

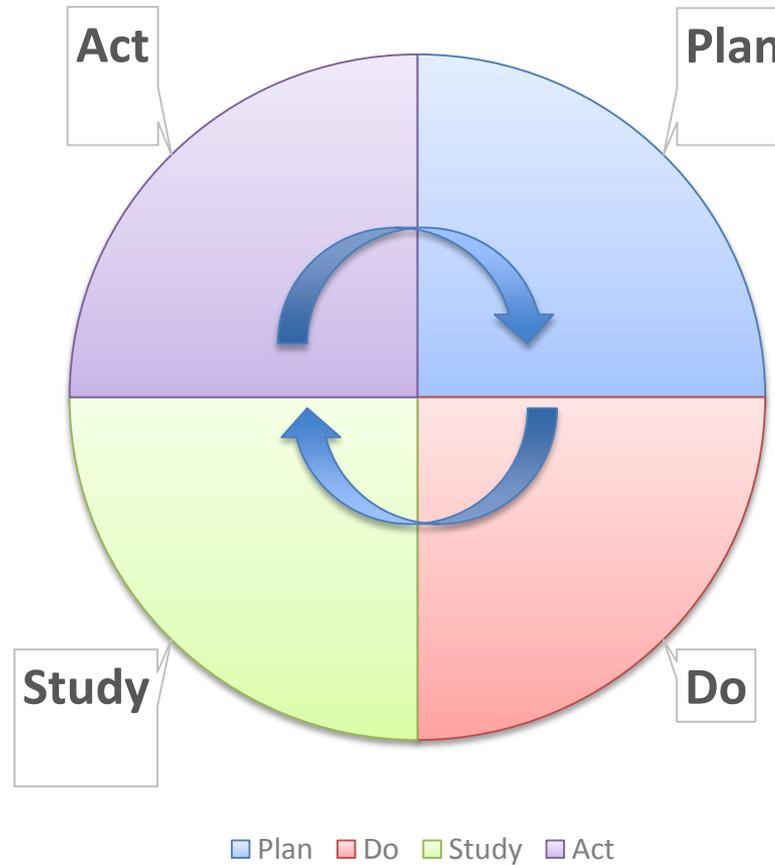


*Advancing Transfusion and
Cellular Therapies Worldwide*

AABB Continuing Medical Education (CME)

ACCME Accreditation and Compliance Measures

The ACCME Quality Model



CME Mission Statement

The AABB CME mission provides a framework for guiding and conducting the organization's CME program and its educational activities.

“The goal of the AABB Continuing Medical Education (CME) Program is to support the AABB mission to advance the practice and standards, transfusion medicine, cellular therapies and patient blood management to optimize patient and donor care and safety. This goal is accomplished by producing relevant, high quality, and cost-effective continuing education that increases the knowledge, competence and performance of physicians and other allied healthcare professionals.”



CME Mission Statement

Content

The American Association of Blood Banks (AABB) content of CME program centers around transfusion medicine, patient blood management and cellular therapies. Emphasis will be placed on education designed to optimize patient and donor care and safety.

Types of Activities

To accomplish the CME mission, the AABB currently develops the following types of educational activities:

- Educational courses and symposia, including didactic presentations, workshops and eLearning.
- Enduring materials include sync-to-slide, audioconferences, certificate program and webinars.

Expected Results

The expected result of AABB educational activities is that participants enhance their knowledge and competency in the subject area(s) offered. We expect to see a change in how one performs in the workspace.



Accreditation Criteria

- Education & Planning
- Evaluation and Improvement

Accreditation Criteria

Education & Planning

- Educational needs (knowledge, competence, or performance) that underlie the **professional practice gaps** of the learners
- Activities that are designed to change **competence, performance, or patient outcomes**
- Activities around content that matches the learners' current or potential **scope of professional activities**
- **Chooses formats for activities** that are appropriate for the setting, objectives, and desired results of the activity

Accreditation Criteria

- Develop activities in the context of desirable **physician attributes**
 - Patient Care, Medical Knowledge, Practice Improvement, Interpersonal/Communication Skills, Professionalism, System-Based Practice
- Develop activities **independent of commercial interests**
- Appropriately **manages commercial support**
- Maintains a **separation of promotion from education**
- Promotes **improvements in health care** and NOT proprietary interest of a commercial supporter

Accreditation Criteria

Evaluation and Improvement

- Analyzes **change in learners** achieved as a result of the overall program's activities
- Gathers data or information and conducts a **program-based analysis** on the degree to which the CME mission has been met through the conduct of CME activities
- **Identifies, plans and implements** the needed or desired change in the overall CME program
- **Demonstrates** that identified program changes or improvements, that are required to improve on our ability to meet CME Mission

Performance and Quality Gaps

Ongoing needs assessment analysis to identify learning gaps:

- **Barriers** that lead to the gaps in individual performance and systems quality
- **Educational needs** related to the gaps, with consideration given to the target audience (e.g., physician, nurse, other members of the care team)
- **Measurable educational objectives** linked to expected results (expressed in terms of changes in competence, performance and patient outcomes)
- **Learning format** preferences of members and stakeholders.

Conflict of Interest Disclosure Form (COI)

- In order for AABB to offer CME credits for a program, speakers and moderator must **complete a Disclosure form and send back to AABB prior to the delivery of the session/program.**
- Presenters are required to disclose:
 - Relevant financial relationships – through consultancy; speaking bureau's; grants, stockholders, etc.
 - Discussion of an off-label and/or investigational drug that is unapproved.
 - Presentation content is libelous or will infringe the rights of any third party and that CME is providing a balanced view of therapeutic options.

Faculty Disclosure Slide



Faculty and Provider Disclosure Form

Name:	Date of Educational Program:
Title of Education Program:	
Presentation Title(s) / Topic(s):	
<i>Note: Each talk needs a learning objective(s) disclosed as the second or third slide of the presentation.</i>	

***Per the Accreditation Council for Continuing Medical Education (ACCME), persons who fail to complete this form are not eligible to be involved in the educational activity.**

#1: Disclosure of Relevant Financial Relationships - Disclose only where the relationship is associated with the content of the activity. List the names of proprietary entities producing, marketing, re-selling, or distributing health care goods or services, consumed by, or used on patients. With the exemption of non-profit or government organizations, and with which you or your spouse/partner have, or have had, a **relevant financial relationship** within the past 12 months.

With respect to this CME activity (check one):

- No, I** (nor my spouse/partner) do not have a relevant financial relationship.
 Yes, I (and/or my spouse/partner) do have a relevant financial relationship. Describe below:

Nature of Relevant Financial Relationship (choose all that apply)	Name of Company(s)
<input type="checkbox"/> Consultant	
<input type="checkbox"/> Speaker's Bureau	
<input type="checkbox"/> Grant/Research Support (Secondary Investigators need not disclose)	
<input type="checkbox"/> Stock Shareholder (self-managed)	
<input type="checkbox"/> Honoraria	
<input type="checkbox"/> Full-time/Part-time Employee	
<input type="checkbox"/> Other (describe):	

#2: Disclosure of Off-Label and/or Investigational Uses - If, at any time, during my education activity, I discuss an off-label/investigative (unapproved) use of a commercial product/device, I understand that I must provide disclosure of that intent.

- No, I** do not intend to discuss an off-label/investigative use of a commercial product/device.
 Yes, I do intend to discuss off-label/investigative uses(s) of the following commercial product(s)/device(s):

Manufacturer(s)/Provider(s):	Product(s)/Device(s):
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#3: Presentation(s) Content: Faculty Responsibility

- The Presenter warrants that nothing in their presentation is libelous or will infringe the rights of any third party. Presenter also warrants that for any third party materials incorporated into their presentation, they have obtained all necessary permission from the copyright owner of such material. Upon request Presenter agrees to furnish copies of said permission(s) to AABB. The Presenter is responsible for all fees, royalties, and other charges for the use of such materials. The Presenter, if a non-AABB Clinic or MCHS physician shall indemnify AABB Clinic for all damages, costs and expenses, including attorneys' fees, incurred by AABB Clinic as a result of a violation of this paragraph.
 - CME must give a balanced view of therapeutic options. Use of generic drug names contributes to impartiality. Also, if your CME educational material or content includes trade names then trade names from several companies should be used where available, not just trade names from a single company.
- I agree to the statements in #3.**

I attest that the information is accurate. Please accept this as my signature.

Name:	Date:
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Commercial Interest

The ACCME defines a "commercial interest" as any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Financial Relationship

Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received, or expected. **ACCME considers relationships of the person involved in the CME activity to include financial relationships of a spouse/partner.**

Relevant Financial Relationship

ACCME focuses on financial relationships with commercial interests in the 12-month period preceding the time that the individual is being asked to assume a role controlling content of the CME activity. ACCME has not set a minimal dollar amount for relationships to be significant. Inherent in any amount is the incentive to maintain or increase the value of the relationship. The ACCME defines "relevant financial relationships" as financial relationships in any amount occurring within the past 12 months that create a conflict of interest. **After you submit the completed disclosure form, it is your responsibility to inform AABB if the status of your financial relationship changes prior to your presentation.**

Off-Label Use and/or Investigational Uses - FDA Statement

Some drugs or medical devices demonstrated have not been cleared by the FDA or have been cleared by the FDA for specific purposes only. The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.

"Off-label" uses of a drug or medical device may be described in CME activities so long as the "off-label" use of the drug or medical device is also specifically disclosed (i.e. it must be disclosed that the FDA has not cleared the drug or device for the described purpose). Any drug or medical device is being used "off-label" if the described use is not set forth on the product's approval label. **AABB complies with the requirements of the National Physician Payment Transparency Program OPEN PAYMENTS (Physician Payments Sunshine Act).**



Commercial Support Agreement



The AABB Standards for Commercial Support of a Continuing Medical Education Activity Commercial Support Agreement

Funds from a commercial source should be in the form of an unrestricted educational grant made payable to AABB, the accredited sponsor for the support of programming. Federal tax ID#: 36-2384118.

All support associated with a CME activity, whether in the form of an educational grant or not, must be given with the full knowledge and approval of AABB. No other funds from a commercial source shall be paid to the director of the activity, faculty, or others involved with the activity.

This document acknowledges the commitment of an unrestricted educational grant, in the amount of _____ from _____ to support the 2016 AABB Annual Meeting CME Activity.

DATE: October 22-25, 2016 LOCATION: Orlando, FL

The grant will be used to defray the costs of the activity. It is understood that this grant is made in compliance with all FDA and ACCME policies and guidelines. It is also understood that this grant is not being given in exchange for any explicit or implicit agreement to purchase, prescribe, recommend, influence or provide favorable formulary status for the grantor's products. By acceptance of this grant the AABB agrees and acknowledges that this payment has not been determined in a manner that takes into account the volume or value of any referrals or business generated between the parties.

Commercial Representative	PRINTED NAME and SIGNATURE	Date
Address		Company Federal Tax I.D. Number
City, State, Zip, Country		
Company Headquarters Contact	Phone #	

I understand that the company named above will be acknowledged on signage and in printed materials with the following statement: "The 2016 AABB Annual Meeting is partially supported by unrestricted educational grants. AABB and the NBF acknowledge the generous support from the following organizations: _____. Upon request, AABB will provide a final financial report of the CME activity.

Please complete and return this form to:

Charisse Diggins, Education Compliance Coordinator
AABB (American Association of Blood Banks)
8101 Glenbrook Road
Bethesda, MD 20814
Phone: 240-333-6609
Email: C.Diggins@aabb.org

Please note: This completed form must be received by September 1, 2016.

AABB Representative	PRINTED NAME AND SIGNATURE	Date
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Presentation Guidelines

- Presentations must be free of commercial bias for or against any product. If commercial products are discussed, the session must present objective information about those products, based on generally accepted scientific evidence. Speakers must not engage in the marketing of product(s) in any way during the presentation.
- The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial entity. Presentations must give a balanced view of therapeutic options.

Presentation Slides

- Most AABB live programs are allowed to offer CME's
- Presentation will be reviewed for CME compliance so that is why we ask for them in advance and no changes can be made after submission.
- Based on the CME compliance review, there may be requested to make changes for compliance. You must discuss these with the presenter before initiating a change.

Presentation Slides

- AABB can provide a PowerPoint slide template if requested (optional to use).
- Logos are not allowed on anything except the opening slide. The speaker may not brand the overall presentation with logos or designs.
- Opening slides must follow the format below:
 - Slide 1: Presentation Title Slide
 - Slide 2: Disclosure Slide - list all commercial relationships relevant to your specific presentation (those provided on the disclosure form). If you do not have anything to disclose, include the disclosure slide and simply put “I have no relevant financial relationships to disclose for this program”
 - If box three is checked on the disclosure form a slide must be inserted with the following language: “I do intend to discuss off-label/investigative uses(s) of the following commercial product(s)/device(s): Company/Product Name”
 - Slide 3: Learning Objectives – at least three.