



Model Comment for CME Providers on the Physician Payment Sunshine Act Section 6002 of PPACA

When writing your comments it is important to be direct and respectful (i.e., we believe that the impact on CME was an unintended consequence.)

I. Introduction

- a. Summarize your comments

II. Background of your Organization

- a. Who you are, how many employees, how long you have been involved in educating physicians

III. Comment and Recommendations

- a. **Accredited, independent CME providers should be exempt from reporting**

- b. ***2 things CME Providers agree with***

- i. Agree with CMS' decision under §403.904 (d)(2)(vi) not to require reporting any offering of buffet meals, snacks or coffee at booths at conferences or similar events where it would be difficult to definitely establish the identities of the individuals who accept the offering.
 - ii. Affirms CMS' decision under §403.904(f)(4) to exclude from reporting educational materials that directly benefit patients or are intended for patient use.

- c. ***2 things CME Providers disagree with***

- i. CME providers (third parties) are not within the intent of the legislation and should be exempt.
 - 1. The “awareness” factor should not apply to accredited CME providers
 - ii. Payments for accredited CME programs and other educational programs must be distinguished clearly
 - 1. However, attributing a payment to CME faculty violates ACCME SCS

IV. The Important Role of CME to the Health Care System

- a. Improved Physician Knowledge, Competency
- b. Improved Patient Outcomes
- c. Reduced Costs, Increased efficiency, collaboration
- d. Lots of positive CME Outcome Studies

V. Private Support of CME

- a. No Bias – 3 large studies
- b. Rural / Inner City Areas
- c. High cost topics; technical; significant resources involved
- d. Best experts in the world

VI. Adequate Conflict Protections Already Exist for Accredited CME

- a. Describe the procedures you go through as a CME provider to ensure independence.
- b. Describe ACCME Enforcement
 - i. 2,4,6 year compliance review/reaccreditation

VII. The Sunshine Act Proposed Rule is Unworkable for Many Reasons

- a. FDA Required REMS - CME
 - i. FDA Penalties for companies not fulfilling REMS
- b. Disagree with CMS' interpretation of §403.904(f)(1) because it directly conflicts with FDA and OIG Guidance on industry-supported CME, ACCME Standards for Commercial Support, and the PhRMA and AdvaMed Codes ("industry codes") and CMS' interpretation underscores the significant penalties and fines CME providers already face under federal law.
 - i. Payments cannot be attributed directly from manufacturers to faculty
 - ii. Payments are made only from CME Providers
 - iii. CME Providers only pick faculty, no input from manufacturer
- c. Disagree with CMS' proposed interpretation of §403.904 (d)(2)(xiv) because this interpretation does not distinguish between accredited CME and other educational programs as described in detail below.

VIII. The Impact on CME Would be Devastating, Ultimately Harming Patient Outcomes

- a. Describe the impact the rules will have on your organization, loss of revenue, increased staffing for compliance.
- b. Proposed rules create significant responsibilities for CME providers to track payments based on applicable manufacturer reporting, not ACCME or other accrediting organization requirements.
- c. As each applicable manufacturer will have different systems and requirements for collecting, recording and reporting such information, each accredited provider would be accountable to align their systems with each applicable manufacturer,
- d. This would include tracking payments for food, travel, lodging and other incidental expenses, given that these categories are already specified in the proposed regulations under "nature of payment" categories

- e. Collecting, recording and reporting requirements will create significant financial, time and labor burdens to the majority of accredited providers, most of whom do not have the systems or support in place to even cursorily meet such obligations
- f. CMS did not calculate or estimate the economic impact this will have on CME stakeholders.