

**Webinar Q&A Log**

*“Working Together to Successfully Transition to the Standards for Integrity and Independence in Accredited Continuing Education”  
October 28, 2021*

Question	Answer(s)
You can't share learner information with exhibitors without their consent? Is opting out sufficient?	This FAQ may be helpful: <a href="https://accme.org/faq/standard-2-what-meant-explicit-consent-learner">https://accme.org/faq/standard-2-what-meant-explicit-consent-learner</a>
(in regards to faculty or planner for multiple activities) if disclosures are up to 24 months, does that mean they are relevant for 2 years or will still need to be collected every year?	Per Standard 3.1, providers 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 an accredited CE activity. Providers can do this for each activity the person will be involved in, or they may collect the information on a periodic basis, such as annually, or biannually, if you so choose. If you choose to collect the information periodically, it will be important to ask the person to update you if anything changes during that time, or you might not collect all financial relationships.
Would this mean that I (the CE coordinator) would need to complete a financial disclosure for each program as well?	Yes. CE staff who are in a position to control the content of CE (including choosing topics, faculty, etc...) need to be included in the collection of all financial relationships for the past 24 mos.
I thought we were only capturing financial disclosures on Clinical Content - that we did not need to do this for non-clinical content (leadership classes)	That's correct. There are 3 exceptions where providers can skip "collecting, mitigating, disclosing". First is non-clinical content, second is when a learner group controls its own content, third is self-directed education (learning from teaching, remediation, personal development plan) for individuals.
Would PI-CME where physicians are doing their own chart reviews for their own performance/practice improvement be considered as self-directed learning, thus not needing a disclosure?	The facts and circumstances are important, as PI CME can address many different areas and be structured differently by different providers. In cases, for example, where the learner is directed to certain resources in Stage B, those individuals who developed or selected the resources would need to like go through a disclosure process, and would be considered in control of content. This is just one example.
Do we need to collect disclosures every 12 months that identifies any relationships within the past 24 months? Or can we just ask for disclosures every 24 months with all relationships in in that timeframe?	Per Standard 3.1, providers 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 an accredited CE activity. Providers can do this for each activity the person will be involved in, or they may collect the information on a periodic basis, such as annually, or biannually, if you so choose. If you choose to collect the information periodically, it will be important to ask the person to update you if anything changes during that time, or you might not collect all financial relationships.
If non-clinical - no matter what, we don't need to collect disclosures? What if speaker has books or products that are relevant to the content?	Per Standard 2, you would need to be sure that the person is not promoting or marketing their book or product, however, if the activity content meets one of the exceptions noted in Standard 3, there is no need to collect financial relationships, mitigate or disclose relationships.

<p>In what cases is Attestation sufficient? (Or if easier to address, in what cases is Attestation alone not sufficient?) We were under the impression that a faculty couldn't mitigate their own conflict, so isn't attestation effectively doing that?</p>	<p>Accredited providers are responsible for reviewing all financial relationships disclosed, assessing which are relevant, and then going through a mitigation process. Explicitly asking a person to attest to using only evidence based recommendations, and ensuring balance in their presentation is acceptable at this point in the process for people who are in the role of a speaker or a writer of CME content. This would NOT be an acceptable mechanism for a planner or reviewer or others who are involved in the development process of the activity.</p>
<p>For enduring materials that are being approved now that will be around longer than a year, will a new disclosures form be needed?</p>	<p>No. This FAQ may be helpful: Will I have to demonstrate compliance with the new Standards for activities planned prior to 2022 but not released or taking place until 2022? <a href="https://accme.org/faq/10236">https://accme.org/faq/10236</a></p>
<p>Can we get the templates from the tool kit, in a format that we can use so as to not have to re-create. You all did such a great job!</p>	<p>They are now available in WORD format on the website.</p>
<p>Did I hear that correctly, if someone that is employed by an ineligible company is speaking on a topic that is not related to their product or device are still able to serve as Faculty?</p>	<p>Yes. Standard 3.2 states: There are three exceptions to this exclusion—employees of ineligible companies can participate as planners or faculty in these specific situations:</p> <ul style="list-style-type: none"> <li>a. When the content of the activity is not related to the business lines or products of their employer/company.</li> <li>b. 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.</li> <li>c. When they are participating as technicians to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.</li> </ul>
<p>Specific question - a speaker has a provisional patent for a medical device and are in process of applying for a utility patent. They will have finalized an LLC company in the next few weeks but the device is not produced or licensed. Does this speaker qualify as an employee/owner of an ineligible company?</p>	<p>No. Owning a patent or receiving royalties for licensing a patent to an ineligible company would be considered a financial relationship that should be disclosed to provider and would not be considered an employee/owner of an ineligible company. If relevant, this type of relationship can be mitigated.</p>
<p>Do you have to offer an option to opt-in/opt-out if you don't even plan to work with commercial entities, meaning you will not be in a position to even share your learner's information with others?</p>	<p>No. The requirement is only in place if you are planning to share learner data with an ineligible company.</p>
<p>If an activity is clinical in nature and the topics may relate to products or business lines of ineligible companies but some of the talks are not clinical in nature and address leadership of communication skills, do we need to gather disclosure information for the non-clinical talks.</p>	<p>For the sections of a larger activity that meet the exceptions, you do not need to collect disclosure (as relevant financial relationships would be impossible). In the context of the larger activity, you are still required to disclose the absence of relevant financial relationships to learners in this hybrid sort of situation.</p>
<p>Would PI-CME where physicians are doing their own chart reviews for their own performance/practice improvement be considered as self-directed learning, thus not needing a disclosure?</p>	<p>Not always. For example in PI CME where the provider is directing the content, or developing or identifying the resources in PART B, there would be individuals who would be in control of content and subject to the requirement to disclose.</p>

<p>A F/U questions to the above, should the decision not to gather disclosure information be made during the planning process as per the older guidelines- unable to find at ACCME's website.</p>	<p>Yes. This would be part of your planning process BEFORE you start working with content/faculty. See Standard 3: <a href="https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-3-identify-mitigate-and-disclose-relevant-financial-relationships">https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-3-identify-mitigate-and-disclose-relevant-financial-relationships</a></p>
<p>If a financial relationship meets the three conditions for being relevant but has since ended at the time of disclosure, do we need to indicate in the disclosure to learner that the relationship ended or can we just disclose it as relevant without an indication that the relationship has currently ended?</p>	<p>If a relationship has ended, it is considered mitigated, and must still be disclosed to learners. You do not need to inform learners that the relationship has ended, nor do you need to disclose any other mitigation strategy. You are required to include a statement that all relevant financial relationships have been mitigated.</p>
<p>Thanks Steve, when you provide “learners in control of content” as an exception - you do not mean residents in training giving case based talks as part of an M&amp;M RSS ? correct? We understand that these residents in training are subject to the full disclosure and mitigation process.</p>	<p>In general, those individuals presenting their own cases during an RSS such as an M&amp;M, are considered learners, and would not be included in the process to identify, mitigate and disclose relevant financial relationships.</p>
<p>If our committee members view these courses can we get commendation credit for team viewing off-site course</p>	<p>YES. Participation in ACCME Academy can count toward the SUPPORTS THE CPD TEAM Commendation Criterion.</p>
<p>Do you need to have new disclosures signed for each event you host in a year. The templates shown on the website requires a date and title that are specific for an event.</p>	<p>Signatures (and forms, themselves) are not an ACCME requirement. What is required is that you COLLECT all financial relationships from everyone who may control content of the education — relationships with ineligible companies over the past 24 mos. For more information, see Standard 3. <a href="https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-3-identify-mitigate-and-disclose-relevant-financial-relationships">https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-3-identify-mitigate-and-disclose-relevant-financial-relationships</a></p>
<p>Are employees of insurance companies ineligible for a medical Coding course?</p>	<p>Insurance companies are likely NOT considered to be ineligible companies. See the examples of companies on the Eligibility page of the Standards: <a href="https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/eligibility">https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/eligibility</a></p>
<p>In cases where a relevant financial relationship was identified by a speaker, would having someone in the CE planning committee who has no relevant financial relationships to peer review content be an acceptable way to mitigate?</p>	<p>Yes.</p>
<p>Can speakers with no relevant financial relationships with an ineligible company insert logos of ineligible companies, brand names etc. as part of their talk? Speakers may do so to illustrate their points on their slides, e.g., showing a sample of a pacemaker with the company’s brand name as part of a talk on pacemakers.</p>	<p>The question you are asking is addressed by Standard 5, 2c. Product or corporate logos/slogans are not allowed in accredited education. <a href="https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-5-manage-ancillary-activities-offered-conjunction-accredited">https://www.accme.org/accreditation-rules/standards-for-integrity-independence-accredited-ce/standard-5-manage-ancillary-activities-offered-conjunction-accredited</a>. However, context is important. For example: we do not prohibit the <i>incidental</i> appearance of a logo in, for example, a demonstration of the implantation of a pacemaker. If you have further questions, please reach out to <a href="mailto:info@accme.org">info@accme.org</a>.</p>
<p>Is there going to be a new flow chart on mitigating conflicts?</p>	<p>We have developed a new PLANNING GUIDE that addresses mitigation processes and strategies. Available now at <a href="http://www.accme.org/standards-resources">http://www.accme.org/standards-resources</a>.</p>