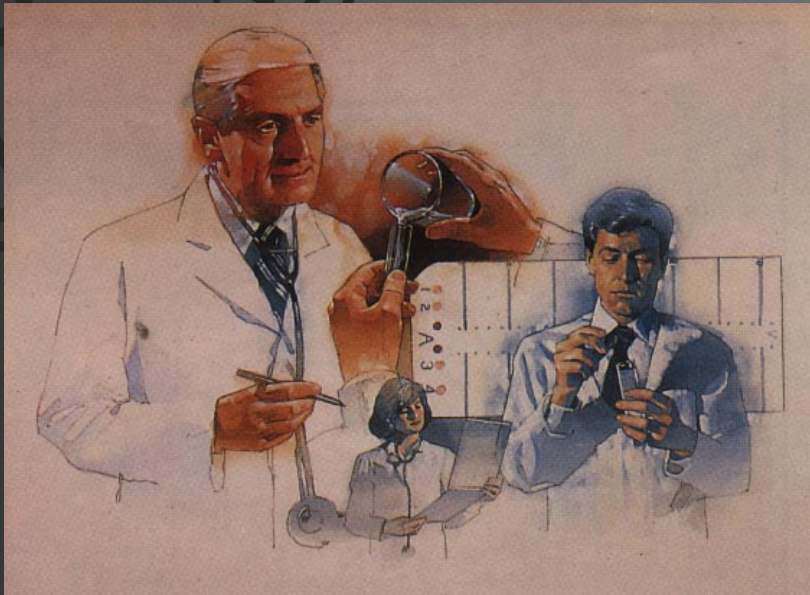


American Medical Association
Physicians dedicated to the health of America



**Standards for Industry-Supported
Multimedia Continuing Medical
Education and Other Communications**

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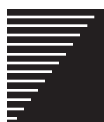


Standards for Industry-Supported Multimedia Continuing Medical Education and Other Communications

Approved by AMA Continuing
Medical Education Program
Committee, May 1, 1995

Approved by AMA CME Advisory
Committee, May 6, 1995

Revised September, 1999



Standards for Industry-Supported Multimedia CME And Other Communications

It is the goal of the American Medical Association to be the medical profession's leading force in pioneering solutions, knowledge and tools that promote health. Through our projects, programs and activities, the AMA pursues being the world's leader in obtaining, synthesizing, integrating and disseminating information on health and medical practice, as the most authoritative voice and influential advocate for physicians and their patients.

With educational grant support from industry, the AMA Division of Industry-Supported Communications develops and distributes multimedia professional education programs, including continuing medical education programs and physician-directed patient education programs, that address both general and specific health education topics. The AMA applies the highest professional standards and rigorous peer review in the development of these programs and in so doing, strengthens the physician-patient relationship.

The guiding principle in this endeavor is to assure physicians that AMA educational materials and other communications are: 1) independent and free of commercial bias; 2) as scientifically accurate and reliable as possible at the time of their release; 3) rigorously peer reviewed; 4) reflect the current available clinical guidelines and opinions; and 5) ultimately beneficial to individual patients and to the public at large.

◆◆◆◆ Description of Product

The AMA, as the leader in professional education and medical publications, is uniquely positioned to develop national physician and patient education programs. These AMA multimedia programs address the entire continuum of medical education and foster improved communication of all health-related information. These multimedia programs also serve to effectively communicate important medical information to physicians and other appropriate audiences, in a manner consistent with the high standards of scientific quality and ethics for which AMA products are known. In addition to print formats, these programs are also presented in a variety of additional formats, including electronic, interactive programs on the world wide web and CD-ROMs, that help insure usage by the appropriate audience. These products are produced, reviewed, and controlled by the AMA. Their development and distribution is supported through grants from one or more commercial supporters.

These standards apply to enduring CME materials, as well as other professional education or communication materials, developed by the AMA. The standards define the relationship between the AMA and the commercial supporter in the development of the material.

■■■■ **Corporate Support Standards**

All programs must comply with the AMA Principles for Corporate Relationships, and the ACCME Standards for Commercial Support of Continuing Medical Education. Commercial supporters must respect the physician's professional obligation to adhere to the AMA ethical guidelines on gifts to physicians and on continuing medical education.

■■■■ **Editorial Control**

The American Medical Association has full control over the planning and context of the program, and over the selection of advisors, contributors, and reviewers. Although AMA has control of the design, content, development, and implementation of such programs, commercial supporters are allowed to review programs to ensure their compliance with federal regulations. AMA editorial control ensures that all programs present a balanced view of therapeutic options. If tradenames are used, those of several companies will be used, rather than only that of a single supporting company. An

AMA program may include a discussion of an unlabeled use of a drug, but such a discussion will clearly indicate the unlabeled or investigational status of the drug. The AMA has complete authority to oversee, review, and accept or reject all projects at any point in the process. While not all AMA multimedia communications are certified for CME (eg, a print or web-based self-study program may be certified, while a physician newsletter may not), all AMA multimedia programs are developed in accordance with both AMA Standards and Ethical Opinions, and the Accreditation Council for Continuing Medical Education (ACCME) Essentials and Standards, and AMA Principles for Corporate Relationships. Upon request, commercial supporters may provide relevant reference works from peer-reviewed scientific journals to assist in program development, but shall not engage in scripting, targeting points for emphasis, or other actions designed to influence the content of the activity. The commercial supporter may recommend faculty for AMA programs, but the ultimate decision resides with the AMA.

◆◆◆◆ Written agreement

A letter-of-agreement between the AMA and the commercial supporter is required that acknowledges that support is received in the form of an educational grant and, that the AMA is solely responsible for the planning and development of the program content. The commercial supporter is acknowledged on all materials as having provided the grant. No mention can be made to a specific product as part of this acknowledgment.

◆◆◆◆ Acknowledgement of Commercial Support

The source of financial support must be clearly acknowledged on all programs. This is specified in the letter-of-agreement, but may include acknowledgement:

- In the front matter of print programs and on web start-up screens.
- At the end of the educational materials.
- In all materials used to promote or build awareness of this program.

◆◆◆◆ Structure of Grant and Use of Funds

Funds from a commercial source should be in the form of an educational grant made payable to the AMA for the support of the program. Commercial supporters cannot, independently, provide any additional funding to the faculty or others involved in an AMA program.

◆◆◆◆ Disclosure

AMA CME programs and other scientific communications are authored by physicians and other experts who are selected by the AMA on the basis of their knowledge of the subject. The collegiality of reliable scientific communications entails full, open exchange of information about a program and its history. The AMA will ensure the disclosure of any conflict of interest, or other relationship between the program faculty and the commercial supporter, and any other commercial entity.

◆◆◆◆ Conduct of Commercial Supporter

The AMA must authorize dissemination of information about this activity by the commercial supporter, and any information must identify the activity as produced by the AMA. The AMA must approve the method of distribution (eg, direct mail, phone, business reply card, sales representative, or other) of the AMA materials to ensure that it is consistent with the educational purpose of the program.

◆◆◆◆ AMA Certified CME Programs

In addition to the previously stated standards for commercial support, the following additional standards must be observed for AMA certified CME programs:

- **AMA PRA Category 1 Credit:** All programs must comply with the basic requirements of the AMA PRA; enduring or self-study materials must meet the criteria for AMA PRA Category 1 enduring materials.
- **Restrictions:** These materials are intended to be educational and the commercial supporter cannot use AMA educational materials for promotional purposes.

**REVIEW PROCESS AND PROCEDURES
OVERVIEW FOR AMA MULTIMEDIA CME
AND OTHER COMMUNICATIONS**

- ▶ A potential topic/program is identified as being of possible interest.
- ▶ The AMA Healthcare Education Products and Standards (HEP) Group conducts an educational needs assessment on the topic of the proposed program.
- ▶ The AMA HEP Group assesses the type of media to be involved, program costs and possible sources of funding.
- ▶ For CME programs, the AMA HEP Group and the AMA Program Committee for CME, review and approve potential topic areas. As deemed necessary, the AMA HEP Group may consult with experts on the subject and media used.
- ▶ When a potential product is approved, the AMA HEP Group prepares a proposal describing the specific program and the development process is prepared and presented to the potential supporting company. Copies of these standards are also reviewed and provided during this presentation. Concurrently, an AMA corporate profile is prepared and submitted to the AMA Corporate Relations Task Force for approval.

- ▶ Commercial supporter agrees to fund project. A letter-of-agreement is prepared by the AMA that specifies the terms, conditions, method(s) of distribution, and purpose of the program, and is forwarded to the commercial supporter for signature and execution.
- ▶ The AMA HEP Group identifies a project editor, who submits signed disclosure/conflict of interest statements.
- ▶ Project editor/author, using all necessary experts and literature reviews/searches, is responsible for the preparation of the program content. The project editor/author is provided necessary guidelines including program specifications, time lines, AMA standards and ACCME guidelines, and information on the critical review process.
- ▶ The AMA HEP Group selects appropriate peer reviewers to assess quality, balance, etc. The material is sent to the reviewers with appropriate instructions and necessary assessment forms. Upon return, concerns are communicated to the project editor/author and addressed. If necessary, additional reviewers may be used and additional critical reviews of the materials at other stages of the development process may be conducted.
- ▶ The AMA HEP Group reviews all material to assure scientific quality and balance.

- ▶ Following certification of the program content by the AMA CME Program Committee, the material is forwarded for production.
- ▶ The material is produced and distributed in accordance with the letter-of-agreement. Any other material included or affixed (eg, special packaging) must receive advance written approval by the AMA.

◆◆◆◆ ADDITIONAL CONDITIONS

◆◆◆◆ Ownership of Copyright

Materials published by the AMA are copyrighted by the AMA which retains the rights therein. Materials remain the property of the AMA and may not be reproduced in any form without written permission from the AMA.

◆◆◆◆ Permissions

The AMA is responsible for securing all necessary permissions to reprint illustrations, tables, etc. The material will not be reprinted or republished if the author and/or publisher object.

◆◆◆◆ Advertising

Advertising is not permitted in AMA printed or web-based CME programs or associated patient education materials. Any material produced by the commercial

supporter or their agencies that advertises this material or is used to educate physicians or the public regarding the material produced must be approved by the AMA at its sole discretion.



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