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Beaumont's Policy on Promotional Materials and Exhibits

The primary purpose of an accredited CE activity is to maintain, develop or increase the knowledge, skills, and professional performance, and relationships that a healthcare professional uses to provide services for patients, the public or the profession.

Promotional Exhibits

The provision of exhibits at accredited CE activities may serve to complement or enhance the activities' value. At the discretion of the course director, exhibitors may be invited to display materials relevant to the subject of the meeting.

1. Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.
2. Exhibit fees shall be set for each activity and will be standard for that activity; potential exhibitors shall have equal access to purchasing exhibit space (first come-first serve).
 - Exhibit fees shall be separate and distinct from educational grants (they are not considered commercial support).
 - All exhibitors must be charged a fee; fees shall not be waived for any exhibitors
 - Different fee amounts can be set based on amount of space (i.e., 3' table vs. 6' table), organization type (i.e. for-profit vs. not-for-profit). All fee options must be made available to all exhibitors.
 - A record of all exhibit payments must be kept and provided to the CME department at the conclusion of the accredited CE activity.
3. All exhibitors must be in a room or area separate from the education and the exhibits must not interfere or in any way compete with the learning experience prior to, during, or immediately after the activity.
4. Employees of the exhibiting company may attend accredited CE activities at the discretion of Beaumont Health for the direct purpose of their own education; they may not engage in sales or marketing activities while in the space or place of the educational activity.
5. Information on the identity of learners at accredited CE activities is considered to be the confidential property of Beaumont Health. Information on learners will only be released to third parties when learners have prospectively authorized the release of this information.
6. Exhibits must be in compliance with ACCME Standards for Integrity and Independence of Accredited Continuing Education.
7. No more than two company representatives for each exhibit will ordinarily be permitted. Space may be a limiting factor.

Live accredited CE activities:

Marketing, exhibits, and nonaccredited education developed by or with influence from an ineligible company or with planners or faculty with unmitigated financial relationships must not occur in the educational space within 30 minutes before or after an accredited education activity. Activities that are part of the event but are not accredited for continuing education must be clearly labeled and communicated as such.

Print, online, or digital continuing education activities:

Learners must not be presented with marketing while engaged in the accredited education activity. Learners must be able to engage with the accredited education without having to click through, watch, listen to, or be presented with product promotion or product-specific advertisement.

Promotional Materials

Product-promotion material or product-specific advertisement of any type is prohibited in or during accredited CE activities. Educational materials that are part of accredited education (such as slides, abstracts, handouts, evaluation mechanisms, or disclosure information) must not contain any marketing produced by or for an ineligible company, including corporate or product logos, trade names, or product group messages.

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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 sellers

Can I use exhibit funds towards the purchase of food for my accredited CE meeting?

No. Due to the Physician Payment Sunshine Act, meals served as part of an accredited CE activity must be paid for with non-commercial funds (i.e., registration fees, membership fees, etc.) when possible. If commercial funds must be used toward the purchase of meals, the meals must be buffet-style and there must be more than 50 participants in attendance.

What is the Physician Payment Sunshine Act?

In August 2013, Congress enacted the Physician Payment Sunshine Act (Sunshine Act) as part of the Affordable Care Act (ACA) in order to ensure transparency in physicians' interactions with the pharmaceutical, biologic and medical device industries as well as group purchasing organizations. The final rule of the Act requires applicable manufacturers to report certain payments or transfers of value to physicians or teaching hospitals, including Beaumont Health System. All data is reported by the manufacturer to the Centers for Medicare and Medicaid Services and is publically available.

What is reported? All direct and indirect payments or transfers of value provided by a manufacturer to a physician, regardless of whether the payments were related to a covered product. The report to CMS will include:

- Physician's name; address; specialty; state professional license number
- Amount and date of the payment (or transfer of value) contributions, food, entertainment, etc.)
- Name of the covered product, if related to the payment
- Form of payment or transfer of value (i.e., cash, cash equivalent, in kind items or services, stock options, etc.)

Continuing Medical Education (CME) Exemption. Payments or transfers of value made as compensation for speaking at CME programs are exempt from the reporting obligation if the event is certified or accredited by the Accreditation Council for Continuing Medical Education (ACCME), American Academy of Family Physicians (AAFP), American Dental Associations' Continuing Education Recognition Program (ADA), American Medical Association (AMA), or the American Osteopathic Association (AOA). In addition, the manufacturer must not pay the speaker directly, select the speaker, or provide the third party (such as the CME provider) with a list of individuals to be considered as speakers for the CME program.*

*This is currently not allowed for CME-certified activities under the ACCME Standards for Integrity and Independence

Other Exclusions. Several types of payments made by manufacturers are excluded from the reporting requirement:

- Educational materials and items that directly benefit patients or are intended to be used with patients
- Loans for <90 days of a covered device or a device under development or a limited quantity of medical supplies
- Product samples and coupons/vouchers intended for patient use without charge
- Meals, snacks, soft drinks, coffee, or items under \$10 per participant made available to all participants of a large-scale conference (large scale is typically categorized as >50 participants)
- Transfers of value of less than \$10 per person, unless the aggregate amount exceeds \$100 per person/calendar year
- Items or services under contractual warranty

When does the Sunshine Act apply to me? If your event is 1) attended by physicians, 2) has physician speakers, and 3) is being financially supported by a manufacturer that makes any prescription drug/biologic or any "non-exempt" medical device or supply.

What reporting is required for a physician presenting at an accredited CE activity? If the presentation is approved for CME/CE credit by one of the accrediting bodies identified above, then payments or other transfers of value provided as compensation are not required to be reported. *Unaccredited/non-certified education is reportable since this type of education program does not require the same safeguards as an accredited and certified program.*

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What reporting is required for a physician attending an accredited CE activity as a learner? If a meal is provided as part of the accredited CE activity, then the value of that meal must be reported *unless* the meal is a buffet meal, snack, soft drink, or coffee made available to all participants of a conference where it is difficult to identify the identity of those who partook in the offering. *Plated meals, or meals where an idea of the number of physicians partaking in the meal can be calculated, are required to be reported.**

Guidelines Related to Exhibit Space/Promotional Opportunities

Department of Health and Human Services: Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers

To reduce the risks that an educational grant is used improperly to induce or reward product purchases or to market product inappropriately, *manufacturers should separate their grant making functions from their sales and marketing functions.* Effective separation of these functions will help ensure that grant funding is not inappropriately influenced by sales or marketing motivations and that the educational purposes of the grant are legitimate. Manufacturers should establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are *bona fide*. The manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored.

Source: <https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>

ACCME Standards for Integrity and Independence of Accredited CE

Is it acceptable to say, "In exchange for \$5,000 of commercial support we will produce the accredited CE activity and as a commercial supporter you will get an acknowledgment and a 4 x 4 sq ft booth in the exhibit hall."? No, in this scenario the ineligible company is giving commercial support AND getting promotional and sales opportunities as a condition of that support. This is **Not in Compliance** with the Standards. The ineligible company should buy advertising and promotion opportunities with resources designated for that purpose. If an agreement for advertising or promotion is struck between the two parties, it must be outside the written agreement for commercial support. With respect to commercial support, the terms and conditions of the support must be described in a written agreement between the accredited provider and the ineligible company. Any event or product that contains advertising or promotional opportunities must not be part of the accredited CE activity and must not be paid for by commercial support. Normally these are assigned to the "exhibit hall," advertising pages or screens or promotional receptions or meals, all of which are clearly identified as such by the learner.

Are advertising and exhibit opportunities always to be offered to commercial supporters? No, payment and arrangements for advertising and exhibits are separate, business transactions. They are payment for the sale of promotional space.

Is the 30-minute time interval required regardless of whether the nonaccredited activity takes place before, during, or after the accredited activity? Yes, there needs to be a 30-minute interval between an accredited and non-accredited session or activity regardless of whether the non-accredited activity is before, after, or both. This time interval is required if the non-accredited activity is either developed by or with an ineligible company, or if individuals with unmitigated, relevant financial relationships with ineligible companies are in control of content.

Does there need to be a 30-minute interval between accredited and nonaccredited education in virtual activities? Yes, the 30-minute interval is required for all live activities, whether the activity takes place in-person or virtually. For live, virtual activities, if the learner will remain in the same "virtual space" for a non-accredited session, then the provider must ensure that there is a 30-minute interval before or after accredited education. If the learner is required to leave the virtual space to transition between accredited and non-accredited activities, and will need to take an action, such as clicking a link that clearly communicates that they are leaving the accredited education, then there is no time-interval requirement.

Source: Accreditation Council for Continuing Medical Education