

Beaumont

Beaumont's Policy on Promotional Materials and Exhibits

The primary purpose of an educational activity is to improve the knowledge, skills and attitude of the physician learner. CME activities should not contain gratuitous advertising or other types of promotion.

Promotional Exhibits

The provision of exhibits at educational activities may serve to complement or enhance the activities' value. At the discretion of the course director, commercial 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.
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. Commercial interest (pharmaceutical/device) representatives may attend CME activities at the discretion of Beaumont Health for the direct purpose of the representatives' own education; however, 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 CME 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 signed a document authorizing this release of information.
6. Exhibits must be in compliance with ACCME Standards for Commercial Support. Checks should be made payable to Beaumont Health. A record of all payments must be kept. No more than two company representatives for each exhibit will ordinarily be permitted. Space may be a limiting factor.

Promotional Materials

Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME. Beaumont Health does not permit subtle advertising in conjunction with CME-certified activities by having book bags, pens, or other accoutrement that bears the name of the manufacturer and/or its products.

- For **print**, advertisements and promotional materials will not be interleaved within the pages of the CME content, including meeting syllabi.
- For **computer based**, advertisements and promotional materials will not be visible on the screen at the same time as the CME content and not interleaved between computer 'windows' or screens of the CME content.
- For **audio and video recording**, advertisements and promotional materials will not be included within the CME. There will be no 'commercial breaks.'
- For **live, face-to-face CME**, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Learners shall not be forced to interact with exhibitors and/or promotional activities. Commercial Interests are not allowed to engage in sales or promotional activities while in the space or place of the CME activity.

Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message.

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

No. Due to the Physician Payment Sunshine Act, meals served as part of a CME-certified 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 Commercial Support.*

Other Exclusions

Several types of payments made by manufacturers are excluded from the reporting requirement, including:

- 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 a CME-certified activity?

If the presentation is CME-certified 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.*

What reporting is required for a physician attending a CME-certified activity as a learner?

If a meal is provided as part of the CME-certified 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.**

CME Guidelines Related to Exhibit Space

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 insure 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: <http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>

Standards for Commercial Support: Appropriate Management of Associated Commercial Promotion

Is it acceptable to say, "In exchange for \$5,000 of commercial support we will produce the CME 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 commercial interest is giving commercial support and getting promotional and sales opportunities. Opportunities for advertising and promotion are being purchased with commercial support and have become a condition of the support. Both of these are **Not in Compliance** with the Standards. The commercial interest 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 commercial supporter. Any event or product that contains advertising or promotional opportunities must not be part of the educational 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.

Sources: Accreditation Council for Continuing Medical Education