



TRAINING FOR VIVA REPRESENTATIVE FOR LIVE IN-PERSON CE EVENTS

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STANDARD V. COMMERCIAL OR PROMOTIONAL CONFLICT OF INTEREST

In 1997 the U.S. Food and Drug Administration (FDA) issued a policy statement entitled “Guidance for Industry: Industry Supported Scientific and Educational Activities.” This policy states that activities designed to market or promote the products of a commercial company (staffed exhibits, live presentations, advertisements, sales activities) are subject to FDA regulation under the labeling and advertising provisions of the Federal Food, Drug and Cosmetic Act.

Activities that are independent of commercial influence and non-promotional are not subject to FDA regulation. In this context, the ADA CERP standards and criteria are designed to ensure separation of promotional activities from continuing dental education (CE) activities in the following ways: 1) Viva Learning Representative must demonstrate that all educational activities offered are independent of commercial influence, either direct or indirect, and 2) Viva Learning Representative must ensure that all financial relationships between the provider and commercial entities, as well as all financial relationships between course planners and faculty and commercial entities are fully disclosed to participants.

CRITERIA

1. Viva Learning Representative must assume responsibility for ensuring the content quality and scientific integrity of all continuing dental education activities. Educational objectives, content development, and selection of educational methods and instructors must be conducted independent of commercial interest.

Presenter slides must be submitted for review by Viva Learning no later than 8 days prior to live event. One slide must outline the learning objectives of the lecture.

2. Viva Learning Representative must ensure that continuing dental education activities promote improvements in oral healthcare and not a specific drug, device, service or technique of a commercial interest.*

Presenter content must be scientifically based and not based on a specific device, product or drug - 'infomercials' will not be accepted as CE worthy.

3. Product-promotion material or product-specific advertisement of any type is prohibited in or during continuing dental education activities. Live promotional activities (staffed exhibits, presentations) or enduring promotional activities (print or electronic advertisements) must be kept separate from CE. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided during CE activities.*

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This is the MOST IMPORTANT criteria that the ADA will scrutinize. It is very important that NO promotional or commercial material is on the SCREEN. No brochures on tables inside the classroom and no posterboards, electronic screens or visual signs of any commercial products are allowed, inside the classroom.

a. For live, face-to-face CE, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CE activity. Providers cannot allow representatives of commercial interests to engage in sales or promotional activities while in the space or place of the CE activity.

If there are any sales people on staff to help staff the CE activity, they cannot be engaged in active sales directly outside (especially inside) the classroom. They can provide information, but active sales is strictly prohibited.

b. For print CE activities, advertisements and promotional materials will not be interleaved within the pages of the CE content. Advertisements and promotional materials may face the first or last pages of printed CE content as long as these materials are not related to the CE content they face and are not paid for by the commercial supporters of the CE activity.

This should be self-explanatory; any ads or promotional material must only appear on the first and last pages of the printed CE material, and CANNOT be from the commercial entity supporting the material. You may say that the CE content has been provided with the commercial support of _____ company.

c. For electronically mediated/computer based CE activities, advertisements and promotional materials will not be visible on the screen at the same time as the CE content and not interleaved between computer 'windows' or screens of the CE content

If CE is provided online, promotional material/ads cannot appear on the same screen as the CE content. Viva Learning already complies with this requirement on our website.

d. For audio and video based CE activities, advertisements and promotional materials will not be included within the CE. There will be no 'commercial breaks.'

e. Educational materials that are part of a CE activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

f. Print or electronic information distributed about the non- CE elements of a CE activity that are not directly related to the transfer of education to the learner, such as schedules and content descriptions, may include product promotion material or product-specific advertisement.

4. Viva Learning Representative must ensure that activities designed to promote drugs, devices, services or techniques must clearly disclose the promotional nature of the activity in publicity materials and in the activity itself. Promotional activities must not be designated for CE credit. The CE hours awarded



must not include the promotional hours. * Adapted from the Accreditation Council for Continuing Medical Education Standards for Commercial Support. ADA CERP Recognition Standards | 7

Any promotional content/training that promotes a commercial product/device is considered Product Training and not eligible for CE Credit.

5. Viva Learning Representative must operate in accordance with written guidelines and policies that clearly place the responsibility for program content and instructor/author selection on the provider. These guidelines must not conflict with ADA CERP standards and criteria for recognition. **Each CE learning experience offered must conform to this policy.**

6. The ultimate decision regarding funding arrangements for continuing dental education activities must be the responsibility of the CE provider. Continuing dental education activities may be supported by funds received from external sources if such funds are unrestricted. External funding must be disclosed to participants in announcements, brochures or other educational materials, and in the presentation itself.

If Viva Learning receives funds and/or product for demonstration purposes, these are considered as 'commercial support,' which is allowed, as long as it is 'unrestricted' meaning that Viva Learning alone decides how to use the funds/products without influence from the supporter.

7. **All marketing material (digital and print) of the CE event must be approved by Viva Learning prior to being sent out to prospective participants. VERY IMPORTANT! The Viva Learning logo can only be used after Viva Learning approves the final draft version.**

8. Arrangements for commercial exhibits or advertisements must not influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CE activities.*

9. Viva Learning Representative must disclose to participants any monetary or other special interest the provider may have with any company whose products are discussed in its CE activities. Disclosure must be made in publicity materials and at the beginning of the educational activity.

If the CE Activity is being 'supported' by a company, it must be disclosed verbally by the lecturer at the beginning of the lecture. This is typically done by the lecturer saying 'Today's CE lecture is generously supported by ____ company, so we thank them for their support.' The first slide must include this disclosure as well.

10. Viva Learning Representative must ensure that a balanced view of all therapeutic options is presented in CE activities. Whenever possible, generic names must be used to contribute to the impartiality of the program presented.

This is a very important point - if one product is mentioned, several should be mentioned, to offer other therapeutic options. Generic names are always preferred to product names.



11. Viva Learning Representative must assume responsibility for the specific content and use of instructional materials that are prepared with outside financial support.

Again, all CE content and presenter slides must be submitted no later than 8 days in advance of the lecture for review by Viva Learning.

12. Viva Learning Representative must assume responsibility for taking steps to protect against and/or disclose any conflict of interest of the lecturers. Signed commercial disclosure statements must be obtained from lecturers.

Viva Learning must have signed statements of Commercial Disclosure from the lecturer prior to the lecture.

13. The Viva Learning Advisory Committee is in-house and is not involved with the on-site delivery of the CE lecture the day-of. All preparations will be made in advance of the lecture.

14. Lecturers must disclose to participants in CE activities any relevant financial relationships that the planners and instructors/authors of a continuing education activity may have that may create conflicts of interest. Disclosure must include the name of the individual, the name of the commercial interest, and the nature of the relationship the individual has with each commercial interest. Disclosure must not include the use of a trade name or product message. For individuals that have no relevant financial relationships, the provider must disclose to participants that no relevant relationships exist. Disclosure must be made before the start of the continuing education activity and must be made in writing, either in publicity materials, course materials, or audiovisual materials.

If the lecturer received compensation from the company supporting the CE lecture, the lecturer must disclose that 'I am a consultant for _____ company, which is providing support for today's CE lecture' or something equivalent to that effect. In addition, we should have his/her signed forms prior to the live event. If there is any printed CE material to be given out in addition to the lecture, that should include the disclosure as well.

RECOMMENDATIONS

A. The following are examples of outside or commercial support that is customary and proper: • Payment of reasonable honoraria • Reimbursement of out-of-pocket expenses for instructors/authors • Modest meals or social events held as part of the educational activity

B. The CE provider and the commercial supporter or other relevant parties should each report to the other on the expenditure of funds each has provided, following each subsidized continuing dental education activity. * Adapted from the Accreditation Council for Continuing Medical Education Standards for Commercial Support.