

ACCME 2022 Language Changes

AAP is an accredited provider of the Accreditation Council for Continuing Medical Education (ACCME) which enables us to award CME credits for our educational activities. ACCME recently released new updates to their CME activity requirements via their updated Standards for Integrity & Independence in Education which go into effect on Jan 1, 2022 and includes new terminology as described below.

New ACCME Terms

- **Standards for Integrity and Independence in Accredited Continuing Education:** Formerly called the ACCME's Standards for Commercial Support, these standards have been updated to be applicable to accredited continuing education across the health professions. The Standards are designed to ensure that CME activities serve the needs of patients and the public, present learners with only accurate, balanced, scientifically justified recommendations, assure healthcare professionals and teams that they can trust accredited continuing education to help them deliver safe, effective, cost-effective, compassionate care that is based on best practice and evidence, and create a clear, unbridgeable separation between accredited continuing education and marketing and sales.

- **Accredited Continuing Education (ACE):** ACCME will now be using the term *accredited continuing education* replacing *continuing medical education* to be inclusive of all health professions. ACCME now includes the term *accredited* to explicitly differentiate between accredited and nonaccredited education providers and education. AAP documents/processes will continue to use the term CME (continuing medical education) in reference to our educational activities that award credit.

- **Eligible organizations:** Organizations eligible to be accredited in the ACCME System are those whose mission and function are (1) providing clinical services directly to patients; or (2) the education of healthcare professionals; or (3) serving as fiduciary to patients, the public, or population health; and (4) other organizations that are not otherwise ineligible. ACCME does not require individuals to disclose financial relationships with *eligible* organizations, just *ineligible* companies.

Examples of eligible organizations include:

| | | |
|-----------------------------------------|----------------------------------------------------------|-------------------------------------------------------|
| Ambulatory procedure centers | Pharmacies that do not manufacture proprietary compounds | Diagnostic labs that do not sell proprietary products |
| Electronic health records companies | Government or military agencies | Group medical practices |
| Health law firms | Health profession membership orgs | Hospitals or healthcare delivery systems |
| Infusion centers | Insurance or managed care companies | Nursing homes |
| Blood banks | Publishing or education companies | Rehabilitation centers |
| Med Schools/Health Science Universities | Software or game developers | |

- **Ineligible companies:** Organizations that are not eligible to be accredited in the ACCME system. ACCME requires individuals to disclose all financial relationships that they have with ineligible companies. This term replaces commercial interest.
 - ACCME defines an *ineligible company* as any company, entity, or other organization whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

The new term is intended to clarify that eligibility for accreditation is not based on whether an organization is for-profit or nonprofit but is based on its primary mission and function. All financial relationships with ineligible companies need to be disclosed, reviewed and mitigated before the start of a CME activity. Examples of ineligible companies include:

| | | |
|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Advertising, marketing, or communication firms whose clients are ineligible companies | Bio-medical startups that have begun a governmental regulatory approval process | Compounding pharmacies that manufacture proprietary compounds |
| Device manufacturers or distributors | Diagnostic labs that sell proprietary products | Growers/distributors/manufacturers/sellers of medical foods and dietary supplements |
| Manufacturers of health-related wearable products | Pharmaceutical companies or distributors | Pharmacy benefit managers |
| Reagent manufacturers or sellers | | |

- **Mitigate:** The term *mitigate* replaces *resolve* in guidance related to relevant financial relationships. This new term clarifies that accredited providers, like AAP, are expected to mitigate the potential effect of all disclosed financial relationships of every individual that controls the content of a CME activity. The expectation to mitigate (resolve) all disclosed financial relationships hasn't changed, only the term used to describe it.
- **Employees and Owners:** ACCME clarified that their rules prohibiting employees of ineligible companies from participating in CME activities also include owners of those companies. Employees and owners are individuals who have a legal duty to act in the company's best interests. Employees are defined as individuals hired to work for another person or business (the employer) for compensation and who are subject to the employer's direction as to the details of how to perform the job. Owners are defined as individuals who have an ownership interest in a company, except for stockholders of publicly traded companies, or holders of shares through a pension or mutual fund. Note: Employees and owners of ineligible companies are considered to have unresolvable financial relationships and must be excluded from participating as planners or faculty and must not be allowed to influence or control any aspect of the planning, delivery, or evaluation of accredited continuing education, except in 3 limited circumstances (to present on basic science, to demonstrate the use of devices, and to speak to content not related to the healthcare products of their company).

What this means

Accreditation staff have updated its CME documentation with the new terminology and these new terms will be used in our updated documents and forms being released in September so please familiarize yourself with them. The only exception will be that we are going to continue using CME (continuing medical education) instead of ACE (accredited continuing education).

FAQ

Q: Do I need to modify our accreditation statement and other materials to replace “continuing medical education” with “continuing education”?

A: No changes have been made to the Accreditation Statement. The ACCME has chosen to use the term accredited continuing education in the Standards to be inclusive of all health professions. There is no expectation that providers will change their terminology. You may continue to use the terms “continuing medical education” or “CME” as appropriate.

Q: Regarding the term ineligible company, will we be considered noncompliant if documents (example: LOAs) still state/use the terms, “commercial interest,” “commercial support,” and “Standards for Commercial Support?”

A: No, you will not be considered noncompliant if their documents or forms use old terminology such as commercial interest. Note that the term commercial support is still used and the definition has remained the same. Since the requirements around disclosure have remained the highest rate of noncompliance for many years, the hope was that organizations would use this opportunity to review their mechanism(s) and align with new terminology.

Please note that these are all new requirements. As further clarification is provided by our accreditor (ACCME), and more questions come in from staff, we will continually update this document.

ENSURING CONTENT IS VALID

AAP is an accredited provider of the Accreditation Council for Continuing Medical Education (ACCME) which enables us to award CME credits for our educational activities. ACCME recently released new updates to their CME activity requirements via their updated Standards for Integrity and Independence in Education which go into effect on Jan 1, 2022 and includes clarification on content validity as described below.

ACCME Requirement

Providers, like AAP, are responsible for ensuring that their education is fair and balanced and that any clinical content presented supports safe, effective patient care. This applies to all CME activities.

- *All recommendations for patient care in accredited continuing education must be based on current science, evidence, and clinical reasoning, while giving a fair and balanced view of diagnostic and therapeutic options.*
- *All scientific research referred to, reported, or used in CME in support or justification of a patient care recommendation must conform to the generally accepted standards of experimental design, data collection, analysis, and interpretation.*
- *Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.*
- *Organizations cannot be accredited if they advocate for unscientific approaches to diagnosis or therapy, or if their education promotes recommendations, treatment, or manners of practicing healthcare that are determined to have risks or dangers that outweigh the benefits or are known to be ineffective in the treatment of patients.*

What this means

While this is not a new requirement, ACCME did move this to #1 in their new Standards to stress its importance. In their roles as planners, creators, and deliverers of education, all individuals associated with AAP CME activities should work to ensure that all medical education content being presented to learners follows the above content validity guidelines.

New Process Note

These expectations will be listed in both our internal Planstone disclosure system and our paper disclosure form. As part of the annual CME disclosure collection process, all individuals will attest that they will ensure content validity as they plan, create and deliver AAP educational content. Staff, planners, and others assigned to review CME activities should ensure these guidelines are met when reviewing the final content that will be presented to learners. Activity managers should remind individuals associated with their activity of these guidelines during the CME invitation and/or development process as well as include this reminder in any materials that you distribute to your planners, presenters or others involved with the activity.

FAQ

Q: What is meant by "giving a fair and balanced view of diagnostic and therapeutic options?"

A: CME must be free of commercial bias and must not promote products or services. CME must promote improvements in healthcare. A "balanced view" means that recommendations or emphasis must fairly represent, and be based on, a reasonable and valid interpretation of the information available on the subject (e.g., "On balance the data support the following..."). A "balanced view of therapeutic options" also means that no single product or service is over represented in the education activity when other equal but competing products or services are available for inclusion.

Q: Do you have any further guidance to share on how to best approach education on evolving trends/topics that are not yet evidence-based? Are there expectations from the ACCME regarding the documentation that would be required for education on these topics?

A: As stated in the Standards, "Although accredited continuing education is an appropriate place to discuss, debate, and explore new and evolving topics, these areas need to be clearly identified as such within the program and individual presentations. It is the responsibility of accredited providers to facilitate engagement with these topics

without advocating for, or promoting, practices that are not, or not yet, adequately based on current science, evidence, and clinical reasoning.” Using COVID19 as an example, it was totally appropriate to discuss the emerging evidence and science around diagnosis and treatment in accredited CME. If the content discussed treatment that was not yet proven, then the expectation would be that would be made known to learners so that debate and discussion could occur. There are no new documentation requirements around content validation. Accredited providers will be asked to describe their mechanisms for ensuring the content is valid in the self-study report completed at the time of accreditation, or if a complaint is received about a specific accredited activity.

Please note that these are all new requirements. As further clarification is provided by our accreditor (ACCME), and more questions come in from staff, we will continually update this document.

LEARNER CONSENT TO SHARE CONTACT INFORMATION

AAP is an accredited provider of the Accreditation Council for Continuing Medical Education (ACCME) which enables us to award CME credits for our educational activities. ACCME recently released new updates to their CME activity requirements via their updated Standards for Integrity and Independence in Education which go into effect on Jan 1, 2022 and includes a new requirement for learner consent as described below.

ACCME Requirement

Accredited providers, like AAP, must not share the names or contact information of learners with any ineligible company or its agents without the explicit consent of the individual learner.

What this means

If an activity has financial/in-kind supporters, exhibitors, advertisers, and/or other external companies where an attendee list has been promised, you cannot share attendee contact information with them unless you first receive learner consent. This requirement only applies to external groups that are ACCME defined ineligible companies (any entity whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients).

Please keep in mind that submitting a reg/attendee list is commonly outlined in both Letters of Agreements (LOAs) for funds or in-kind support and Exhibitor Agreements so activity managers should be cognizant of this expectation when entering into agreements with external entities.

Starting with any activity that launches on or after January 1, 2022, if you plan to share a registration/attendee list with an external entity you must first allow learners to opt-in or opt-out of sharing their contact information and then ensure you only share the information of the attendees who provided their consent. You can secure consent from learners (1) during the registration process, (2) during the evaluation process, or (3) during any other part of the activity as you see fit however the consent statement must be clearly visible. If the statement is hidden in a long list of terms and conditions, that would not meet the expectation.

Below you will find sample language that you can incorporate into your activity to secure learner consent. You can select the option that best fits your activity needs. If you plan to use language other than what is listed, please have it reviewed and approved by the Accreditation Unit prior to use.

Consent to Share Your Information

1. Your contact information (name, address, phone, and/or email) may be shared with exhibitors, advertisers, financial/in-kind supporters, and/or others external parties for promotional purposes. You may **opt-in/opt-out** of having information used for purposes either directly or indirectly related to this activity by checking this box .
2. I **give/do not give** permission to share my contact information with external sources.
3. May we share your contact information with external sources? Yes/No

New Process Note

The Accreditation Unit will need copy of the document that you utilize to receive learner consent (such as your registration or evaluation forms) as evidence that this question was asked and to save in the accreditation file for your activity.

FAQ:

Q: Is there a way we can include this question in the pre-registration on NetForum or Webex?

A: It is the responsibility of the activity manager to ensure this feature is in place for their activity. We have reached out to IT and reg staff in Meeting Services for guidance in facilitating this. Please see pages 3-4 of this document on steps to follow if Meeting Services will be handling registration for your activity. If registration will be handled outside of

Meeting Services, you can simply add the consent question as one of your registration or evaluation questions. Regardless of which option you use, please remember to only share the names of learners who provided consent. Please reach out to accreditation staff if neither of these options work for you and we will do our best to assist. Please also remember that you are required to provide the Accreditation Unit of the document you use to address this question as part of the accreditation file for your activity.

Q: Does it matter if you choose the option for learners to opt out versus opt in?

A: No, you can choose which ever option you prefer for your learners.

Q: Will Development be involved with this? We should alert them of this new sharing information rule.

A: Yes, we have also shared this information with Meeting Services.

Q: What is meant by “explicit consent of the learner”?

A: AAP is expected to explain to learners that you intend to share their information with an ineligible company. You can do that at registration; however, the learner must have the ability to opt out and still register for your activity. The consent statement must be clearly visible. If the statement is hidden in a long list of terms and conditions, that would not meet the expectation.

Q: Does an accredited provider, like AAP, have to give a list of its participants to its commercial supporters?

A: No. If, however, an accredited provider chooses to do so, it must obtain the consent of each individual learner, per the new Standards.

Q: Can you provide further clarification on the term “explicit consent”? Is it acceptable for a learner to opt out, or is each learner required to opt in?

A: Either opt in or out is acceptable. The intent is informed consent of the learner if the learner’s personal information will be shared. This is consistent with many US-based state privacy laws. It is acceptable to present the learner with the opportunity to opt out (of the sharing of his/her information), as long as the learner is actively presented the explicit option and must make an affirmative choice, e.g., it is not buried in a long list of terms/conditions, and the learner is still able to register and participate in the education even if opting out.

Please note that these are all new requirements. As further clarification is provided by our accreditor (ACCME), and more questions come in from staff, we will continually update this document.

Steps for Adding Consent Questions (for Registration handled by Meeting Services)

Below are the instructions for adding the “Consent to Share Contact Information” question to the registration process when Meeting Services is handling the set up. This also includes adding the “Are You a NAPNAP Member” to your registration form as well. The instructions are meant to guide you through including one or both questions on the registration form you submit to Kim Chamberlain and running the report in netFORUM (NF) post activity to obtain information on which learners opted in or out.

Registration handled by Meeting Services

We are asking that on your upcoming Events that the registration form include the following survey questions/responses: Questions to be included on registration form/survey:

1. Are you a NAPNAP member? Yes / No
2. May we share your contact information with external sources? Yes / No

Staff Note: You can use any of the language options listed on pg 1, if you plan to use different options it must be reviewed and approved by the Accreditation Unit prior to use.

Populating Report in NetForum:

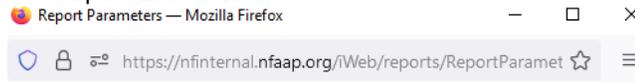
Activity Managers Should Access the Reports Module and Pull This Report

Module = Events
Category = All
Delivery Method = Run Immediately

- Under group registrant reports
- Select AAP Housing Survey Response Report
- Click Go icon or X icon ((Go icon downloads a PDF) X icon downloads an excel file)

| report | description | suggested format | sample | run |
|------------------------------------|------------------------------------------------------------------------------------------------------|------------------|--------|-----|
| AAP Housing Survey Response Report | Report extracts out the housing requests needed by attendee, so that hotel arrangements can be made. | Excel | | |

• Report Launches



AAP Housing Survey Response Report

Report Parameters

Event Type: Annual Leadership Forum (dropdown)

Event Name: 2009 Annual Leadership Forum -> ALF09 (dropdown)

Registration Start Date: [calendar icon]

Registration End Date: [calendar icon]

Go

- Populate report fields based on your Event, and click **Go**

* If sharing contact information with an external source, please do not provide AAP ID numbers in the report.

Independent Registrations Set up Outside of Meeting Services

Questions to be included on your registration form/survey:

1. Are you a NAPNAP member? Yes /No
2. May we share your contact information with external sources? Yes / No

Staff Note: You can use any of the language options listed on pg 1, if you plan to use different options it must be reviewed and approved by the Accreditation Unit prior to use.

* You should only include the individuals who provided their consent on the report you share with external sources. Please do not provide AAP ID numbers in the documentation you provide them.

FACULTY PROMOTION AND MARKETING IN CME ACTIVITIES

AAP is an accredited provider of the Accreditation Council for Continuing Medical Education (ACCME) which enables us to award CME credits for our educational activities. ACCME recently released new updates to their CME activity requirements via their updated Standards for Integrity and Independence in Education which go into effect on Jan 1, 2022 and includes clarification on faculty promotion as described below.

ACCME Requirement

Accredited education must be free of marketing or sales of products or services. Faculty must not actively promote or sell products or services that serve their professional or financial interests during accredited education.

What this means

This is not a new rule as the goal of accredited education has always been to prevent bias in educational content and to that end, ACCME has always required that there is to be no marketing or promotion during any part of a CME activity. What this updated requirement serves to clarify is that rule is applicable to all planners, faculty, speakers, presenters, authors, panelists, trainers, moderators, etc. as individuals who may not actively promote or sell products/ services (including AAP products and materials) that serve their own professional or financial interest in a CME activity. While this requirement holds true for any promotion during the CME activity, if there is a promotional event going on in a separate and designated spot outside of the educational space, that is acceptable. It is also acceptable for presenters to announce a website, book, etc. that was used as a resource, but they must stop short of asking or encouraging learners to purchase this resource.

New Process Note

Activity managers should continue to ensure that promotion is kept separate in their educational activities which includes prohibiting presenters from self-promoting any of their own products/services. A reminder that this is prohibited should be shared with individuals involved with your activity and included in any instructional or guidelines materials that you distribute. Monitoring your activity for bias should continue to occur and you should inform accreditation staff if you witness any violations of this rule.

FAQ

Q: Does the new promotional rule only apply to materials that have monetary value?

A: No, this updated standard applies to ALL materials as the goal is to provide learners with unbiased non-promotional medical education during a CME activity.

Q: Can faculty reference and encourage learners to review something that was used as a resource in their educational session?

A: Yes, they can mention it as a resource but cannot ask or encourage learners to go and buy it.

Q: Can the speaker announce something like, “Come to the meet and greet to speak to “xyz””?

A: Learners can be advised of additional events or sessions taking place during a CME activity but a presenter should not use their allotted time as an educator to encourage learners to buy any of their materials.

Q: If you refer to a resource and inform learners they can go to a website and download a free toolkit is this ok?

A: Yes, you can advise learners of a free resource and how they can access it.

Q: Can you provide a link and/or image for a resource so that learners can view it easily?

A: You can mention it as a resource but cannot ask or encourage learners to go and buy it. As with all images used in an educational activity, you should always ensure you are following all applicable copyright rules.

Q: The AAP is not a commercial interest, but there are resources/items that are available for purchase, does this mean we cannot promote them?

A: You can mention AAP items as a resource, even if they are a free member benefit, but cannot ask or encourage learners to go and buy it.

Q: A faculty member just wrote a book that will be published, can they say anything about the book in their CME session?

A: Yes, they can mention it as a resource but cannot ask or encourage learners to go and buy it

Q: Can I have a rotating slide between sessions of my in-person event that advises learners of future course offerings?

A: Yes since no one associated with your educational event is actively asking learners to purchase registration to future activities, but instead you are passively sharing this information as a future learning opportunity to all learners, this is ok.

Q: What do I do if a presenter does promote their own book during an educational session?

A: As part of your area's processes and procedures for planning and implementing your CME activities, activity managers should work with their Directors, SVP, and/or planners to identify ways to clearly communicate this expectation to individuals involved with delivering educational content. If the situation does occur, you should work with this same set of individuals to identify a course of action to remediate the situation, up to and including, disqualifying the individual from participating in future events. If you are involved in a situation where this has occurred, please advise the Accreditation Unit of the circumstances at your earliest opportunity.

Q: Does “actively promote or sell products or services” include books, even if those books are not on a clinical topic? How does this Standard apply to books that are authored by faculty, who receive royalties, but are published/branded by an eligible organization?

A: Yes, the Standard seeks to ensure that the accredited education is free from any kind of sales/promotion. Using the sale of a book as an example - a faculty member can include authorship of the book in her list of credentials. A faculty member can cite a book or research that she authored. The faculty member cannot say – “please buy my book immediately following this event, in the back of the room.” It is acceptable to host a book signing event before or after the education – in another room. Books can be made available for purchase, just not in the room or space where the education is occurring.

Please note that these are all new requirements. As further clarification is provided by our accreditor (ACCME), and more questions come in from staff, we will continually update this document.

NON-EDUCATION SESSIONS - 30 MIN INTERVAL REQUIREMENT

AAP is an accredited provider of the Accreditation Council for Continuing Medical Education (ACCME) which enables us to award CME credits for our educational activities. ACCME recently released new updates to their CME activity requirements via their updated Standards for Integrity and Independence in Education which go into effect on Jan 1, 2022 and includes clarification on keeping education separate from promotion as described below.

ACCME Requirement

Providers, like AAP, must ensure that learners can easily distinguish between CME content and other content or activities that take place during an educational event.

- *Live activities: Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible company or with planners or faculty with unmitigated financial relationships must not occur in the educational space within 30 minutes before or after an accredited education activity. Activities that are part of the event but are not accredited for continuing education must be clearly labeled and communicated as such.*
- *Print, online, or digital activities: Learners must not be presented with marketing while engaged in the CME activity. Learners must be able to engage with the accredited education without having to click through, watch, listen to, or be presented with product promotion or product-specific advertisement.*
- *Educational materials that are part of the CME activity (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible company, including corporate or product logos, trade names, or product group messages. Information distributed about the CME activity that does not include educational content, such as schedules and logistical information, may include marketing by or for an ineligible company.*

What this means

The ACCME has defined how much time (a 30-minute interval) must separate CME sessions/components from marketing, promotional or non-CME session/components of an activity if they are held in the same room as the CME sessions. This rule is not new; ACCME has always required that promotion in the same room (space) cannot occur immediately before/after CME sessions. This change in the Standards is only to clarify what ACCME means by promotion (marketing, advertising exhibiting components) and nonaccredited education (education where disclosure information was not collected or there were financial relationships disclosed that were not able to be successfully mitigated). The requirement was also updated to replace “immediately” with 30 minutes. This change also requires that activities that are part of the event, but are not designated for CME credit, must be clearly labeled and communicated as such to learners.

The 30 minute interval is applicable for all activities, whether it is virtual, in person, or a combination of formats.

- For any in person sessions or components of an activity: if the CME and the non-CME components are taking place in the same physical room there must be a 30-minute interval between the two events. If the learner is required to leave the original educational space and move to another room/hall then the 30 minute interval does not apply. Remember, this applies to all CME activities, in any formats, that incorporate face-to-face interactions with learners.
- For online components of an activity: if the learner will remain in the same virtual space for the CME and the non-CME components then there must be a 30-minute interval between the two events. Alternatively, if the learner is required to leave the virtual space to transition between a CME and non-CME component (ie clicking a link that communicates they will be leaving the educational space to participate on a separate screen/channel) then the 30 minute interval is not required. Remember, this applies to any activity, live or enduring, that delivers any part of its content via the internet. At no point should an online learner encounter promotional material or commercial breaks.
- Promotional activities that need the 30 minute interval include marketing and exhibitor events, product theaters (only approved for NCE), or other components that involve ineligible companies if they take place in the same room/screen as the CME content.
- Non accredited education applies to any medical education content being delivered during any part of a CME activity for which disclosure information was not collected or disclosed relationships were not able to be successfully mitigated.

- It is no longer acceptable to determine that CME will not be awarded to that particular segment; now the 30 minute interval would need to be in place if that component takes place in the same room/screen as the CME content.
- If the non-CME component is not educational in nature (such as a meal or guided meditation break) or would not cause any planners or presenters to have relevant financial relationships (such as a committee update session, business meeting, legislative update, awards ceremony), then the 30 minute interval is not required.
- When planning a CME activity, think about how you are delivering the education and keep in mind this separation requirement for any of the non-CME components you are integrating into your activity. When creating the agenda for a CME activity, look carefully at any component that does not award CME credits to see if the 30 minute interval is required to ensure you have the space for it when assigning locations. The Accreditation Unit can assist with any content of which you are uncertain.

New Process Note

The Accreditation Unit will:

- continue to review all final agendas and content descriptions to ensure the correct number of CME credits are being designated for the appropriate content and to ensure promotional opportunities are kept separate from the education.
- start requesting clarification on the location of any promotional, marketing, exhibit, and non-educational components to ensure they are not occurring in the same room/screens as the CME sessions (or that they have the 30 minute interval in place if they are).
- review learner materials (agendas, programs, etc) to ensure that the activity manager has clearly labeled all non-CME components of an activity as such for easy identification by learners.

FAQ

Q: If the non-education session takes place in another room is the 30 minute interval required?

A: No, there is no 30 minute interval required if the non-CME session, component or activity takes place in another room/screen. You should however clearly label this as a non-CME for learners.

Q: Will there be a more comprehensive list of what specific non-education activities need to be separated by 30-minutes?

A: Marketing/promotional events, exhibits, advertising, product theaters (only approved for NCE), as well as educational sessions/components not awarding CME credit because disclosure information was not collected or could not be successfully mitigated, all need the 30 minute interval if they are taking place in the same room/screen as the CME content. Involvement with ineligible companies or missing/unmitigated financial disclosures are 2 key indicators that a 30 minute interval will be required for that component. Reach out to the Accreditation Unit on any specific component about which you are uncertain. Please remember, if the non-CME component is not educational in nature (such as a meal or guided meditation break) or would not cause any planners or presenters to have relevant financial relationships (such as a committee update session, business meeting, legislative update, awards ceremony), then the 30 minute interval is not required.

Q: Is it ok to have a business lunch in the same room as Council or Section program that just wrapped up?

A: Yes, a meal can occur without the need for a 30 minute interval as CME credits are not awarded for the time learners spend breaking for a meal and business meetings do not award CME credit.

Q: Is it ok to have a non-CME event in the same room directly after CME components are completed for the day?

A: It depends as you have to look at the reason why the event is not awarding CME credit. If it is in the same room/screen as your last CME session but there is no CME content being delivered during the event (business meeting, legislative update, awards ceremony, reception) then the 30-minute rule would not apply. However, if it is a promotional event by an ineligible company or an educational event but you did not receive, or were unable to mitigate, the presenters financial disclosures then the 30 minute rule applies.

Q: Will there be any leniency while COVID-19 restrictions are still in place and groups are handling capacity issues?

A: No, the rules will go into full effect on 1/1/2022

Q: Are we going to need to have people who don't typically disclose now disclose (ie award winners)?

A: No, an award ceremony is not educational content that would be designated for credit therefore the people involved in the ceremony do not need to disclose nor would the 30 minute interval apply.

Q: What about scenarios where a disclosure cannot be mitigated and therefore CME needs to be stripped from the activity?

A. The purpose of these requirements is to ensure that learners receive unbiased medical education outside of the control of a commercial interest when attending your event. If you have an individual where financial relationships cannot be successfully mitigated, then you should identify a replacement (per the AAP CME Disclosure Policy: "all potential conflicts of interest identified through the review of the *AAP Full Disclosure Statement* forms must be mitigated in order for individuals in a position to influence and/or control CME content to be confirmed for the educational assignment"). At a minimum the 30 minute interval applies.

Q: Will development be informed of these updates?

A: Yes, we have also shared this information with Meeting Services staff since they are involved with meeting logistics for some AAP CME activities.

Q: What about if a group is having their business meeting after the course in a different room, does the 30 minutes still apply?

A: No.

Q: What if it is a luncheon that is sponsored (never been CME approved, award recipient gives an education acceptance speech). Is this ok?

A: Yes, meals that are made available to learners during a CME activity, for which you used commercial support funds, would not be considered marketing, exhibits, or nonaccredited education, and therefore the 30-minute interval between CME content and the meal would not be required, even if the meal is held in the same space.

Q: Can they take CME away from a sponsored breakfast?

A: No since a breakfast session should not award CME credits. If you are allowing learners to eat breakfast during a morning CME session the 30 minute interval would not be required as there should never be any involvement/influence on that breakfast session, or any aspect of your educational activity, from a commercial supporter.

Q: Will poster sessions need to be separated by the 30 minute interval?

A: ACCME has confirmed poster sessions that are not designated for CME credit would be considered "nonaccredited education" and would be expected to include a 30-minute interval between the CME sessions and the poster sessions if they are held in the same space.

Q: What about NCE- the 30 minute intervals will pose a big problem for hosted events

A: While NCE typically takes place in a convention center with numerous rooms, considering the pandemic, virtual environments, and the numerous activities that take place at the annual meeting, we understand that this requirement may still have an impact on NCE as well as other AAP CME activities. We encourage each activity manager that oversees educational activities to look at each individual event that you oversee to determine the impact that this requirement might have and reach out to the Accreditation Unit to discuss in more detail so that we can help find a solution.

Q: How are we going to sell sponsorship packages, if being in a different room doesn't remove the 30 min interval? This seems like an impossible ask and will have economic toll on chapters while COVID-19 restrictions on capacity remain.

A: Fortunately, being in a different room does remove the requirement of a 30 minute interval, this interval only applies if the events take place in the same space (room/screen/channel).

Q: Can a provider offer ineligible companies different levels of designation for different amounts of commercial support?

A: Yes.

Q: Is the 30-minute time interval required regardless of whether the nonaccredited component activity takes place before or after the CME session?

A: Yes. There needs to be a 30-minute interval between a component that awards CME credit and one that does not regardless of whether the nonaccredited component is before, after, or both. As noted in the Standards, this time interval is required if the nonaccredited activity is either developed by, or with, an ineligible company or if individuals with missing or unmitigated relevant financial relationships with ineligible companies are in control of content.

Q: What if I get a last minute disclosure that can't be successfully mitigated, can I just not award CME credits for that session or do I have to implement the 30 minute interval even though location logistics are routinely finalized that late in the process?

A: The 30 minute interval does apply for educational components that have missing or unmitigated financial relationships. Activity managers should collect disclosures upon invite of individuals who will be associated with your activity and not confirm their participation until disclosures are submitted so that you can ensure successful mitigation prior to the person participating in your activity. If this situation still occurs then you would need to work out the last minute logistics of incorporating a 30 minute interval before and/or after that specific session that was not awarding CME credits such as changing the time of the session, changing speakers, looking at the room assignments to hold the session in a separate space and avoid the 30 minute interval, or canceling the session entirely.

Q: For NCE's Section/Council programs can we incorporate non-CME poster sessions within our assigned room at the convention center/hotel?

A: Per ACCME, poster sessions are considered non-accredited education and are required to be held in a separate space from the credit bearing sessions or need to be conducted 30 minutes before or after the CME components.

Q: Does there need to be a 30-minute interval between accredited and nonaccredited education in virtual activities?

A: The 30-minute interval is required for all activities, whether the education is delivered in-person or online. For online components, if the learner will remain in the same "virtual space" for a non-CME component, then you must ensure that there is a 30-minute interval before or after the CME components. If the learner is required to leave the virtual space to transition between accredited and nonaccredited components, and will need to take an action, such as clicking a link that clearly communicates that they are leaving the accredited education, then there is no 30 minute interval required.

Q: Advertising is mentioned in this requirement, where can advertising for ineligible companies appear related to educational events?

A: ACCME requires the separation of education from all promotional activities, materials and messages. Many activity managers create a print or text based document that goes along with an activity and provides information that is supplementary to the education content - like reproductions of slides, graphics or other handouts. These documents, in print or electronic, are an integral part of the education and as such cannot have any advertising, corporate logo, trade name or a product-group message of an ineligible company associated with them.

Q: Also, can we include advertising in a printed or digital handout that contains abstracts if we don't provide CME credit for the abstracts?

A: It would depend on what the handout, with abstracts, is used for in relation to the CME activity. If the abstracts are referenced during the activity or serve as a component of the content, then there can be no advertising in the handout. If the abstracts are not referenced as part of the CME content, and appear in the handout with other logistical information about the activity, then advertising is allowed.

Please note that these are all new requirements. As further clarification is provided by our accreditor (ACCME), and more questions come in from staff, we will continually update this document.

DISCLOSURE QUESTIONS / PLANSTONE SYSTEM CHANGES

AAP is an accredited provider of the Accreditation Council for Continuing Medical Education (ACCME) which enables us to award CME credits for our educational activities. ACCME recently released new updates to their CME activity requirements via their updated Standards for Integrity and Independence in Education which go into effect on January 1, 2022 and includes new disclosure requirements as described below.

ACCME Requirement (text bolded by AAP)

Many healthcare professionals have financial relationships with ineligible companies. These relationships must not be allowed to influence accredited continuing education. Providers are responsible for identifying relevant financial relationships between individuals in control of educational content and ineligible companies and managing these to ensure they do not introduce commercial bias into the education. Financial relationships of any dollar amount are defined as relevant if the educational content is related to the business lines or products of the ineligible company. Accredited providers must take the following steps when developing accredited continuing education:

- 1. Collect information:** Collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies **within the prior 24 months**. There is no minimum financial threshold; individuals must disclose **all financial relationships**, regardless of the amount, with ineligible companies. Individuals must disclose regardless of their view of the relevance of the relationship to the education. Disclosure information must include:
 - Name of the ineligible company with which the person has a financial relationship.
 - Nature of the financial relationship. Examples of financial relationships include employee, researcher, consultant, advisor, speaker, independent contractor (including contracted research), royalties or patent beneficiary, executive role, and ownership interest. Individual stocks and stock options should be disclosed; diversified mutual funds do not need to be disclosed. Research funding from ineligible companies should be disclosed by the principal or named investigator even if their institution receives the research grant and manages the funds.
- 2. Exclude owners/employees of ineligible companies:** Review information about financial relationships to identify any owners or employees of ineligible companies. These individuals must be excluded from controlling content or participating as planners or faculty in accredited education. There are three exceptions to this exclusion—employees of ineligible companies can participate as planners or faculty in these specific situations:
 - When the content of the activity is not related to the business lines or products of their employer/company.
 - When the content of the accredited activity is limited to basic science research, such as pre-clinical research and drug discovery, or the methodologies of research, and they do not make care recommendations.
 - When they are participating as technicians to teach safe and proper use of medical device; do not recommend whether or when a device is used.
- 3. Identify relevant financial relationships:** Review the information about financial relationships to determine which relationships are relevant. Financial relationships are relevant if the educational content an individual can control is related to the business lines or products of the ineligible company.
- 4. Mitigate relevant financial relationships:** Take steps to prevent all with relevant financial relationships from inserting commercial bias into content.
 - Mitigate relationships prior to the individuals assuming their roles. Take steps appropriate to the role of the person. For example, steps for planners will likely be different than for faculty and would occur before planning begins.
 - Document the steps taken to mitigate relevant financial relationships
- 5. Disclose all relevant financial relationships to learners:** Disclosure to learners must include each of the following:
 - Name of the individuals with relevant financial relationships
 - Name of the ineligible companies with which they have relationships
 - Nature of the relationships
 - Statement that all relevant financial relationships have been mitigated

Additionally:

- Identify ineligible companies by their name only. Disclosure to learners must not include ineligible companies' corporate or product logos, trade names, or product group messages.
- Disclose absence of relevant financial relationships. Inform learners about planners, faculty, and others in control of content (either individually or as a group) with no relevant financial relationships with ineligible companies.
- Learners must receive disclosure information, in a format that can be verified at the time of accreditation, before engaging with the education.

What this means

- Financial relationships must be disclosed from the past 24 months instead of past 12 months.
- ALL financial relationships with ineligible companies must be disclosed, not just those relevant to the activity.
- AAP disclosure grid will be updated to contain a statement indicating all disclosed relationships have been successfully mitigated. Updated grid will be circulated in September.

- Off-label disclosure question will no longer be asked, instead a statement informing learners that off-label discussion may occur during the activity will be added to the AAP disclosure grid that is used for all activities.
- The previous Standards said a “commercial interest could not control content.” The new Standards explicitly adds that the people who are owners or employees of ineligible companies cannot control content.
- The CME Employee/Owner COI Relationship form is being updated and will be circulated in September.
- These ACCME changes have allowed for a transition to a once-a-year disclosure process for internal AAP activities that utilize Planstone and will mirror the current Leadership disclosure collection processes.

New Process Note

- Individuals will disclose all financial relationships they have with ineligible companies, currently or within the last 24 months, one time annually for CME activities, eliminating the current process of disclosing for every activity or role.
- Since at the time of an annual disclosure call, individuals may not know the specific content areas in which they will be involved, they will no longer be asked to input the clinical/non-clinical topics they are speaking on when they disclose in Planstone. Activity managers will now supply this information for super users to enter in Planstone when setting up an activity.
- We have been working with Planstone, Dave Andrews and Stephanie Tait to ensure this process is efficient and effective. Resources, instructional documents, and training for staff are currently being drafted as we finalize our online disclosure system and scheduled to be circulated in September.

FAQ'S

Q: When will the new disclosure questions be available, updated in Planstone?

A: Release is tentatively scheduled for Oct 1, 2021.

Q: Is it possible to send the disclosure information and documents as soon as they are released since our system will need to be updated accordingly?

A: Yes, we will send out to all activity managers as soon as we have the Planstone disclosure questions and system finalized.

Q: Is the disclosure for 12 months at the time of launch or is it just when planning begins?

A: Disclosures should be collected as soon as you ask a person to participate and before the person starts their role in the activity. Each person should disclose all relationships they have with ineligible companies currently or within the last 24 months and all disclosed relationships should be reviewed and mitigated by Dr. Haftel prior to confirming that individual's participation. Remember, the purpose of the disclosure process is to determine if anyone involved in a CME activity has any financial relationships with industry that would disqualify them from participating in your activity. If they do, a replacement will need to be identified which is why it is best practice to have disclosure information collected at the time you invite an individual so any disclosed relationships can be reviewed, mitigated, and any associated issues resolved well in advance of you finalizing your agenda.

Q: Our team renews editors midway through the year and will be sending out disclosures soon, should we wait?

A: No, you should continue with current disclosure processes until the launch of new questions. Please note that at the time the annual call goes out in October, individuals involved with planning and delivering 2022 activities who have already disclosed will need to re-disclose to answer the new disclosure questions.

Q: Do authors have to re-disclose? They disclose at the beginning of their submission process, our team will need to submit a ticket to update their benchpress system.

A: All disclosure processes should continue as they have been until official word comes out that the new process will be starting (there will be education/training/docs created to facilitate this change). Some individuals may need to re-disclose, as that can't be avoided, but after this initial launch all users will only be doing 1 disclosure once a year so minimal disclosure work will be required after that point.

Q: Do faculty/planning group members need to redisclose if the project starts in fall of 2021?

A: Everyone will be asked to submit new disclosure information answering the new questions in Oct 2021 (tentative). Disclosure information using the new questions must be secured for all activities that launch in 2022, even if an individual already disclosed for the activity prior to Oct 2021. Individuals would not need to redisclose for an activity that already launched in fall 2021.

Q: Do PREP writers need to disclose before every meeting?

A: It is fine to ask individuals if they have any changes to their disclosure information at the start of your planning meetings. Prior to launch, activity managers should compile all disclosed relationships that are relevant to each person's role in your activity and share the information with learners before they start your activity.

Q: Can NCE Abstracts be excluded from this process? Not sure how this would be managed in this new process.

A: NCE disclosure processes should continue as is for now. Once all other activities have transitioned to the new annual collection process, discussions will occur to determine the specific needs for NCE.

Q: Will there be educational docs/info that will highlight the changes so that those disclosing will understand the updates?

A: Yes, we will be sharing educational documents with both our joint and direct providers as well as instruction to users who submit disclosures in Planstone.

Q: Will this resolve the issue of asking a person to disclose for all roles? Or will they still need to disclose all relationships for each individual role they are involved in?

A: A person who is serving in multiple roles should be attached to the CME activity for each role in which they are involved. Planstone will then only ask an individual to disclose once for all roles.

Q: Who will input the clinical/non-clinical topics in Planstone?

A: Activity manager will supply each super user with the topic information that needs to be entered in Planstone for each individual associated with the activity.

Q: How or where does the clinical/non-clinical topic get entered in Planstone by staff?

A: Super Users will enter this information for each person in the "Presentation Tab" within the Planstone System. Instructional documents will be supplied to staff detailing these steps.

Q: Can the system determine if there are duplicates?

A: No, the system cannot easily determine duplicates. There are filter options that can assist in this process, but Planstone does not have a feature that automatically informs you of any duplicates.

Q: Are we prohibited from using any Employees of ineligible companies in our CME activities?

A: ACCME prohibits employees/owners and scrutinizes these activities very closely so in practice this should not be a common occurrence but rather used in special case scenarios when no other individual is available to serve in that role. If this the case you must ensure the employee/owner is participating in 1 of the 3 special uses cases that our accreditor allows (technician, basic science, no relation to company product lines) and submit the CME Employee/Owner COI Relationship form.

Q: Will there be an updated COI Employee form?

A: The CME Employee/Owner COI Relationship form has been updated and will continue to be a required submission for any individual in your activity that discloses an employee/owner relationship. The spouse option has been deleted and it now asks staff to select the reason why a person with an employee/owner relationship is participating in the activity versus using a person without that type of relationship.

Q: Because we are no longer using the “off label discussion” question, is there a way we can include something in the grid to indicate that off label medications may be discussed?

A: A standard statement has been added to disclosure grid template: This activity may contain off-label discussion.

Q: Is it ALL relevant relationships w/ineligible companies ONLY or all relationships regardless of it being an ineligible company?

A: It's all relationships, regardless of relevancy, with ineligible companies only in the past 24 months.

Q: Is the 24 month look back for both leadership and CME? (Or is it just for CME?)

A: Now that we are merging both Leadership and CME questions, the first 5 disclosure questions will be for Leadership and ask for a 12 month look back. One additional CME question will ask for a 24 month look back.

Q: If all relationships with ineligible companies now need to be disclosed, who determines which relationships are applicable, or relevant, to my specific activity?

A: All individuals affecting content will disclose in Planstone and Dr Haftel will review to determine if there are any relevant relationships and document how they should be mitigated. As the activity manager you can add any comments regarding relevancy that you want her to consider in the notes section on the Disclosure Form in Planstone.

Recently disclosed relationships:

| Company Name | Role | Self/Family | Notes | |
|-----------------------------------------------------|----------|-------------|-------|-------------------------------------------------------------------------------------|
| As of 11/11/20, my spouse is employed by [redacted] | Employee | Family | |  |



Remember, it is very important to review all disclosure information prior to sending for Dr Haftel's review and ensure the educational topics and sufficient relationship details are included in the notes section so that Dr Haftel has enough information to conduct the review and select the appropriate mitigation strategy. Remember, any requests for additional information will delay completion of the review and mitigation process. It is the responsibility for each activity manager to ensure the mitigation strategy identified by Dr Haftel is implemented for each applicable individual.

Q: What if member has stock in Dairy Queen, will this need to be shown on the disclosure grid?

A: Typically, anything that is disclosed on the audit report will be shown on the grid. For those who control content, ACCME has clarified that we must disclose to learners all relevant financial relationships (as determined by Dr. Haftel) that they have with ineligible companies. If the DQ relationship is not relevant to their role in your activity it does not need to appear on the grid that is shared with learners.

Q: Does a Vanguard 401k need to be included in the disclosure?

A: Stocks and bonds, excluding mutual funds, need to be disclosed. You can ask the individual who submitted this relationship to clarify if Vanguard 401K is a mutual fund. If it is not, then it does not need to be disclosed.

Q: Do people need to update if they have a new relationship immediately or can they wait until the next disclosure period (next editorial board meeting)?

A: They should notify AAP staff immediately if their disclosure information changes. Prior to launch, activity managers should compile all disclosed relationships that are relevant to the individual's role in your activity and share the information with learners via the AAP disclosure grid before they start your activity.

Q: Will the leadership groups also be required to disclose for 24 months?

A: No leadership questions will continue to ask for 12 months, only the CME disclosure questions will ask for 24 months.

Q: Should anybody who could potentially be used as a one-off if something comes up. 24 months is kind of a lot to remember and look back at that far

A: Its best to include as many potential CME people in the 1st call that goes out annually asking everyone to disclose and just send individual requests to one-offs as they arise. 24 months is mandated by our accrediting agency so there is nothing we can do to change that, just advise people to remember as best they can

Q: If a person has already disclosed for AAP National and a joint is using that person, can they use the disclosure that AAP national has on file? Or do they need to collect a new disclosure?

A: Currently, each joint provider should collect their own disclosure via the AAP disclosure form. We are in process of determining potential ways to incorporate shared disclosures and will provide updates as we have more information.

Q: When is a company that is developing its first product considered to be an ineligible company?

A: A biomedical startup is considered an ineligible company if it has begun a governmental regulatory approval process. Drugs: The ACCME considers the submission of the Investigational New Drug Application (IND), which must be approved before clinical trials can begin, as the point of entry into the government regulatory approval process. Once a company makes this submission, it would be considered an ineligible company. Medical devices: When a company initiates a premarket approval (PMA) process submission it would then be considered an ineligible company.

Q: If an individual reports that they own stock in an ineligible company, how should the relationship be managed?

A: Individuals who may be in a position to control accredited continuing education are expected to disclose all their financial relationships with ineligible companies within the past 24 months to the AAP.

- Individuals who own stock (not through a mutual fund or pension plan) in privately held ineligible companies are considered owners or employees and therefore must be excluded from controlling content or participating as planners or faculty in accredited CE, unless they meet the exceptions for employees/owners.
- Individuals who own stock in publicly traded ineligible companies are not considered owners or employees. AAP is expected to determine if the relationship is relevant to the educational content. If so, we need to take steps to mitigate the relationship and disclose the relationship to learners.

Q: Are patent holders who receive royalty payments from ineligible companies considered to be owners of those companies?

A: No. Individuals who receive patent royalties from ineligible companies are not considered owners or employees of those companies. Those individuals may control content if the appropriate steps are taken. Individuals who may be in a position to control content are expected to disclose all their financial relationships with ineligible companies within the past 24 months to AAP, including royalty payments. You must then determine if the relationship, in this case, royalty payments, is relevant to the content. If so, take steps to mitigate the relationship and disclose the relationship to learners.

Q: If an individual reports that they have stock options with an ineligible company, how should we manage the relationship?

A: Individuals who may be in a position to control content are expected to disclose all their financial relationships with ineligible companies within the past 24 months to AAP, including contracts to purchase stock at an agreed-upon price (stock options). You are expected to determine if the relationship, in this case, stock options, is relevant to the educational content. If so, we need to take steps to mitigate the relationship and disclose the relationship to learners. Note: An individual who holds stock options in an ineligible company is not considered an owner or employee of that ineligible company.

Q: Do I need to collect new disclosure information for previously released enduring materials that will be available to learners after January 1, 2022?

A: No. You are not expected to comply with new disclosure requirements or obtain new disclosure information from those in control of content for a previously released activity, even if the activity is available to learners in 2022 or

beyond. Please note that the activity is subject to the Content Validity of Enduring Materials policy, so you must ensure that the content is still up-to-date and accurate at least every three years or earlier if the content warrants review.

Q: Can providers collect financial disclosures as we create the content for each activity or on a yearly basis?

A: You can choose whether to collect disclosure information when planning each activity or on a periodic basis, such as annually or biannually. If you choose to collect the information periodically, it is important to ask the person to update the disclosure if anything changes to ensure you have up-to-date, accurate information. Remember that you must collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months of their involvement with a CME activity.

Q: What is meant by a "format that can be verified at the time of accreditation"?

A: As part of the accreditation process, the ACCME will select a sample of CME activities to verify that learners received the appropriate disclosure information. Because the ACCME is not present at the time the disclosure occurs, we ask that you save documentation that will allow us to verify it took place – in whatever format disclosure is made. Specifically, we will want to verify that disclosure to learners included:

- a. The names of the individuals with relevant financial relationships.
- b. The names of the ineligible companies with which they have relationships.
- c. The nature of the relationships.
- d. A statement that all relevant financial relationships have been mitigated.

Q: Is it necessary to collect disclosure information on financial relationships from a speaker each and every time the speaker participates in a CME activity?

A: No. It is not necessary to collect disclosure information on relevant financial relationships from a speaker, planner, or author each and every time that individual has control over the content of a CME activity. The Standards require that we show the ACCME that everyone who has control of CME content has disclosed all relevant financial relationships with any commercial interest to AAP. Disclosure can occur by utilizing disclosure information from a database, previous CME activities, or another institution and then verifying that those relationships (or lack of relationships) are current and applicable to the applicable CME activity.

Q: What does the ACCME mean by nature of the relationship related to providing disclosure to learners in the Standards?

A: *Nature of the relationship* means the role they play or service they provide in exchange for some form of compensation from an ineligible company (e.g., independent contractor including contracted research, consulting, promotional speaking and teaching, membership on advisory committees or review panels and board membership). ACCME has not set a minimum dollar amount for relationships to be disclosed. Inherent in any amount is the incentive to maintain or increase the value of the relationship therefore the dollar value of the relationship does not need to be disclosed.

Q: Who are examples of "others" in control of content as described in the Standards?

A: The Standards state that AAP must "collect information from all planners, faculty, and others in control of educational content about all their financial relationships with ineligible companies within the prior 24 months." If someone in connection to the activity has the opportunity to affect the content, they are "in control of content." Those individuals in a position to control the content of an educational activity might include (but are not limited to):

| | | | |
|-------------------|-----------------------|------------------------------|-------------------|
| Planners | Faculty | Authors | Committee members |
| Content reviewers | Editors | Staff | Moderators |
| Panelists | Co-authors/presenters | Others involved with content | |

People sometimes make the mistake of only collecting information about financial relationships from faculty or authors but do not collect that information from others, such as committee members, who may be in control of content. This would be a cause of noncompliance.

Q: Can we leave it up to an individual who controls content to determine if his/her financial relationship is relevant and needs to be mitigated?

A: No, you cannot delegate the responsibility for identifying relevant financial relationship solely to the person with the financial relationship.

Q: Does the ACCME require a signed disclosure form as the means to demonstrate compliance with the Standards?

A: No. The ACCME does not require that we use a disclosure form to collect information about financial relationships of all persons in control of content of an educational activity. A disclosure form is one mechanism that can be used to obtain (and show that they possess) this information. Other examples could include collecting the information verbally and recording it in a spreadsheet, table, or database and collecting disclosure information electronically (for example, via e-mail, web-based form, or database). The ACCME requires AAP to obtain information about the financial relationships of all persons in control of content. The obtaining of this information is a key component of the process to ensure the independence of educational activities. ACCME allows providers to choose the mechanism(s) to obtain this information that best suits their organizational needs and can be used to demonstrate compliance to the ACCME.

Q: Do I need to use different approaches to mitigate relevant financial relationships for planners than I use for other persons in control of content, such as authors, speakers and reviewers?

A: Most likely, yes. Some mechanism(s) that are employed to mitigate relevant financial relationships for authors, speakers, and reviewers (e.g., peer-review of content) do not address the role(s) that planners have in controlling decisions that occur before content is developed for a CME activity. This influence may include choosing topics and faculty for the CME activity. To mitigate the relevant financial relationships of individuals involved in the planning of CME activities, we need to implement mechanisms that ensure independence in the planning process, itself, prior to the development of educational content and instruction.

Q: What is the ACCME's definition of an ineligible company?

A: Companies that are ineligible to be accredited in the ACCME System (ineligible companies). These are companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. Examples of such organizations include:

- Advertising, marketing, or communication firms whose clients are ineligible companies
- Bio-medical startups that have begun a governmental regulatory approval process
- Compounding pharmacies that manufacture proprietary compounds
- Device manufacturers or distributors
- Diagnostic labs that sell proprietary products
- Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
- Manufacturers of health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers or sellers

Q: Can faculty take an active role in the mechanism(s) to mitigate relevant financial relationships?

A: Yes. The ACCME considers faculty to be agents of the accredited provider. So, when AAP, after identifying that a financial relationship is relevant, directs teachers/authors to take actions to assist in the mitigation of relevant financial relationships (such as terminating the relationship with the ineligible company), then AAP's mitigation mechanism is implemented. You should then monitor the effectiveness of the actions taken by the teachers/authors to mitigate these relationships. Keep in mind that simply monitoring the CME content for commercial bias at the time of presentation is not an acceptable mitigation mechanism.

Q: Can we use tabs, links, or other electronic mechanisms to transmit disclosure information to learners?

A: Yes, it is acceptable to use tabs, links, or other electronic mechanisms to make disclosure information available to learners. Regardless of the method of disclosure, all required ACCME information specified in the Standards must be transmitted to the learner prior to the learner beginning the CME activity and should be clearly marked and accessible to learners. Please keep in mind that all other required CME language that appears in the verification requirements must still be automatically shown to all learners before they start the activity.

Q: For a journal-based CME activity, do I need to identify, mitigate, and disclose to learners the relevant financial relationships for the authors of the article?

A: No. If you are creating a journal-based CME activity, the ACCME does not expect you to identify, mitigate, and disclose to learners the relevant financial relationships of the article's authors and editors. That process is handled by the journal editors. Disclosure by authors is a standard component of published articles, and the editorial review process manages the mitigation of relevant financial relationships. The accredited provider does, however, need to identify, mitigate, and disclose relevant financial relationships for those involved in planning the journal-based CME activity, e.g., the person(s) choosing the article(s) and/or writing the evaluation mechanism. The ACCME has two expectations about the publication that issued the article:

- The publication cannot be owned by an ACCME-defined ineligible company.
- The publication must have in place a process that manages the disclosure of authors, editors, and peer reviewers involved in the process of reviewing and publishing the article. The process must be accepted within the scientific publication community. For example, the publication follows the International Committee of Medical Journal Editors' (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (<http://www.icmje.org/recommendations/>).

Q: Are stock options in a privately-held company considered an ownership stake?

A: No. If an individual has stock options with an ineligible company that have not been exercised, they do not yet have a financial relationship, nor would they be considered an "owner" of that ineligible company until or unless they exercise those options and the company is privately held.

Q: Can you provide some examples of when an individual would *not* be in control of content, and confirm when individuals *are* considered to be in control of content?

A: If an individual participates in any aspect of planning (identifying needs/gaps, selecting faculty, development or review of content, determination of evaluation mechanisms, etc.) that person is controlling content. A person who negotiates for hotel space, or virtual hosting, of an educational activity is likely not controlling content.

Please note that these are all new requirements so as further clarification is provided by our accreditor (ACCME), and more questions come in from staff, we will continually update this document.

UPDATED AAP CME DOCUMENTS

AAP is an accredited provider of the ACCME which enables us to award CME credits on our educational activities. ACCME released new updates to their CME activity requirements via their updated Standards for Integrity and Independence in Education which go into effect on January 1, 2022 and we have updated several of our CME documents and templates to address these changes as described below.

Please discard all previous versions of these documents that you may have housed in your files. Note: additional documents have been updated but are tailored to specific activities and will be provided with your approval notices. Moving forward please ensure you only use the documents provided with your approvals.

Abstract:

- Edited to reflect new terminology.
- Updated to reflect new disclosure requirements to secure ALL financial relationships not just relevant relationships, disclose all relationships within the past 24 months not 12 months, and removal of the requirement to collect disclosure information for spouse/partner.
- Updated to collect names of any external partners/collaborators associated with the activity.
- Updated to determine if the activity is addressing the Academy's Equity, Diversity and Inclusion Initiative.
- Updated to include new requirement for securing learner consent before sharing participants contact information and the new attachment that should be submitted to demonstrate compliance.
- Updated to include new requirement for 30-minute intervals between specific CME and non-CME components of an activity and the new attachments that should be submitted to demonstrate compliance.
- Updated to include the new attachment for any ads that are distributed within the activity to demonstrate compliance.

Extending an Activity Worksheet

- Edited to reflect new terminology.
- Updated with a new submission time frame of 30 days prior to activity end date (previously required submission for review and approval no later than 6 months prior to activity end). Please note this 30-day time frame as you will need to ensure you can address any feedback and upload updated disclosures and verification requirements to the activity before the start of the extension date.

Required CME Evaluation Questions:

- Updated to include a sample Learner Consent question. If you need to secure consent for an activity but are unable to collect it before or during an activity, you can ask this question during the eval process.

Exhibit and Ad Protocols

- Edited to reflect new terminology.
- Updated to include new requirement for securing learner consent before sharing participants contact information.
- Updated to include new requirement for 30-minute intervals between specific CME and non-CME components of an activity.

Slide Syllabus Requirements

- Edited to reflect new terminology.
- Edited to reflect minor updates to content validity.
- Updated to reflect new disclosure requirements.

Guidelines Intellectual Property Plagiarism Policy

- Edited to reflect new terminology.

Informational One-Pagers on Changes to ACCME Standards

- Created to clearly outline the new changes to the ACCME standards