

**ADA CERP
STANDARD V. COMMERCIAL OR PROMOTIONAL
CONFLICT OF INTEREST**

EXAMPLES OF POLICES AND FORMS

This document includes generic examples of documents related to ADA CERP Recognition Standard V. The Commission for Continuing Education Provider Recognition offers these examples as resources for providers of continuing dental education. Providers may adapt these documents to the specific requirements of their individual programs.

Examples provided:

- CE provider policy for commercial support and conflict of interest
- Letter of agreement for commercial support of a CE activity
- Conflict of interest declaration form for instructors
- Published disclosure of commercial support
- Published disclosure of instructors' and planners' relevant financial relationships

Providers are not required to use these exact documents. Use of these documents will not guarantee that a program will be found in compliance with Standard V.

ADA CERP RECOGNITION STANDARDS AND PROCEDURES (Excerpt)

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 (CDE) activities in the following ways: 1) CDE providers must demonstrate that all educational activities offered are independent of commercial influence, either direct or indirect, and 2) CDE providers 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. CDE providers 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.
2. CDE providers must ensure that continuing dental education activities promote improvements in oral healthcare and not a specific drug, device, service or technique of a commercial entity.*
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 CDE. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided during CDE activities.*
 - a. For live, face-to-face CDE, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CDE activity. Providers cannot allow representatives of commercial interests to engage in sales or promotional activities while in the space or place of the CDE activity.
 - b. For print CDE activities, advertisements and promotional materials will not be interleaved within the pages of the CDE content. Advertisements and promotional materials may face the first or last pages of printed CDE content as long as these materials are not related to the CDE content they face and are not paid for by the commercial supporters of the CDE activity.
 - c. For electronically mediated/computer based CDE activities, advertisements and promotional materials will not be visible on the screen at the same time as the CDE content and not interleaved between computer ‘windows’ or screens of the CDE content
 - d. For audio and video-based CDE activities, advertisements and promotional materials will not be included within the CDE. There will be no ‘commercial breaks.’
 - e. Educational materials that are part of a CDE 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- CDE elements of a CDE 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.

** Adapted from the Accreditation Council for Continuing Medical Education Standards for Commercial Support.*

4. CDE providers that also offer 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 CDE credit. The CDE hours awarded must not include the promotional hours.
5. CDE providers 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 CDE 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 CDE 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.
7. CDE providers receiving commercial support must develop and apply a written statement or letter of agreement outlining the terms and conditions of the arrangement and/or relationship between the provider and the commercial supporter.
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 CDE activities.*
9. CDE providers must disclose to participants any monetary or other special interest the provider may have with any company whose products are discussed in its CDE activities. Disclosure must be made in publicity materials and at the beginning of the educational activity.
10. CDE providers must ensure that a balanced view of all therapeutic options is presented in CDE activities. Whenever possible, generic names must be used to contribute to the impartiality of the program presented.
11. CDE providers must assume responsibility for the specific content and use of instructional materials that are prepared with outside financial support.
12. CDE providers must assume responsibility for taking steps to protect against and/or disclose any conflict of interest of the advisory committee, CDE activity planners, course directors and instructors/authors involved in planning or presenting courses. Signed conflict of interest statements must be obtained from all advisory committee members, CDE activity planners, course directors and instructors/authors.
13. The advisory committee must be involved in evaluating and taking steps to protect against conflicts of interest that CDE activity planners, course directors and instructors/authors may have.
14. Providers must disclose to participants in CDE 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 entity, and the nature of the relationship the individual has with each commercial entity. 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.

** Adapted from the Accreditation Council for Continuing Medical Education Standards for Commercial Support.*

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 CDE 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.

XXXXX [Name of CE Provider]
**Guidelines Regarding Management of Commercial Support and Commercial Conflicts of Interest
in CE Activities**

XXXXX, in planning continuing education activities, will adhere to the following policies, in accordance with ADA CERP Recognition Standards and Procedures:

1. XXXXX shall be responsible for the content, quality, and scientific integrity of all CDE activities.
2. XXXXX shall be responsible for selecting instructors/authors for CDE activities.
3. Program topic selection will be based on perceived needs for professional information and not for the purpose of endorsing specific commercial drugs, materials, products, treatments, or services.

XXXXX shall:

4. Assure that presentations give a balanced view of all therapeutic options.
5. Assure that commercial exhibits do not influence planning nor interfere with the presentation of CDE activities.
6. Prohibit any product-promotion material or product-specific advertisement of any type in or during continuing dental education activities:
 - a. For live activities, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CDE activity; representatives of commercial interests may not engage in sales or promotional activities while in the space or place of the CDE activity.
 - b. For print CDE activities, advertisements and promotional materials will not be interleaved within the pages of the CDE content. Advertisements and promotional materials may face the first or last pages of printed CDE content as long as these materials are not related to the CDE content they face and are not paid for by the commercial supporters of the CDE activity.
 - c. For electronically mediated/computer based CDE activities, advertisements and promotional materials will not be visible on the screen at the same time as the CDE content and not interleaved between computer 'windows' or screens of the CDE content
 - d. For audio and video-based CDE activities, advertisements and promotional materials will not be included within the CDE. There will be no 'commercial breaks.'
 - e. Educational materials that are part of a CDE 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- CDE elements of a CDE 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.
7. Be responsible for making ultimate decisions regarding funding arrangements for CDE activities.
8. Assure that commercially supported social events at CDE activities do not compete with, nor take precedence over, the educational events.
9. Instruct presenters/authors to avoid recommending or mentioning commercial products by trade name, using generic terms whenever possible. When reference is made to a specific product by its trade name, reference shall also be made to competitive products.
10. Require course planners, instructors/authors to disclose in writing any financial relationships that they or their immediate family members may have had with commercial companies in any amount occurring in the last 12 months that are relevant to the content of the CDE activity.
11. Publish planners' and instructors' relevant financial relationships in course materials available to participants before the start of the CDE activity.

Commercial support

12. Funds received from commercial sources in support of any educational programs shall be unrestricted and XXXXX shall retain exclusive rights regarding the selection of presenters, instructional materials, program content and format, etc.
 - a. Commercial support accepted by XXXXX for any CE activity shall only be used for:
 - b. the payment of reasonable honoraria and expenses to instructors; the payment of the cost of modest meals or social events held as part of an educational activity; or
 - c. educational materials, such as equipment or supplies for hands-on courses.
13. Commercial support of CE activities must be given by the supporter/sponsor to XXXXX; the supporting company may not make payments directly to any speaker in a CE activity.
14. Any and all commercial support received shall be acknowledged in program announcements, brochures, and the on-site program book.

XXXXX [Name of CE Provider]

LETTER OF AGREEMENT FOR COMMERCIAL SUPPORT OF CONTINUING EDUCATION ACTIVITIES

Regarding Terms, Conditions and Purposes of an Educational Grant between _____ (Provider), an ADA CERP approved provider of continuing dental education, and _____ (Company providing commercial support) for support of a continuing dental education (CDE) activity.

Title of CDE Activity: _____

Location: _____ Date(s) _____

Company (Commercial Supporter): _____

Contact Person: _____

Title: _____

Address: _____

Telephone: _____ Fax: _____ E-mail: _____

The above company wishes to provide support for the continuing education activity named above by means of (indicate which option):

- 1. Unrestricted educational grant in the amount of: \$ _____
2. Support for catering functions in the amount of: \$ _____
3. In-kind support (e.g., donation or loan of equipment, supplies, etc.)

CONDITIONS

- 1. Statement of Purpose: program is for scientific and educational purposes only and will not promote the Company's products, directly or indirectly.
2. Control of Content and Selection of Presenters and Moderators: The Provider is solely responsible for selection of course content, instructors and moderators based on their qualifications, independence and balance. The Company will not suggest speakers or direct the content of the program.
3. Disclosure of Financial Relationships: The Provider will ensure meaningful disclosure to the audience at the time of the program, of (a) Company funding and (b) any significant relationship between the Provider and the Company (e.g., grant recipient).
4. Involvement in Content: there will be no "scripting", emphasis, or direction of content by the Company or its agents.
5. Ancillary Promotional Activities: No promotional activities will be permitted in the same room as the educational activity. No product advertisements will be permitted in the same room as the educational activity.

6. Objectivity and Balance: The Provider will make every effort to ensure that data regarding the Company's products (or competing products) are objectively selected and presented, with favorable and unfavorable information and balanced discussion of prevailing information in the product(s) and/or alternative treatments.
7. Limitations on Data: The Provider will ensure, to the extent possible, meaningful disclosure of limitations on data, e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.
8. Opportunities for Debate: The Provider will ensure meaningful opportunities for questioning or scientific debate.
9. Independence of the Provider in the use of Contributed Funds:
 - a. funds are to be in the form of an educational grant made payable to XXXXX;
 - b. all other support associated with this CE activity (e.g., educational materials, course supplies, etc.) must be given with the full knowledge and approval of XXXXX;
 - c. no funds from the company will be paid directly to the program director, instructor/author, or others involved with the CE activity.
10. The Provider and the Company agree to abide by all the requirements of the ADA CERP Recognition Standards.
11. The Provider shall acknowledge educational support from the Company in program brochures, syllabi, and other program materials
12. Upon request, the Provider shall furnish the Company with a report concerning the expenditure of the funds provided.

AGREED

Company Name: _____

Company Representative: _____

Company Address: _____

Signature: _____ Date: _____

CE Provider Name: _____

CE Provider Representative: _____

CE Provider Address: _____

Signature: _____ Date: _____

EXAMPLE OF DISCLOSURE FORM

[Name of CE Provider]

DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS AND CONFLICTS OF INTEREST

Relevant Financial Relationships

For a person involved in the planning, administering or presentation of a continuing dental education activity, ADA CERP considers relevant financial relationships to be financial relationships in any amount, occurring in the last 12 months, that are relevant to the content of the CDE activity and that may create a conflict of interest. ADA CERP considers relevant financial relationships of the person involved in the CDE activity to include financial relationships of a family member. **Relevant financial relationships must be disclosed to participants in CDE activities *in writing*.**

Conflicts of interest

ADA CERP considers that a conflict of interest may exist when an individual has an opportunity to affect the content of continuing dental education activities regarding products or services of a commercial interest with which he/she has a financial relationship.

DISCLOSURE: [Provider name] requires those in a position to control the content of a CE activity to disclose any financial relationships (including those of immediate family members) within the last 12 months that are relevant to this educational activity. [Provider name] will evaluate this information for conflicts of interest and may, at its discretion, make changes to the CE activity to reduce the possibility for conflict of interest. Failure to disclose or a false disclosure will require [Provider Name] to remove you from the program and to identify a replacement for your participation.

Check one box below and complete as appropriate:

I, the undersigned, declare that neither I nor any member of my family have a financial arrangement or affiliation with any corporate organization offering financial support or grant monies for this continuing dental education program, nor do I have a financial interest in any commercial product(s) or service(s) I will discuss in the presentation.

OR

I, the undersigned, (or an immediate family member), have a financial interest/arrangement or affiliation with the corporate organization offering financial support or grant monies for this continuing dental education program, or I do have a financial interest in any commercial product(s) or services I will discuss in the presentation.

Financial Relationship

Company Name

Grants/research support

Consultant

Stock Shareholder

Governance

Honorarium

Employee

Other financial or material support

Describe nature of relationship:

Name (printed)

Signature

Date

DISCLOSURE OF COMMERCIAL SUPPORT TO THE CE PROVIDER—EXAMPLES

Standard V.6

The ultimate decision regarding funding arrangements for continuing dental education activities must be the responsibility of the CDE 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 the CE provider accepts support from a commercial company for a CE activity, it must disclose this to the participants of the activity. Disclosure of commercial support may be published in course brochures, program guides, signs, introductory slides, etc. Disclosure must include the name of the company and may include the company logo. Disclosure should *not* include product names or product group messages.

EXAMPLE 1.

[Name of provider] gratefully acknowledges the generous support of XYZ Company.

EXAMPLE 2.

Support for this activity provided by the XYZ Company.

EXAMPLE 3.

*[Name of provider] wishes to thank the following companies
for their generous support of this program:*

Note: Paid advertising, such as sales of pages in a program book, or display banners, for example, are not considered commercial support. Guidelines for managing advertising in association with CE activities are discussed in Standard V.3.

Similarly, exhibit booths where companies pay a flat fee to exhibit their products in a booth or a table top display (in a separate space from the CE activity), are not considered commercial support. These should be considered separate advertising or marketing opportunities, and should not influence the planning, content, or presentation of CE activities. Guidelines for managing exhibits are discussed in Standards V.3 and 8.

PUBLISHED DISCLOSURE OF PLANNERS' AND INSTRUCTORS' RELEVANT FINANCIAL RELATIONSHIPS

Standard V.14

Providers must disclose to participants in CDE 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 entity, and the nature of the relationship the individual has with each commercial entity. 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.

RELEVANT FINANCIAL RELATIONSHIPS: For a person involved in the planning, administering or presentation of a continuing dental education activity, relevant financial relationships are financial relationships in any amount, occurring in the last 12 months, that are relevant to the content of the CDE activity and that may create a conflict of interest. ADA CERP considers relevant financial relationships of the person involved in the CDE activity to include financial relationships of a family member. Relevant financial relationships must be disclosed to participants in CDE activities.

--CERP Glossary

CE providers must also publish information on any relevant financial relationships that **individual instructors and CE planners** may have. This is **in addition** to disclosure of any commercial support the CE provider has received. This information is usually gathered from the Disclosure of Conflicts of Interest forms that providers collect from instructors and planners.

Disclosure must be published *in writing* before the start of the CE activity. Possible options for publishing disclosure information include:

- Course handouts
- Program guides
- Course brochures and catalogues
- Introductory presentation slides

Disclosure must include:

1. Speaker/planner name
2. Name of company
3. Nature of relationship

Disclosure *must not* include:

- Product name or product message

PUBLISHED DISCLOSURE OF RELEVANT FINANCIAL RELATIONSHIPS—EXAMPLES

The following are provided as a few possible examples of disclosures that comply with the ADA CERP requirements for publishing disclosures of relevant financial relationships.

EXAMPLE 1: Published list (course handout, program guide, course catalogue, etc.)

Disclosure of Relevant Financial Relationships

Instructors

Dr. John Smith: *No relevant financial relationships to disclose.*

Dr. Mary Brown: *Research grants from XYZ Company; consultant fees from ABC Corp; speaker fees from Widget Manufacturing.*

CE Planning Committee

Members of the CE planning committee have no relevant financial relationships to disclose.

EXAMPLE 2: Speaker bio (course brochure, program book, course catalogue, handout, etc.)

Dr. John Smith is associate professor in the department of periodontology at State University. Dr. Smith earned his dental degree from ABC University School of Dentistry and completed his residency in periodontology at XYZ University.

Dr. Smith has no financial relationships relevant to this presentation to disclose.

EXAMPLE 3: Introductory presentation slides

John Smith, DDS
Associate professor, periodontology
State University

Financial disclosure: Paid consultant for XYZ Company

Mary Brown, DMD
Neither I nor members of my immediate family have any financial interests to disclose relating to the content of this presentation.