financial relationships to create actual conflicts of interest when individuals have both a financial relationship with a commercial interest and the opportunity to affect the content of a CE Activity about the products or services of that commercial interest.

Some of the ways that a conflict of interest may be resolved include:

- Having the individual with the relevant conflict of interest excluded from participating in developing, presenting, or reviewing the CE Activity content,
  - Asking the individual with the relevant conflict of interest to remove themselves from the relationship with the commercial entity for at least 12 months,
  - If the individual with the conflict of interest is a member of CMSCE, replacing the individual with another member who does not have a conflict of interest,
  - Having the content of the CE Activity reviewed by representatives of the target audience to ensure that the content is not biased in any way, and
  - Having CMSCE review the content of the CE Activity to ensure that there is no mention of a specific product or commercial entity.
5. The AD will ensure disclosure of relevant financial relationships is made available to all learners in advance of the CE Activity by including the marketing language issued by CMSCE (upon approval of the CE Activity) in the activity's promotional materials. This information includes the name of the individual, the name of the commercial interest, and the nature of the relationship the person has with each commercial interest.
  6. The AD submits the Form **CMSCE-4: Design & Development** to the CMSCE for review and approval prior to implementation or marketing of the activity.
  7. CMSCE reviews all CE Activity content and promotional materials throughout the development process to ensure that they are not biased in any way and do not mention a specific product or commercial entity.

**References:** IACET Standard 6.4, ACCME Standard of Commercial Support 2.1, 2.2, 2.3 and ACCME Criteria 7 and 9, ACCME Policies: Financial Relationships and Conflicts of Interest and Disclosure of Financial Relationships to the Accredited Provider

**Related Documents:** Form **CMSCE-4: Design & Development**, CMSCE Activity Developer Guide, Administrative Review Checklist

## CMSCE Calculation of CE and CME Credits Policy

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) to calculate Continuing Education Units (CEUs) and AMA PRA Category 1 Credit™ credits in accordance with the accrediting body requirements.

**Purpose:** In order to be compliant with accrediting body requirements, CMSCE must strictly follow the rules for calculation of credits.

**Responsibilities:** The Activity Developer (AD) is responsible for implementation of this policy and the CMSCE is responsible for monitoring compliance.

### **Process/Procedures:**

1. CMSCE has included the exact requirements regarding calculation of credits from the accrediting bodies on the **Form CMSCE-4: Design & Development**.
2. The AD indicates compliance with these requirements when signing this form and submitting it to CMSCE for review and approval prior to implementation of learning activity. As an addendum to this form, the AD submits actual course materials and any pilot testing results.
3. CMSCE monitors compliance by reviewing the course materials and any pilot testing results and recalculating the credits to confirm the accuracy of the AD's submission.
4. CMSCE documents this review on the Administrative Review Checklist.

**References:** IACET Standard 2.3, AMA PRA booklet

**Related Documents:** **Form CMSCE-4: Design & Development**, CMSCE Activity Developer Guide, Administrative Review Checklist

## **CMSCE Commercial Support/Reimbursement of CE Developers/Presenters Policy**

**Policy:** CMSCE will consider accreditation of activities developed using commercial support only if the Activity Developer provides documentation CMSCE deems sufficient to demonstrate the entity providing commercial support does not control and/or influence the content of the activity.

In addition, CMSCE reserves the right to accredit only those activities for which it has sufficient resources to support the additional administrative functions required to ensure the activity is compliant with this policy.

Any honoraria and related expenses reimbursed from government funds must be disbursed in accordance with applicable Federal laws and CMS policy.

**Purpose:** CMSCE has developed this policy in order to ensure compliance with Federal law, CMS and other agency policies (such as the General Services Administration (GSA), and with CE accrediting body requirements.

**Responsibilities:** The AD is responsible for implementing this policy and the CMSCE team member assigned to the event is responsible for monitoring compliance.

### **Process/Procedures:**

1. In the Financial/Compliance section of Form CMSCE-4: Design & Development, the AD indicates compliance with General Services Administration (GSA) and CMS policy regarding commercial support.
2. As part of its compliance review prior to implementation of the activity the CMSCE will review the plans for reimbursement of content creators/presenters to ensure compliance with this policy.

**References:** ACCME Criterion 8

**Related Documents:** Form CMSCE-4: Design & Development, CMSCE Activity Developer Guide, Administrative Review Checklist, GSA travel management policy, GSA Policy on Management and Approval of Conferences and Award Ceremonies

## CMSCE Compliance with Accrediting Body Standards Policy

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) to review all accrediting body standards/requirements on a regularly scheduled basis in order to ensure that all requirements are met and that improvements are made.

**Purpose:** Because accrediting body requirements may change or because an accrediting body may provide additional clarification about existing requirements, CMSCE needs to review CE processes periodically to ensure compliance. This review is necessary to ensure the integrity and quality of the learning activities and the consistent application of the requirements. In addition, CMSCE will keep current by subscribing to newsletters, reading FAQs, and in other activities offered by the accrediting organizations.

**Responsibilities: CMSCE is responsible for this review, as follows:**

**IACET team lead:** The IACET team lead will ensure compliance with the current IACET standard. They will also communicate with IACET and complete any required documentation and reporting requirements. In addition, they will work with the ACCME team lead to facilitate activities within CMS.

**Administrative:** The administrative position will lead the annual review of the CMSCE program to make sure it is compliant with the accrediting body requirements. The position will also be the lead on quality assurance reviews of CE files and will complete reporting requirements as specified by the team leads and management as necessary.

**ACCME Team Lead:** The ACCME team lead will ensure compliance with the ACCME's requirements. They will also communicate with ACCME and complete any required documentation and PARS reporting requirements. In addition, they will work with the IACET team lead to facilitate activities within CMS.

**Nurse Consultant:** The role of the nurse consultant is to advise the CMSCE Advisory Committee and the CMSCE Team on issues related to the nursing community and will provide support and reviews for CE activities and continuous program improvement as necessary.

**Physician Consultant:** The role of the physician consultant is to advise the CMSCE Advisory Committee and the CMSCE Team on issues related to Continuing Medical Education, such as content, target audience, or an issue that might impact our physician audience. With regard to a time commitment in this capacity, the CMSCE Advisory Committee meets annually and as needed to assess the ongoing continuous improvement of the CMSCE Program and provide guidance to the CMSCE Team as appropriate.

**Budget Consultant:** The budget consultant will ensure that CMSCE bills are paid in a timely fashion and all budgetary issues are in compliance with the accrediting bodies' requirements.

**Other:** Division Director of the component within the agency facilitating the CMSCE Program. The responsibility of this position is to provide outreach and information to upper management and to report as required on program improvements and annual program data.

**Process/Procedures:**

1. CMSCE has created and will maintain the currency of the CMSCE Accrediting Body Crosswalk in order to facilitate compliance with accrediting body requirements. This crosswalk is included in the CMSCE Administrative Guide. It records each accrediting body's CE requirements and indicates how CMSCE policies, procedures, and forms meet these requirements.
2. Quarterly, the accrediting bodies' FAQs, standards, and criteria will be reviewed for any changes or clarifications. Based on these changes or clarifications, the crosswalk and CMSCE's policies, processes, and forms that are affected by these changes will be updated in order to better comply with the accrediting bodies.
3. If an accrediting body notifies CMSCE that a change or clarification to processes/policies/web page is needed, updates will occur immediately. An assigned CMSCE member, who will report the findings to the other members of CMSCE at the next scheduled meeting, will complete this review.
4. On an annual basis, CMSCE will conduct a review of all CMSCE policies, processes, and forms against the accrediting bodies' criteria to ensure they are entirely representative of these criteria. This review will also include a review of all processes and procedures and completion of the CMSCE Annual Self-Audit Checklist. If needed, the reviewer will also prepare a revision of CMSCE's mission statement involving the purpose, content, target audience, format and expected result of CMSCE. The CMS mission statement will also be consulted to confirm that CMSCE's mission is aligned with the overall CMS mission. CMSCE will identify and implement changes to better meet our mission through tracking activity and user data summaries in order to better define CMSCE's goal and target audience. These changes will be documented and measurable so that they may be reviewed to see the impact of said changes on CMSCE. In addition, the annual review will involve the discussion of how to better integrate CME into the process for improving professional practice, how the use of non-education strategies could enhance change, how to identify factors outside CMSCE's control that impact patient outcomes, how to implement the use of educational strategies to remove or overcome barriers to physician change, how to better collaborate and cooperate with other stakeholders, and how CMSCE can position itself to influence the scope and content of the activities.

**References:** IACET Standard 2.1 and 2.2; ACCME "Maintaining Compliance: Self-Monitoring"

**Related Documents:** CMSCE Activity Developer Guide, Administrative Review Checklist, CMSCE Accrediting Body Crosswalk

## CMSCE Pilot Testing Policy

**Policy:** Pilot testing is required for all CMSCE activities (live and enduring) to establish the average length of the activity before credit can be offered. Testing will be an accurate portrayal of the learning activity and involve individuals who represent the target audience of the activity.

**Purpose:** In order to be compliant with accrediting body requirements, CMSCE must pilot test live and enduring activities.

**Responsibilities:** The Activity Developer (AD) is responsible for implementation of this policy and the CMSCE is responsible for monitoring compliance.

### Process/Procedures:

1. Pilot test the activity with a representative target audience prior to the activity and provide:
  - a. Attestation for learning time; or
  - b. Recording of presentation so CMSCE can determine learning time.
2. The Pilot test during the activity:
  - a. You cannot provide amount of CE credit to learners beforehand; and
  - b. Attest for length of learning time or if in-house, CMSCE may be able to attend and record learning time.
3. CMSCE is not required to attend and if you do not agree to attest to learning time, your activity will not be approved.
4. CMSCEC monitors compliance by reviewing the course materials and pilot testing results.
5. CMSCE documents this review on the Administrative Review Checklist.

**References:** IACET Standard 2.3

**Related Documents:** Form CMSCE-4: Design & Development, CMSCE Activity Developer Guide, Administrative Review Checklist

## CMSCE Intellectual Property Rights Policy

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) to comply with copyright law by addressing the ownership of intellectual property rights in the design and delivery of learning activities.

**Purpose:** Copyrights give an author the exclusive right to reproduce, sell, distribute, revise, display, perform, broadcast, or record a work. The purpose of this policy is to ensure that any reproduction or other use of a work used in a CE Activity either is done with the permission of the copyright owner or is be permitted by an exception contained in the Copyright Act.

**Responsibilities:** The content creator/presenter and Activity Developer (AD) are responsible for complying with protecting intellectual property rights. CMSCE is responsible for monitoring this compliance.

### Process/Procedures:

1. Each content creator/presenter will check and then sign **Form CMSCE-3: Attestation & Disclosure**, which states, "I confirm that (1) the materials are original, and do not contain any material that would violate the copyrights, trademarks, or other property rights of others (2) that I have obtained sufficient rights with respect to any third-party materials included in the materials to provide the license herein."
2. The AD will verify that all content creators/presenters have signed this agreement and will indicate this by signing **Form CMSCE-4: Design & Development**.
3. CMSCE monitors this compliance and will not approve implementation of the learning activity until this is ensured.

**References:** IACET Standard 6.5, ACCME Policy on Internet CME, Copyright Law <http://www.copyright.gov/title17>

**Related Documents:** **Form CMSCE-3: Attestation & Disclosure**, **Form CMSCE-4: Design & Development**, CMSCE Activity Developer Guide, Administrative Review Checklist

## CMSCE Joint Provider & Co-Sponsor of CE Activities Policy

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) to only enter joint sponsorship or co-sponsorship of CE Activities only with other Federal government agencies.

**Purpose:** The purpose of this policy is to establish that no requests for joint provider or co-sponsor relationships of CE Activities by non-governmental agencies will be considered by CMSCE. Due to staff, budget and resource limitations, CMSCE cannot currently support being a joint provider of CE activities with other private or public entities.

**Responsibilities:** N/A

### Process/Procedures:

1. **Activity Developers** indicate any joint provider or co-sponsor relationships on question 3 in Section V of **Form CSMCE-4: Design & Development**.
2. CMSCE analysts review question 3 in Section V of **Form CSMCE-4: Design & Development** to confirm that any joint provider or co-sponsor relationships of the CE Activity are in conjunction with a Federal government agency.

### References:

**Related Documents:** CMSCE Administrator Guide, Administrative Review Checklist, **Form CMSCE-4**, CMSCE Accrediting Body Crosswalk

## CMSCE Learner Feedback Policy

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) that each learning activity will have a method to evaluate learners and provide feedback to learners on their mastery of learning objectives.

**Purpose:** It is important for learners to receive feedback so they understand the aspects of training that they have mastered or where they need further study.

**Responsibilities:** The Activity Developer (AD) is responsible for implementing this policy and the CMSCE committee member assigned to the activity is responsible for monitoring compliance.

**Process/Procedures:**

1. On the **Form CMSCE-4: Design & Development**, the AD provides information about learner evaluation and documents the plan for learner feedback.
2. On this form, CMSCE provides guidance to the AD that learner performance is generally improved by providing timely and specific feedback during the learning activity in addition to a post-assessment.

**References:** IACET Standard 8.3 and ACCME Criterion 5 and 17

**Related Documents:** **Form CMSCE-4: Design & Development**, CMSCE Activity Developer Guide, Administrative Review Checklist

## CMSCE Learner Records Policy

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) that all persons with access to learner CE records abide by CMSCE procedures that ensure the privacy and information security of learners' records. Records will be released only with the permission and notification of the learner. It is CMSCE policy that learners are notified of the policy for release of records prior to the end of the learning activities and have access to their own records within 15 business days.

**CMSCE Learning Records Retention:** Activity Developers must have a procedure in place to maintain participant records for 7 years. The procedure must include passing them from one contractor/component to another when applicable. If your activity is hosted on the Medicare Learning Network (MLN) Learning Management System (LMS), then you do not need to hold participant records (transcripts, certificates and learning records) as the MLN LMS already keeps these for 7 years. Be sure to include a review of these records as part of your components annual CE self audit. Learners must be aware of the process in place for requesting their learner records/transcripts or certificates.

### Administrative Records

Participant transcripts, certificates and learning records	7 years
Routine correspondence	7 years
Legal and controversial correspondence	Permanently
Internal reports, including milestone communications, related meeting agendas/minutes and reports	7 years

**Purpose:** Information security and privacy of personal information and learning accomplishments is a right of all learners. It is also important that learners be able to have a copy of their records in a timely manner because these records are often used by learners to document completion of continuous learning for professional certification.

**Responsibilities:** Activity Developers (ADs) and CMSCE are responsible to ensure that anyone with access to learner records abides by these policies and procedures.

### Process/Procedures:

1. Learners will be notified of the policy for release of records prior to the end of the learning activity and CMS will provide a written copy of this policy upon request.
2. For non Learning Management System (LMS) activities, CMSCE requires the AD to maintain a permanent records systems for each learner and activity as follows (and CMSCE maintains a copy as a backup):
  - AD's name and address
  - Learner's name

- A unique identification number such as SSN or Provider Education Number
  - Learning program title
  - Completion date of the learning program
  - Number of credits awarded
  - Description of any transcript codes, if utilized
  - Additional information, such as the learner's current address, telephone number, and assessment scores, is optional.
3. Records will be retained for a minimum of 8 years.
  4. Past participants who wish to access their records or transcripts may e-mail CMSCE at [CMSCE@cms.hhs.gov](mailto:CMSCE@cms.hhs.gov).
  5. All systems for maintaining learner record maintenance must meet CMS security requirements.
    - ADs with a Learning Management System (LMS) or other database are expected to adhere to the same security policy as is required for the Medicare Learning Network® (MLN) LMS. For a copy of that policy, please contact CMSCE.
    - ADs without an LMS or other database should refer to the CMS security policies located at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/index.html>

**References:** IACET Standard 9.2, 9.3, and 9.4, ACCME Activity and Attendance Records Retention Policy

**Related Documents:** Form CMSCE-4: Design & Development, CMSCE Activity Developer Guide, Administrative Review Checklist

## CMSCE Non-Discrimination Policy

**Policy:** It is the policy of Centers for Medicare & Medicaid Services Continuing Education (CMSCE) that the individuals involved in developing, administering, and delivering learning activities are expected to maintain a high standard of professionalism, and that they are not to discriminate or make discriminatory remarks based on gender, ethnicity, religion, age, disability, socioeconomic status, and/or sexual orientation.

**Purpose:** CMSCE has written this policy in order to ensure that Continuing Education (CE) Activities comply with Federal law as well as with accreditation organization requirements.

**Responsibilities:** The Activity Developer (AD) is responsible for the implementation of this policy and CMSCE is responsible for monitoring compliance.

### Overview of Process/Procedures:

1. By signing the **Form CMSCE-4: Design & Development**, the AD documents his/her monitoring of this policy.
2. The AD submits the **Form CMSCE-4: Design & Development** to CMSCE prior to implementation of the learning activity.

**References:** IACET Standard 6.3, Section 5 U.S.C. 2302(b)(1) Prohibited Personnel Practices, Civil Service Reform Act of 1978 (CSRA)

**Related Documents:** **Form CMSCE-4: Design & Development**, CMSCE Activity Developer Guide, Administrative Review Checklist