

CME Policy and Procedures for Full Disclosure and Identification and Resolution of Conflicts of Interest

The following policy governs all American Academy of Family Physicians (AAFP)-produced CME activities of all types, including live, performance improvement in practice, point of care, enduring materials, medical journals.

1. Disclosure of Financial Relationships

The existence of any financial relationship or interest an individual in a position to control content currently has, or has had, within the previous 12 months, and 12 months into the foreseeable future, must be disclosed in writing to the AAFP prior to confirmation of the individual's participation. NOTE: *FPM JOURNAL* AUTHORS MUST DISCLOSE RELATIONSHIPS IN EXISTENCE WITHIN THE PREVIOUS 36 MONTHS AND INTO THE FORESEEABLE FUTURE. Any conflicts of interest must be identified and resolved prior to the individual's confirmation as an activity planner, faculty, author, or other content controlling role. It is necessary to update disclosure information should the status change during the course of the CME activity.

The intent of this policy is not to prevent individuals from participating, but rather is to identify and resolve any conflicts of interest. Should resolution be impossible, a replacement for the individual must be chosen.

Because the review, identification, and resolution process must take place prior to the activity, all individuals in a position to control content must return the disclosure information by the due date. Additional clarification is asked of those who participate in speakers' bureaus to assist the AAFP reviewers in understanding the nature of the speakers' bureau relationship (a list of recommended speakers acting independently of any guidance or direction from a commercial interest versus a list of speakers who are acting as agents, or who are contractually bound as agents of the commercial interest) in order to assure that participation will not be in conflict with previous commitments. Additional clarification is asked about manuscript preparation to clarify the role of the author and any others who participated in creation of a manuscript for print or other enduring educational materials.

The disclosure information will be reviewed and, should a potential conflict be identified, additional information or dialogue may be required. Failure to disclose within the necessary timeframe will result in withdrawal of the invitation to participate.

Acknowledgement of all relevant disclosures as determined by the AAFP - including nothing to disclose or existence of affiliation(s), and/or financial relationship(s) or interest(s) - for every individual who serves in a position to control content of the educational activity must be presented in writing to the learners prior to presentation or publication.

2. Disclosure of Unlabeled/Investigational Uses of Products

AAFP believes that it is important for faculty and authors to clarify for learners when an unlabeled use of a commercial product, or an investigational use not yet approved for any purpose, is discussed within an educational activity. Faculty and authors should disclose that the product is not labeled for the use under discussion or that the product is still investigational.

For live activities, should an unplanned discussion of unlabeled or investigational uses of a product occur (usually in the course of a question and answer session), faculty should clarify for the learners that the use under question/discussion is unlabeled or investigational prior to answering the question or responding to the discussion point.

Acknowledgement of planned discussion of unapproved or investigational uses of products should be presented in writing to the learners prior to the start of the activity, or (for enduring materials/medical journals) at the point that first mention is made of the unapproved/investigational use in the activity.

3. Failure or Refusal to Disclose/False Disclosure

Failure or refusal to disclose, false disclosure, or inability to work with the AAFP to resolve an identified conflict of interest will result in withdrawal of the invitation to participate and replacement of the individual.

4. Identification and Resolution of Conflicts of Interest

- a. The AAFP will inform all individuals who are invited to serve in roles that can control the content of an educational activity (faculty, planners, authors, editors, staff, etc.) of the AAFP Policy on Full Disclosure. Confirmation of service is contingent upon provision of disclosure by the date requested, and review of disclosure information and resolution of any conflicts of interest.
- b. Each individual nominated for a content-controlling role must complete his/her disclosure online. NOTE: AT THIS TIME, *FPM* JOURNAL AUTHORS COMPLETE DISCLOSURE FORMS ON PAPER. That individual is the only person who will be given the entry passcode to his/her individual disclosure record and who will be authorized to enter and update information on their disclosure form. The AAFP will have read-only access, will proceed through a review of the submitted information and, should any of the disclosed information trigger a concern regarding a possible conflict of interest, may seek input from the candidate and/or other individuals prior to confirming the candidate's service.
- c. Should no conflicts of interest be identified, the individual may be confirmed in his or her role in the activity.
- d. Should a potential conflict of interest be identified, the individual will be contacted and asked for clarification or additional information. Upon receipt and review of this additional information, methods of resolution will be identified and discussed with the

individual. Resolution methods may include, but not be limited to, one or more of the following:

- i. Peer review of content prior to the activity to ensure evidence-based content using best available, highest strength of evidence. The activity faculty or authors must be responsive to revision requirements
 - ii. Assigning a different topic for the individual
 - iii. Assigning a different faculty/author for a topic
 - iv. Cancellation of the faculty/author
- e. The resolution process and outcome will be documented in the activity file, with a copy forwarded to the AAFP CME Credit Systems and Compliance Department for tracking and reporting purposes.
- f. On-site and post-activity audits will be conducted at random to ensure that AAFP CME activities are unbiased and reflect fair balance.

FPM UPDATE: 4/30/14