Clarification of Owner, Employee, or Owner of Private Stock Relationship Accreditation Rules

The following is clarification of the ACCME requirements regarding speakers for accredited continuing education who have disclosed they are an owner, employee, or owner of private stock of an ineligible company* on their electronic Financial Disclosure Form (FDF). Individuals who are owners, employees, or who have private stock with ineligible companies are considered to have unmitigable financial relationships.

As an early/first step when booking speakers, we recommend that the Lead Planners/Planning Committee ask about owner, employee, or private stock ownership relationships since the ACCME does not allow a mitigation plan for these relationships unless they meet one of the exceptions. If a relationship is disclosed, perhaps consider an alternate speaker or request presentation slides early to determine whether one of the exceptions can be met. The three allowable ACCME exceptions are noted below.

Exceptions

Owners, employees, or owners of private stock of ineligible companies **can** participate as planners or faculty in these specific situations:

- a. When the content of the accredited activity <u>is not related to the business lines or products</u> of their employer/company.
- b. When the content of the accredited activity <u>is limited to basic science research</u>, such as pre-clinical research and drug discovery, or the methodologies of research, and they <u>do not make care recommendations</u>. [i.e., if touching humans (must be disqualified); entering FDA pre-approval phase (must be disqualified); if in clinical trials, it is not basic science research (must be disqualified).]
- c. When they are <u>participating as technicians</u> to teach the safe and proper use of medical devices, and do not recommend whether or when a device is used.

Source: Standard 3: Identify, Mitigate, and Disclose Relevant Financial Relationships | ACCME

Review Process

In the event an individual discloses an owner, employee, or owner of private stock relevant financial relationship, the ACE Team will begin the review process. The speaker will need to provide their presentation slides (draft is fine). The ACE Team will initiate the *Owner, Employee, or Private Stock Ownership Relationship Review Form* for the Lead Planner and Medical Director/Associate Dean for InterProfessional Educational Practice (IPEP) to document their findings and determine eligibility to proceed, recuse, or forgo credit. This process can take up to 15 business days to complete. See flowchart for outline of the disclosure, relevant financial relationship(s), and mitigation process.

* Ineligible companies are those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients.

Examples of such organizations include:

- Advertising, marketing, or communication firms whose clients are ineligible companies
- Bio-medical startups that have begun a governmental regulatory approval process
- Compounding pharmacies that manufacture proprietary compounds
- Device manufacturers or distributors
- Diagnostic labs that sell proprietary products

- Growers, distributors, manufacturers, or sellers of medical foods and dietary supplements
- Manufacturers of health-related wearable products
- Pharmaceutical companies or distributors
- Pharmacy benefit managers
- Reagent manufacturers or sell