

THE SUNSHINE ACT

*ITS IMPLICATIONS FOR CONTINUING
MEDICAL EDUCATION*



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BACKGROUND

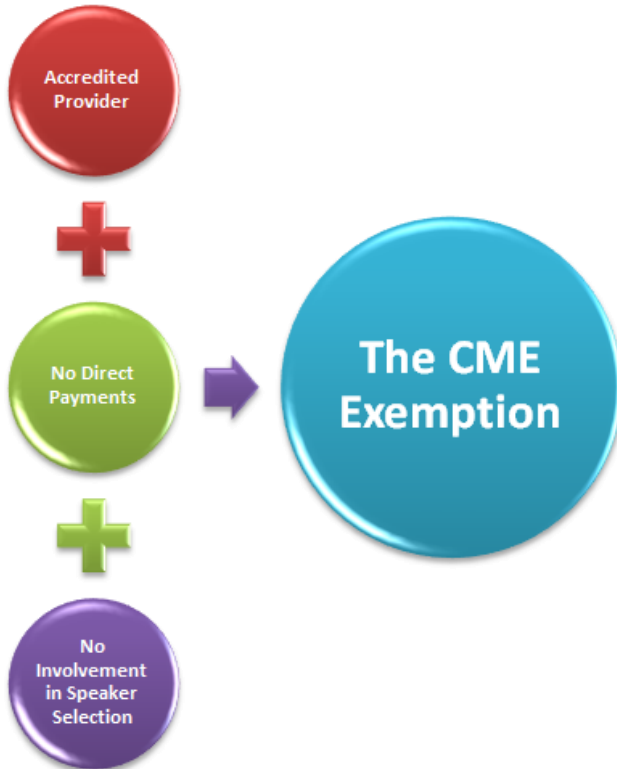
- Addresses “physician sunshine” provisions of The Affordable Care Act (a.k.a. “ObamaCare”).
- Requires certain manufacturers of pharmaceuticals and medical devices to report to the US Centers for Medicare and Medicaid (CMS) payments of value to physicians and teaching hospitals.
- Payments made in association 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

#	Data Element Name	Definition / Description	Data Type	Format	Required?	Field Size	Validation	Public Display
Submission File Information (this section contains data elements which are reported once per submission file)								
1	Applicable Manufacturer or Applicable GPO Submitting File Name	Textual proper name of either the Submitting Applicable Manufacturer or Submitting Applicable Group Purchasing Organization (GPO). If this file is a single Applicable Manufacturer/GPO's set of payments and/or transfer(s) of value records, this Applicable Manufacturer/GPO name will be used for all records in the file. If this file contains a Consolidated Report, this Applicable Manufacturer/GPO Name will be used as the Consolidated Reporter and the Applicable Manufacturer/GPO Names and OPEN PAYMENTS system IDs of the sub-companies making the payments/transfers of value will be recorded with every payment or transfer of value record in the file.	Text	Free form text	Yes	≤ 100 Char	Match the name on file for associated Registration ID	Yes
2	Applicable Manufacturer or Applicable GPO Submitting File Registration ID	OPEN PAYMENTS system generated identifier used to identify the Applicable Manufacturer or GPO (populated only with CMS provided identifier). If this file is a single Applicable Manufacturer/GPO's set of payment/transfer of value records, this Applicable Manufacturer/GPO ID will be used for all records in the file. If this file contains a Consolidated Report, this Applicable Manufacturer/GPO ID will be used as the Consolidated Reporter and the Applicable Manufacturer/GPO Names and OPEN PAYMENTS System IDs of the sub-companies making the payments/transfers of value will be recorded with every payment/transfer of value record in the file.	System generated	System generated	Yes	System generated	Match the Registration ID on file	No
3	Consolidated Report Indicator	Indicator showing if this submission file constitutes a Consolidated Report.	Boolean	"Y" = Yes; "N" = No	Yes	1 Char	Limited to characters Y or N	No
4	Resubmission File Indicator	Indicator showing if this submission file contains payment(s) and/or transfer(s) of value that are amended or corrected versions of previously submitted records.	Boolean	"Y" = Yes; "N" = No	Yes	1 Char	Limited to characters Y or N	No
5	Original File Submission ID	OPEN PAYMENTS system generated identifier used to identify the original file submission. This data will be reported to the submitter after a successful submission and should only be reported back in a resubmission for file identification purposes.	System generated	System generated	Yes IF Line 4 Resubmission File Indicator = "Y"	System generated	Matches Original File Submission ID on file for associated Registration ID	No
Submission Record Information (all sections from here to end of template contain data elements that are reported once per payment/transfer of value)								
Recipient Demographic Information								
6	Covered Recipient Type	Indicator showing if recipient of the payment or transfer of value is a physician covered recipient or a teaching hospital. Standardized list of covered Teaching Hospital names and information will be provided.	Enumeration	"1" = Physician "2" = Teaching Hospital	Yes	1 Char	Allowed values limited to: "1" or "2"	Yes
7	Teaching Hospital Name	The name of the Teaching Hospital receiving the payment or transfer of value. Standardized list of covered Teaching Hospital names and information will be provided.	Text	Text from Standardized Selection	Yes IF Line 6 is Covered Recipient Type = "2" (Teaching Hospital)	≤ 100 Char	Matches the hospital name provided in list for a given TIN	Yes
8	Teaching Hospital Tax ID Number (TIN)	Tax Identification number of Teaching Hospital receiving the payment or transfer of value. Standardized list of covered Teaching Hospital names and information will be provided.	Text	XXXXXXXXXX	Yes IF Line 6 is Covered Recipient Type = "2" (Teaching Hospital)	9 Char	Matches a TIN provided on teaching hospital list	No



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.

