



June 21, 2013

Dear CME Compliance Officer / General Counsel:

Given the impending August 1 implementation date for the Physician Payment Sunshine Act, as well as the prevalent confusion concerning some of its basic provisions, I wanted to share with you the following opinions and supporting documentation from the CME Coalition. The CME Coalition is a Washington, DC - based 501(c)(6) nonprofit organization that is comprised of 16 commercial supporters, CME providers, physician groups and other stakeholders dedicated to the promotion of accredited continuing medical education. I serve as its Senior Advisor, and we have been very engaged with CMS, the White House, Members of Congress, and numerous other stakeholders on Sunshine Act implementation over the past three years.

Although a certain degree of uncertainty lingers regarding the degree to which CMS is going to require the reporting or tracking of certain transfers of value, we strongly believe that there is ample guidance in the Final Rule to move forward with designing CME programs that are exempted from the Act's reporting requirements. And while we expect further guidance in the coming weeks concerning important issues regarding the treatment of meals, speaker travel costs and the treatment of non-listed accrediting bodies, we are confident that commercial supporters can move forward with CME programs that meet the following criteria (without the need to report any data). Simply put:

- 1.) The event must be accredited by one of the five accrediting bodies listed in the Final Rule, physicians may not receive payment or value directly from a manufacturer, and the manufacturer cannot select the speaker or provide a list of individuals to be considered as an event's speakers or attendees;
- 2.) Any meals or refreshments provided to attendees must be provided "buffet-style" in a "large group" setting; and

3.) Any costs related to a speakers' participation must meet the standards outlined by the accrediting body.

For your edification, I am attaching some documents which I hope will help to clarify the current state of affairs for you. First, I am attaching a legal memorandum commissioned by the CME Coalition from the law firm of Alston & Bird which lays out a conservative interpretation of the Final Rule, but also identifies a clear path for executing a "Sunshine-exempt" CME program. Secondly, I have included a list of questions and proposed answers that the CME Coalition submitted to CMS on April 25, 2013 seeking further clarification of the Final Rule on certain important topics. Third, please find the text of an email we sent to CMS on May 27 following our meeting, which outlines our positions on certain pending issues. And finally, please find a memorandum we drafted for CMS identifying other accrediting bodies that CMS should consider including in their list of recognized authorities.

Thank you,

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