THE SUNSHINE ACT

ITS IMPLICATIONS FOR CONTINUING MEDICAL EDUCATION

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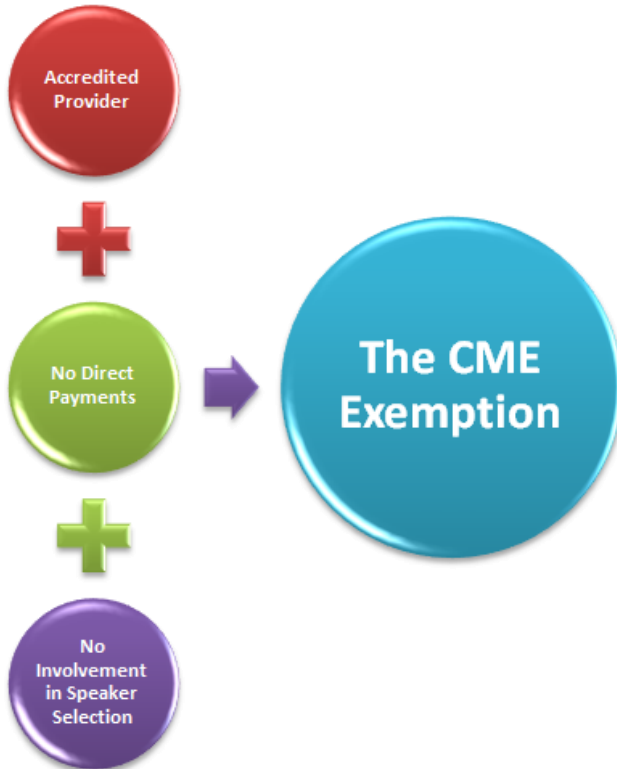
BACKGROUND

- Addresses "physician sunshine" provisions of The Affordable Care Act (a.k.a. "ObamaCare").

- Requires certain manufacturers of pharmaceuticals and medical devices to report to the US Centers for Medicare and Medicaid (CMS) payments of value to physicians and teaching hospitals.

- Payments made in association with certified CME activities are completely exempt from reporting if specific criteria are met.

BASIS FOR THE CME EXEMPTION

Payments to physician-speakers are exempt if the following three criteria:

- Such compensation relates to an event that is in compliance with the accreditation standards of the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Family Physicians (AAFP), American Dental Association (ADA), AMA, and the American Osteopathic Association (AOA)
- Payments are NOT made directly by the manufacturer
- The manufacturer cannot select the speaker or provide a list of individuals to be considered as speakers

SPECIAL MEAL REPORTING CRITERIA

Whether or not the educational activity is certified for CME, meals do not have to be reported for either attendees or speakers if:

- They are valued under $10, or
- They are provided at a buffet setting, or as a boxed take-away meal or a coffee break

TAKE AWAY: Do not ever offer plated meals at any event!

SUMMARY OF THE CME EXEMPTION

- CMS excluded reporting of any educational value associated with a CME event that meets all three criteria stated previously.

- Applicable manufacturers are not responsible for reporting payments made to CME vendors that are used to subsidize attendees' tuition fees for CME events.

CME ACTIVITIES THAT INCLUDE PROMOTIONAL EVENTS

- Manufacturers that support promotional events of any kind must report to the CME the value of meals, educational materials, speaker honoraria and travel.

- Reporting must include the name of the physician attendee or physician faculty together with the value of monies provided to them.

- This information will be posted on a CME website accessible by the public and other governmental institutions and agencies

CME ACTIVITIES THAT INCLUDE PROMOTIONAL EVENTS

- For CME activities that include promotional events (i.e., product theaters, non-CME certified portions or presentations, etc.), the previous information on payments must be broken out and provided to the CMS.

- The CME provider is not responsible for reporting to CMS, but the applicable manufacturer will require the CME provider to enumerate such information for them.

- Most physicians do not want their names on the public list and due caution is suggested before entering into any promotional event of any kind.

EXEMPTION APPLIES ONLY TO CME-CERTIFIED ACTIVITIES

- Reporting requirements only apply to physicians and not to nurses or other non-physician health professionals.

- The exemption DOES NOT APPLY to CE activities certified for nursing or pharmacy education in which a physician may attend
  - Therefore, reporting is required relative to physicians attending such non-CME certified events.

IMPORTANT NOTE REGARDING PAYMENTS TO ATTENDEES

For certain international meetings in which traditionally manufacturers have provided travel and registration funds directly to attendees to offset their costs of attending an international meeting, such payments are not permitted either by the ACCME or the AMA, and thus knowledge of such payments would break the exemption of the Sunshine Act for CME activities.

IMPORTANT NOTE REGARDING PAYMENTS TO ATTENDEES

Conversely, if an educational event was not certified for CME as a result of such payments to attendees, then requirements for reporting would now apply if the event were held in the United States.

SUNSHINE ACT RULE PERTAINING TO FELLOWS

While payments to medical residents was exempted from reporting requirements due to the fact that they generally do not as yet have a national provider identifier (NPI) number, the exemption DOES NOT APPLY to fellows in training because they do have a NPI.