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**ACPE Standards for Continuing Pharmacy Education (CPE)**

**Standard 5: Standards for Integrity and Independence**

**Frequently Asked Questions**

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| **Eligibility** |

**What is ACPE's definition of an ineligible company?**

Eligibility information is incorporated into the [Standards for Integrity and Independence in Accredited Continuing Education](https://www.acpe-accredit.org/pdf/StandardsforIntegrityandIndependenceEffective010122.pdf). Companies that are ineligible to be accredited 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:

* Pharmaceutical companies or distributors
* Device manufacturers or distributors
* Manufacturers of health-related wearable products
* 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, i.e., outsourcing facilities
* Diagnostic labs that sell proprietary products
* Growers, distributors, manufacturers or sellers of medical foods and dietary supplements
* Pharmacy benefit managers
* Reagent manufacturers or sellers

**How can I determine if my organization is an ineligible company?**

ACPE defines ineligible companies as those whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients. ACPE provides a set of self-assessment questions that can help an organization determine whether it falls under the definition of an ineligible company.

Structured Self-Assessment Related to ACPE's Definition of an Ineligible company

1. Does your organization, or a part of your organization, produce, market, re-sell, or distribute healthcare products used by or on patients?
2. Does your organization advocate for, or on behalf of, an ineligible company?
3. Does your organization have a parent company that…
	* produces, markets, re-sells, or distributes healthcare products used by or on patients, and/or…
	* advocates for, or on behalf of, an ineligible company?
	* (A "parent company" is a separate legal entity that owns or fiscally controls an organization.)
4. Does your organization have a sister company that…
	* produces, markets, re-sells, or distributes healthcare products used by or on patients, and/or…
	* advocates for, or on behalf of, ineligible companies?
	* (A "sister company" is a separate legal entity which is a subsidiary of the same parent company that owns or fiscally controls an organization).

4a. If Yes to 4, does your organization share management, employees, or governance structure with the sister company?

4b. If Yes to 4, are any owners, employees, or agents of the sister company involved in the planning, development, or implementation of educational content?

4c. If Yes to 4, does the sister company control or influence, in whole or in part, the operations of your organization?

If your organization answers yes to any of these questions, it would be defined as an ineligible company. If after answering these questions your organization still has questions regarding its status, contact ACPE staff at ceinfo@acpe-accredit.org.

**What is an example of a corporate structure where an ACPE-accredited provider has a sister company that is an ineligible company and meets the ACPE's requirements for independence?**

The most common example ACPE has seen of a corporate structure that involves an eligible organization in association with an ineligible company is one in which both organizations are owned by a separate holding (or parent) company. The holding company does not participate in or control the day-to-day operations of its subsidiaries, is responsible solely for the oversight of the profit and loss statements of its subsidiaries and is controlled or managed by individuals who are different from those in control of its subsidiaries. In these circumstances, an accredited CE provider can have a sister company that is an ineligible company, as long as each company is a separate legal entity and there are proper firewalls in place between them. In order for an accredited provider to be independent from an ineligible sister company, the CE provider must:

* Not be owned or controlled by an ineligible company;
* Have separate management;
* Be the employer of record;
* Have a governance structure which is separate from the governance structure of the ineligible company; and
* Receive any funds from an ineligible company only as commercial support or as payment for allowing associated commercial promotion with a CE activity.

**What principles guide ACPE in evaluating an organization as an ineligible company?**

What follows are guiding principles developed by ACPE in the evaluation of organizations as it pertains to the definition of an ineligible company:

* If entities are owned and operated by or on behalf of providers of patient care, then they should not be deemed ineligible (e.g., hospitals, long-term care facilities, hospice)
* If there is a parent company that is not an ineligible company and it has two independent subsidiaries (corporation A and corporation B), where corporation A includes the CPE unit and corporation B provides branded products, then corporation A should not be deemed an ineligible company. (A "parent company" is a separate legal entity that owns or fiscally controls an accredited provider or non-accredited organization.)
* If a company provides pharmacist-provided patient care services (i.e., pharmacies), then the company should not be deemed an ineligible company.

If a company provides proprietary formulas and/or formulations and the company has influence (on patients and/or prescribers) on the prescribing of the resultant product(s), then that company should be deemed an ineligible company.

**When is a company that is developing its first product considered an ineligible company?**

A biomedical startup is considered an ineligible company if it has begun a governmental regulatory approval process.

* Drugs: ACPE considers the submission of the Investigational New Drug Application (IND), which must be approved before clinical trials can begin, as the point of entry into the government regulatory approval process.  Once a company makes this submission, it would be considered an ineligible company.
* Medical devices: When a company initiates a premarket approval (PMA) process submission, it would then be considered an ineligible company.

**Why will ACPE not allow ineligible companies to act as joint providers?**
Joint providers are educational partners and are expected to routinely have a role in making decisions about the elements of the planning process. Since providers “must ensure that all decisions related to the planning, faculty selection, delivery, and evaluation of accredited education are made without any influence or involvement from the owners and employees of an ineligible company,” the joint provider cannot be an ineligible company.