Impact of Physician Payment Sunshine Act on CME

The Physician Payment Sunshine Act (Sunshine Act) is part of the Affordable Care Act (ACA) and was recently created by Congress 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, which went into effect August 1, 2013, 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 will be publically available beginning in September 2014.

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:

- The physician's name; address; specialty; state professional license number
- The amount and date of the payment (or transfer of value)
- The nature of payment (e.g., consulting/speaking fees, royalties, honoraria, gifts, charitable contributions, food, entertainment, etc.)
- The name of the covered product, if related to the payment
- The form of payment or transfer of value (i.e., cash, cash equivalent, in kind items or services, stock, stock options, any ownership interest, dividends and return on investments)

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 not more than 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
- 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

Sunshine Act CME-Related Frequently Asked Questions

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 <u>not</u> required to be reported. Unaccredited/non-certified education <u>is</u> 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.*

*As a result of the Sunshine Act, many manufactures are either no longer funding food and beverages as part of CME activities or are restricting meals to buffet or boxed meals only; CME is available to help you navigate through these new regulations as you plan your CME events.

Resources

Click on title to access website.

- Centers for Medicare & Medicaid Services
- American Medical Association
- Policy and Medicine