



Guidance for ACPE-Accredited Providers Regarding CPE Activities related to Compounding Frequently Asked Questions

What are compounding companies/pharmacies?

Compounding companies/pharmacies tailor pharmacologic therapies for patient specific needs. They also innovate and develop new formulations and methods of compounding. FDA classifies compounding pharmacies into 503A and 503B. These categories are considered traditional compounding, whereas manufacturing is the FDA and DEA approved mass production of drug products through pre-set formulas or doses without customization to individual patient needs.

What are the characteristics of 503A and 503B compounding companies/pharmacies?

Both 503A and 503B companies/pharmacies compound customized pharmaceutical products that are not commercially available, often using a proprietary formula. United States Pharmacopeia (USP) formally defines compounding as “the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order, or initiative based on the practitioner/patient/ pharmacist/compounder relationship in the course of professional practice”. 503A pharmacies are pharmacies that compound a prescription specific to a particular patient need. 503B companies (or outsourcing facilities) manufacture in mass with or without prescriptions that would be sold to healthcare facilities and pharmacies and must comply with current good manufacturing practice. Though 503B companies are considered traditional compounding, they are closer in line with manufacturing and thus would be considered commercial interests.

What are compounding supply companies?

Compounding supply companies provide active pharmaceutical ingredients and excipients, equipment, specialty pharmaceuticals, compounding support, formulas, education services, lab services, training and regulatory support, etc. to compounding companies/pharmacies and must also comply with FDA laws and policies.

Is a compounding pharmacy or compounding supply company a commercial interest?

ACPE defines a commercial interest as any entity producing, marketing, reselling, or distributing health care goods or services consumed by, or used on, patients. If a company is owned and operates on behalf of providers of patient care or provides pharmacist-provided patient care

services, as a 503A compounding pharmacy would qualify, then it should not be deemed a commercial interest.

If a company produces, markets, sells/resells, or distributes proprietary formulas, formulations, and/or pharmaceutical ingredients and the company has influence on the prescribing of or treatment with the resultant product(s), then that company should be deemed a commercial interest. This applies to any company FDA-registered as a 503B outsourcing facility (<https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>), as well as any that are not currently registered as such but are still engaged in large-scale, non-patient specific compounding.

Additionally, a company designated as an FDA-registered manufacturer (e.g., manufacturers pharmaceuticals and/or sells patented or licensed products) or licensed, registered, and/or accredited as a wholesale drug distributor (e.g. NABP Drug Distributor Accreditation) should be deemed a commercial interest.

Would ACPE allow compounding/compounding supply companies to act as joint providers?

ACPE-accredited providers that collaborate on content development with ACPE and/or non-ACPE accredited providers are engaging in joint providership. Commercial interests cannot be accredited providers and cannot be joint providers. Thus, if the compounding/compounding supply company is deemed a commercial interest, they may not act as a joint provider. To maintain CPE activities as independent from commercial interests, the following cannot be in the control of a commercial interest: (i) identification of CPE needs, (ii) determination of educational objectives, (iii) selection and presentation of content, (iv) selection of all persons and organizations that will be in a position to control the content of the CPE, (v) selection of educational methods, and (vi) evaluation of the activity.

What role can a compounding/compounding supply company have if they are deemed a commercial interest?

They may provide commercial support (financial or in-kind contributions) used to pay all or part of the costs of a CPE activity, and they should only be designated as such.

Can employees of commercial interests serve as planners or speakers in accredited CPE activities?

If an employee of a commercial interest wishes to serve as a planner or speaker in an accredited CPE activity, they may so long as the content of CPE that the employee controls DOES NOT relate to the business lines and products of its employer. (For more on the role of commercial interest employees, see Guidelines for the Standards for Commercial Support on the [ACPE website](#).)

What are some of the responsibilities of an accredited provider when creating a CPE activity related to compounding?

- A. Accredited providers should first confirm that any organizations or groups involved in planning, development, delivery, and/or evaluation of compounding CE activities are not commercial interests, as defined in this document and the [Standards for Commercial Support](#).
- B. Activities should meet the definition of CPE and include recommendations and/or methods of compounding that conform to generally accepted standards and provide a balanced perspective of evidence-based options while avoiding promotion/endorsement/advocacy of proprietary compounding services, formulas, etc.
- C. Use of unmarked active pharmaceutical ingredients, excipients, and bases within the CE. Products and supplies should be free of commercial interest names or corporate logos. If any brand names are used as opposed to generic options, all brand names for a given generic product should be listed.
- D. Use of venues or sites for simulation/hands-on compounding education that are not owned or controlled by a commercial interest, as educational content cannot be housed on a platform or distributed by any entity deemed a commercial interest.