

On behalf of Educational Measures, LLC, I write in response to Section III.I, Reports of Payments or Other Transfers of Value to Covered Recipients, within the Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015? proposed rule as published in the July 11, 2014, Federal Register.

On July 3, the Centers for Medicare and Medicaid Services (CMS) proposed eliminating the CME exemption? of the Sunshine Act, which explicitly exempts speaker compensation at certain accredited events from reporting requirements. As currently written, the Sunshine Act Final Rule requires three standards be met before a payment to a CME program can be considered Sunshine exempt.? First, the program must meet the accreditation or certification requirements of one of five explicitly mentioned bodies: ACCME, AOA, AMA, AAFP or ADA CERP. Second, the manufacturer must not select the speaker nor provide the CME provider with a set of individuals to be considered as speakers. Third, the manufacturer must not directly pay the speaker.

In an effort that it purports is intended to expand the list of educational events where speakers expenses would be exempt from reporting, on July 3rd, CMS proposed to remove the CME exemption in its entirety. According to CMS, speaker payments would now simply fall into the indirect payment? exemption of the Sunshine Act, which excludes from reporting any payments where the manufacturer remains "unaware" of the identity of the physician during the next 18-month period.

Educational Measures strongly disagrees with the proposal to remove the CME exemption as we believe its removal could ultimately expand the reporting requirements for accredited CME for the following reasons:

1. Unworkable Awareness Standard for CME: The indirect payment? exemption that CMS relies on disappears if, within 18 months, the applicable manufacturer finds out, or becomes aware? of the identity of the physician recipient. Because CME presenters are always publicly listed, as a practical matter, speaker payments will have to be reported as a general rule.

2. Attendees: Because current CMS guidance that CME event attendees are only exempt from reporting the educational value or the value of tuition-related materials provided at accredited CME events per Section 403.904(g), the entire status of attendees is now jeopardized as a result of the proposal to eliminate this very provision, and they may have to be considered (and reported) as indirect payments. CMS needs to clarify whether this reporting exemption still exists for attendees, and if so, what kind of events qualify.

3. Preamble vs. Final Rule: Whereas the revised rule being proposed would be silent on any special treatment for CME-related payments, CMS only suggests that indirect payments to speakers would be exempt from reporting in its proposed preamble to the Rule. This causes concern because preamble language on its own is not considered reliable from a legal standpoint. A definition or even acknowledgement of accredited or certified continuing medical education? would, therefore, be absent from the Final Rule, making the status of CME-related payments very uncertain.

We urge CMS to avoid discarding the CME exemption, which was carefully considered before it was enacted and remains critical to the education of our health care providers. We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have.