

Society for Healthcare Epidemiology of America Policy on Disclosure, Review and Management of Potential Conflicts of Interest

Purpose

The Society for Healthcare Epidemiology of America (SHEA) works to maintain the utmost quality of patient care and healthcare worker safety in all healthcare settings. In this role, SHEA issues guidelines, provides education and training, and offers opinions on a wide range of issues in healthcare epidemiology, infection prevention, and patient and healthcare worker safety. In order for SHEA to be effective in these, the organization must ensure that its primary goals are not adversely affected by competing interests and real or perceived conflicts of interest. As such, there should be no question whether a position taken by SHEA was established in accordance with its primary mission and not for the purpose of financial or other gain by some or all of its members. In addition to potential financial conflicts of interest, SHEA members may also hold positions in other organizations, the views of which may not coincide with those held by SHEA. The Society must overall ensure that decisions made are truly in the best interest of the Society and its goals, and not those of other organizations.

To this end, SHEA must ensure not only that there are no genuine conflicts of interest, but also that there are no perceived conflicts of interest on the part of members who hold positions of responsibility within the organization or who engage in work on behalf of SHEA. **It is therefore the policy of the organization that all financial relationships and organizational affiliations that potentially pose a conflict of interest be disclosed, reviewed and, where appropriate, managed to ensure the highest level of transparency and accountability.** SHEA is committed to maintaining a process that is consistent, transparent and reflects evolving best practice in disclosure and management of potential conflicts of interest. Thus, SHEA's policies for disclosure, review and reporting potential conflicts of interest will continue to evolve.

Submission of Financial Relationship and Organizational Affiliation Disclosure Statements

SHEA members and others in the following roles are required to submit annual disclosure statements (see Appendix 1) outlining all financial relationships with commercial entities and organizational affiliations relevant to healthcare:

- Board of Trustees Officers and Members
- SHEA Employees or Contractors
- Volunteers working on behalf of SHEA (e.g., as committee members, liaisons, task force members)
- Editor and Associate/Assistant Editors of *Infection Control and Healthcare Epidemiology*
- Writing groups associated with guidelines, policy position papers or other official products of SHEA
- Individuals associated with planning and delivery of SHEA educational programs

An updated disclosure statement must be submitted annually to the SHEA headquarters, covering the past two calendar years. Planners, faculty and invited speakers for SHEA sponsored educational activities will also complete a disclosure and attestation statement (see Appendix 2) for **each** educational activity in which they participate, in accordance with requirements of the Accreditation Council for Continuing Medical Education (ACCME) and SHEA's standing policy on conflict identification and resolution for CME programs.

Statements of Board members and SHEA employees are due by the first Board meeting of each calendar year. Conflict of interest statements from other members in positions of responsibility are due no later than January 31. Members who are appointed to a position of responsibility during the calendar year are required to complete their conflict of interest statement within 30 days of their appointment. Conflict of interest statements will be sent to the SHEA Executive Director and maintained on file at SHEA headquarters for a minimum of seven (7) years. Members who are required to submit a disclosure form and who fail to do so by the appropriate deadline will not be allowed to serve in their SHEA leadership role until the statement is filed. Failure to submit after reasonable reminders or a period of 60 days will result in termination from office or position and potential exclusion of future activities sponsored by SHEA.

An updated conflict of interest statement should be made during the calendar year if there are any new relationships or affiliations to disclose.

Annual and Periodic Review of Disclosure Statements

All disclosure statements will be reviewed by a Conflict of Interest (COI) Review Committee that consists of six (6) individuals, including the SHEA Immediate Past President (1 year term), the Executive Director, the CME Steering Committee Chair (for term of office), a second Committee chair designated by the President (for term of office), the Treasurer of the Board of Trustees (for term of office), and an at-large member (3-year term).

In addition, the statements of each group (e.g., Board, Committees, Task Forces) are reviewed by the Chair of that body and shared with the full group. It is the responsibility of each group to determine if any conflicts of interest exist and what steps are required to effectively manage that conflict in execution of their charge and activities.

Statements from guideline/position paper authors will be reviewed by the Executive Director, the journal editor, the Chairs of the Guidelines and Policy Committees, the Chair of the Publications Committee, and the Board Member who is liaison to the Publications Committee.

No individual will be permitted to be the sole reviewer of their own conflict of interest statement.

Any identified potential conflicts of interest will be brought to the attention of the group within which the individual participates to determine appropriate management and resolution of the potential conflict. The Board will be notified of such identified potential conflicts and the review and management strategy employed to resolve the conflict. Board resolution will be sought in the event a potential conflict exists at the Chair level or when appropriate management and resolution cannot be determined.

Notwithstanding the above outlined process, ACCME requirements dictate that the CME Steering Committee conducts review of planner, faculty and invited speaker disclosures annually and for each CME activity sponsored by SHEA prior to its execution. Forms and processes for review and management of potential conflicts of interest relevant to CME activities are outlined in the following document: *SHEA Conflict of Interest Identification and Resolution Policy*.

Defining Potential Financial Conflicts of Interest

Relationships or affiliations that pose a potential conflict of interest are financial arrangements that could be construed to have any reasonable direct bearing on the activities undertaken and positions taken by SHEA. Although financial ties to pharmaceutical and medical device companies are of high visibility, ties to any company or trade group that sells healthcare epidemiology, infection prevention, or patient safety associated products or services to patients or healthcare organizations are of potential concern.

Therefore, SHEA requires disclosure of any financial relationships with any proprietary entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients are disclosed. In addition to these direct financial relationships, SHEA requires disclosure of indirect financial and organizational relationships where an individual's work contributes to the benefit of his/her organization (e.g., product development, known patents)

Potential conflicts may arise not only from the direct financial dealings of the member, but also because of the financial dealings of anyone with whom the member would directly share the reported income (such as a spouse, domestic partner, or business partner – termed "partner" in the financial conflict of interest statement).

Potential financial conflicts of interest to be reported include, but are not limited to:

- Employment/Service;
- Advisory/Consultant Role;
- Ownership Interests (including stock or stock options, except when invested in a diversified mutual fund not controlled by the covered individual);
- Honoraria (e.g. Speakers' bureaus; honoraria for a talk/presentation about the clinical aspects of a disease)
- Research Funding;
- Patent;
- Expert Testimony;
- Other Remuneration (e.g. the value of trips, travel, gifts, or other in-kind payments not directly related to research activities)

Exact dollar amounts will not be required to be disclosed, but ranges of financial interest will be reported. Disclosures will encompass the **total amount for the previous two calendar years**. Ranges to be reported are:

≤\$10,000

≥ \$10,001 up to \$25,000

> \$25,000

Defining Organizational Affiliations and Non-financial Conflicts of Interest

SHEA members in positions of responsibility may also have positions of responsibility in other organizations.

Examples of such relationships include, but are not limited to, the following:

- Elected or appointed responsibility in other professional societies
- Service on committees or advisory bodies that provide advice to governmental or non-governmental agencies or regulatory entities
- Participation in editorial bodies for other professional medical publications,

These positions may not be remunerated in any fashion, and thus may not represent a potential financial conflict of interest. Nevertheless, the nature of the relationship may be construed to constitute a potential competing interest or bona fide conflict of interest if the views and positions of that organization are not necessarily aligned with the views and positions of SHEA. Because such relationships are not as easily defined as monetary amounts, exact guidance for disclosure is difficult to provide. As a general rule, disclosure of elected or appointed roles within other related organizations is a minimum threshold.

Use and Disposition of Disclosures

SHEA will maintain records of disclosed relationships for seven (7) years. In addition, SHEA will take the following steps to ensure transparency of this information:

- Disclose summaries of all reported relationships to learners and other users of SHEA educational activities, including CME activities sponsored by SHEA.
- Provide summaries of disclosures to accompany all guidelines, position papers and other work products that are published in ICHE or other peer-reviewed journal, or disseminated as an official SHEA document or product.
- Post summary disclosure information for Board members, staff and Committee chairs on the SHEA website.
- Make disclosure summary information available upon request to public requestors.

Frequently Asked Questions

What is SHEA's definition of potential "conflict of interest"?

Conflict of interest is difficult to define, yet many people think they know it when they see it. Legal definitions are very specific and cover relatively few situations; most conflicts exist in the area where ethics and public perception are more relevant than statutes or precedents. Generally speaking, conflict of interest arises whenever the personal or professional interests of an individual (leader, volunteer, employee) are potentially at odds with the best interests of SHEA. Conflict of interest does not imply an ethical breach.

The recent Institute of Medicine report on conflict of interest defined conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." The primary interests of concern include "promoting and protecting the integrity of research, the welfare of patients and the quality of medical education." The secondary interest, according to IOM "may include not only financial gain but also the desire for professional advancement, recognition for personal achievement and favors to friends and family or to students and colleagues."

Who must disclose?

All of the following individuals in position of responsibility within SHEA must disclose financial relationships and organizational affiliations that pose potential conflict of interest on an annual basis:

- Officers and Board of Trustees Members
- SHEA Employees
- Volunteers working on behalf of SHEA (e.g., as liaisons, task force members)
- Editor and Associate/Assistant Editors of *Infection Control and Healthcare Epidemiology*
- Authors of guidelines/position papers to be published with official SHEA approval
- SHEA Committee and Taskforce Members
- Planners, Faculty and Invited Speakers involved with SHEA educational programs

Must I disclose any financial relationship that represents a potential conflict of interest?

Yes, all financial relationships, including but not limited to those listed below, must be disclosed covering the past two years at the time of disclosure.

- Employment/Service;
- Advisory/Consultant Role;
- Ownership Interests (including stock or stock options, except when invested in a diversified fund not controlled by the covered individual);
- Honoraria (e.g. speakers' bureaus; honoraria for a talk/presentation about the clinical aspects of a disease)
- Research Funding;
- Patent;
- Expert Testimony;
- Participation on a governmental or other committee (e.g. IOM) that may preclude you from representing the Societies views
- Other Remuneration (e.g. the value of trips, travel, gifts, or other in-kind payments not directly related to research activities)

What does "Nothing to Disclose" mean?

This means that the individual has no financial or non-financial relationships with any proprietary entity related to healthcare. For purposes of disclosure for educational programs, this statement covers financial relationships only. Note that the SHEA Disclosure form requires disclosure of primary employment at a minimum.

What must be done if changes to my information occur after I disclose?

Disclosures are required at least annually. If new or changed information emerges prior to the next annual submission period, the individual should complete a new disclosure within 60 days.

Do I need to disclose financial relationships of my partner that are potential conflicts of interest?

Yes. The form indicates whether a SHEA member is reporting a potential conflict for themselves or a partner.

When must I disclose financial relationships or organizational affiliations that pose a potential conflict of interest?

Disclosure occurs annually or upon assumption of official responsibility with SHEA (e.g., appointment to a task force or invitation to speak at an educational program). Board and committee chairs should file their disclosures no later than January 30th each year and thereafter only upon changes in information.

I have not filed my disclosure form. Can I still participate in my official responsibilities for SHEA?

No. Any individual required by this policy to submit a disclosure form who fails to do so by January 30 will receive a reminder from the headquarters office. Failure to submit the required disclosure within 30 days of the reminder will result in inability to participate in SHEA activities that made the individual subject to this policy. Individuals appointed to ad hoc activities for SHEA during a calendar year have 60 days to submit required disclosure; reminder and termination of duty policies apply.

How are disclosures reviewed and managed?

SHEA headquarters staff receives disclosure forms, which are retained electronically for 7 years. Staff monitors receipt and verifies compliance with the policy. Disclosures are reviewed by a Conflict of Interest Review Committee that consists of the Past President, Treasurer, the CME Steering Committee chair, an additional committee chair appointed by the Board President, an at-large SHEA member and the SHEA Executive Director.

Committee chairs and Board Committee liaisons review Committee member disclosures and all disclosures are shared with the group for review and management.

Speaker agreements containing financial disclosures of planners and faculty for CME activities of SHEA are reviewed prior to each activity by the SHEA Senior Education Manager and the CME Steering Committee.

Individual groups (e.g. committees) determine the required actions to manage an identified potential conflict of interest. Potential conflicts of chairs or issues involving inability to resolve a potential conflict are brought to the Board of Trustees for management and resolution.

Original adopted: October 2007

Amendments approved by Board of Trustees June 3, 2010

Appendix 1

**Society for Healthcare Epidemiology of America
Financial Relationship and Organizational Affiliation Disclosure Form**

Instructions: Please read, complete, sign, and date this disclosure form.

All volunteer members participating in SHEA activities and the professional staff should act in the best interest of SHEA. Decisions always should be based solely on the best interest of SHEA, its membership, and the public. Decisions should not be influenced by personal financial interest or by other extraneous considerations. A potential conflict of interest exists if a person has a financial or other beneficial interest that might bias his or her decisions or actions related to SHEA activities. **SHEA determines whether a relationship or affiliation poses a potential conflict of interest; therefore, full disclosure for purposes of organizational governance is required.**

Each volunteer member has a high duty and obligation to disclose all financial relationships and organizational affiliations and to abstain from any decision where a conflict of interest is determined to exist. The disclosure forms are reviewed by both the Conflict of Interest (COI) Review Committee and, for each group (e.g., committees, task forces) by the chair of such group to determine potential areas of conflict of interest that may require management. Disclosure information will be made available to members of such groups. Disclosures will also be reported on SHEA’s website for Board of Trustees and Committee chairs.

Acknowledgement of this policy and disclosure filing will be done by each volunteer member and senior staff annually or at the inception of an activity (e.g., task force) and kept on file in the SHEA headquarters office. **In between annual filings, it is the responsibility of each individual to disclose in writing any new relationships or affiliations that pose a potential conflict of interest.**

Please consider your activities and financial relationships/investments and affiliations **currently and for the preceding two years** when responding. Attach additional pages if necessary.

1. PRIMARY EMPLOYMENT (and other salaried positions): If self-employed, but formally paid through a corporation or other entity, indicate “self-employed” under Employer.

Employer	Position

2. FINANCIAL RELATIONSHIPS/INCOME

Company/ Organization Name	Check all that apply
For Interests ≤ \$10,000	
	<input type="checkbox"/> Advisory/Consultant Role; <input type="checkbox"/> Expert Testimony; <input type="checkbox"/> Honoraria; <input type="checkbox"/> Ownership Interests; <input type="checkbox"/> Stocks/Bonds; <input type="checkbox"/> Patent, copyright, license (describe): _____; <input type="checkbox"/> Other Remuneration (describe): _____
	<input type="checkbox"/> Advisory/Consultant Role; <input type="checkbox"/> Expert Testimony; <input type="checkbox"/> Honoraria; <input type="checkbox"/> Ownership Interests; <input type="checkbox"/> Stocks/Bonds; <input type="checkbox"/> Patent, copyright, license (describe): _____; <input type="checkbox"/> Other Remuneration (describe): _____
	<input type="checkbox"/> Advisory/Consultant Role; <input type="checkbox"/> Expert Testimony; <input type="checkbox"/> Honoraria; <input type="checkbox"/> Ownership Interests; <input type="checkbox"/> Stocks/Bonds; <input type="checkbox"/> Patent, copyright, license (describe): _____; <input type="checkbox"/> Other Remuneration (describe): _____
	<input type="checkbox"/> Advisory/Consultant Role; <input type="checkbox"/> Expert Testimony; <input type="checkbox"/> Honoraria; <input type="checkbox"/> Ownership Interests; <input type="checkbox"/> Stocks/Bonds; <input type="checkbox"/> Patent, copyright, license (describe): _____; <input type="checkbox"/> Other Remuneration (describe): _____
	<input type="checkbox"/> Advisory/Consultant Role; <input type="checkbox"/> Expert Testimony; <input type="checkbox"/> Honoraria; <input type="checkbox"/> Ownership Interests; <input type="checkbox"/> Stocks/Bonds; <input type="checkbox"/> Patent, copyright, license (describe): _____; <input type="checkbox"/> Other Remuneration (describe): _____
	<input type="checkbox"/> Advisory/Consultant Role; <input type="checkbox"/> Expert Testimony; <input type="checkbox"/> Honoraria; <input type="checkbox"/> Ownership Interests; <input type="checkbox"/> Stocks/Bonds; <input type="checkbox"/> Patent, copyright, license (describe): _____; <input type="checkbox"/> Other Remuneration (describe): _____
	<input type="checkbox"/> Advisory/Consultant Role; <input type="checkbox"/> Expert Testimony; <input type="checkbox"/> Honoraria; <input type="checkbox"/> Ownership Interests; <input type="checkbox"/> Stocks/Bonds; <input type="checkbox"/> Patent, copyright, license (describe): _____; <input type="checkbox"/> Other Remuneration (describe): _____

For Interests \$10,001 to \$25,000

Advisory/Consultant Role; Expert Testimony; Honoraria; Ownership Interests; Stocks/Bonds;
 Patent, copyright, license (describe): _____ ; Other Remuneration (describe): _____

Advisory/Consultant Role; Expert Testimony; Honoraria; Ownership Interests; Stocks/Bonds;
 Patent, copyright, license (describe): _____ ; Other Remuneration (describe): _____

For Interests > \$25,000

Advisory/Consultant Role; Expert Testimony; Honoraria; Ownership Interests; Stocks/Bonds;
 Patent, copyright, license (describe): _____ ; Other Remuneration (describe): _____

Advisory/Consultant Role; Expert Testimony; Honoraria; Ownership Interests; Stocks/Bonds;
 Patent, copyright, license (describe): _____ ; Other Remuneration (describe): _____

3. RESEARCH GRANTS/CONTRACTS - If you are currently listed or have in the past 24 months been listed as PI or other investigator (including clinical studies) please indicate the following:

Funding Agency	Institution/Group/Title of Study

4. ORGANIZATIONAL BENEFIT – Are there any monies obtained or assigned by a university, department, institution, foundation, private enterprise group, or any other entity as a result of your activities (e.g., known patents; unrestricted educational grants)?

Sponsor	Institution	Activity	Value
			<input type="checkbox"/> ≤\$10,000; <input type="checkbox"/> \$10,001–\$25,000; <input type="checkbox"/> >\$25,000
			<input type="checkbox"/> ≤\$10,000; <input type="checkbox"/> \$10,001–\$25,000; <input type="checkbox"/> >\$25,000
			<input type="checkbox"/> ≤\$10,000; <input type="checkbox"/> \$10,001–\$25,000; <input type="checkbox"/> >\$25,000

5. ACTIVITIES WITH OTHER ORGANIZATIONS: Do you currently serve in any official capacity, including any decision-making capacity or national or state leadership, with any other professional societies, voluntary health organizations, editorial boards, federal or state agencies, internet companies, or other entities that currently engage in activities that could be considered competitive to SHEA's interests or activities in areas such as education, advocacy, research, fundraising, etc.?

Organization	Position

6. FAMILY OR OTHER RELATIONS – In accordance with SHEA's disclosure policies, relevant financial or other relationships of members of your immediate family should also be disclosed. This includes but is not limited to spouse/domestic partner, parents, siblings, and children. To the best of your knowledge, please list any significant relationships or activities where members of your family may be involved as they relate to Society activities.

Relation (Spouse, child, etc.)	Activity	Value
		<input type="checkbox"/> ≤\$10,000; <input type="checkbox"/> \$10,001–\$25,000 <input type="checkbox"/> > \$25,000

		<input type="checkbox"/> ≤\$10,000; <input type="checkbox"/> \$10,001–\$25,000 <input type="checkbox"/> > \$25,000
		<input type="checkbox"/> ≤\$10,000; <input type="checkbox"/> \$10,001–\$25,000 <input type="checkbox"/> > \$25,000

I certify that I have read SHEA's Policy on Conflict of Interest and have disclosed all declarable relationships as defined therein, if any.

Signature

Date

Print Last Name

SHEA Position(s) (e.g., Board, Committee Chair, Task Force, Writing Group)

Deliberate failure to comply with this disclosure requirement may result in a disqualification from current and future participation in SHEA-sponsored activities.

Mail or Fax to: Society for Healthcare Epidemiology of America
1300 Wilson Boulevard, Suite 300
Arlington, VA 22209
Fax: 703-684-1009

FINANCIAL RELATIONSHIP DISCLOSURE FORM					
Name: <<First Name>> <<Last Name>> <<Credentials>>					
Role: <<Faculty Role>>					
Activity Title: <<Activity Title>>					
Activity Date: <<Activity Date>>					
1. I DO NOT have any financial relationships within the past 12 months with any proprietary entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients to disclose.					<hr/> Signature Date
2. I DO have a financial relationship(s) within the past 12 months with a proprietary entity(ies) producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients to disclose. <i>Please complete the remainder of this form.</i>					<hr/> Signature Date
Information regarding financial relationships					
Indicate below for which proprietary entities in the year prior to the date of your signature that you performed the listed role by placing a checkmark (✓) in the corresponding box.					
Please do not disclose participation in or honoraria received for a CME activity					
Proprietary Entity (list manufacturer name)	Consultant	Researcher	Speakers Bureau Member	Stockholder (excluding diversified mutual funds)	Other (please indicate specific role or financial relationship)

Are you an employee of a proprietary entity which produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients (do not include hospitals, clinics, or medical centers)?

YES, Part-Time YES, Full-time NO

If yes, please list company name _____

Does your spouse or life partner have a financial relationship with a proprietary entity which produces, markets, re-sells, or distributes health care goods or services consumed by, or used on, patients?

YES NO If yes, please describe the nature of the relationship and with whom

Have you received any royalties from healthcare product patents?

YES NO If yes, please state the company name _____

Do you earn greater than 10% of your annual income from any single proprietary entity?

YES NO If yes, please state the company name _____

ATTESTATION FORM

Name: <<First Name>> <<Last Name>> <<Credentials>>

Role: <<Faculty Role>>

Activity Title: <<Activity Title>>

Activity Date: <<Activity Date>>

DECLARATION

In light of the relationships/affiliations you designate, ***WE ASK THAT YOU ATTEST THAT:***

1. relationships/affiliations will not bias or otherwise influence your involvement in the CME activity
2. practice recommendations that are relevant to the companies with whom you have relationships/affiliations will be supported by the best available evidence or absent evidence will be consistent with generally accepted medical practice
3. all reasonable clinical alternatives will be discussed when making practice recommendations
4. any reference to unlabeled/unapproved uses of drugs or products in my presentation will be disclosed to the audience

Additional information may be requested to resolve a conflict of interest. All identified conflicts of interest will be resolved and disclosure made to participants prior to the start of the CME activity.

Signature _____ Date _____

Return completed form via e-mail/PDF, mail, or fax to:

Attn: Jane Radford, MHA

SHEA Senior Education Manager

Society for Healthcare Epidemiology of America

1300 Wilson Blvd., Suite 300

Arlington, VA 22209

(703) 684-1006 office

(703) 684-4799 direct

(703) 684-1009 fax

jradford@shea-online.org