



September 2, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
ATTN: CMS-1612-P  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Tavenner:

On behalf of Med-IQ, LLC, an accredited provider of continuing medical education (CME), we wish to thank you for the opportunity to provide feedback on the proposed changes to guidance for the Open Payments reporting program.

While we recognize the value and support the Open Payments program to create transparency around the nature and extent of the relationship between industry and physicians, I am writing to express our deep concern with the proposed changes to the Medicare Policies' Physician Fee Schedule, specifically the provision regarding the Reports of Payments or Other Transfers of Value to Covered Recipients.

In reading the Proposed Rule Changes, three main themes are quite evident:

1. A proposed change to correct an unintended consequence of the current *§403.904(g)* regulatory text, which currently excludes reporting of payments associated with accredited or certified CME activities that meet the standards of the ACCME, AAFP, ADA CERP, AMA, and the AOA. The unintended consequence of naming certain accrediting bodies has implied an apparent endorsement by CMS of these groups, thus leading other accrediting organizations that follow similar strict guidelines as those outlined in *§403.904(g)(1)(i)* to seek similar exemption.
2. That CMS has no interest in reviewing the accreditation standards nor establishing an oversight process for enforcement of these standards, for any and all organizations seeking similar exemption
3. The proposed change to eliminate *§403.904(g)* because of redundancy with *§403.904(i)(1)* will create a new and significant unintended consequence of excluding all accredited and certified CME from the reporting exemption, because of the language contained therein, specifically "...if the manufacturer does not know (as defined in

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§403.902 the identity of the covered recipient during the reporting year of by the end of the second quarter of the following reporting year.” This new unintended consequence raises serious concerns because this type of information, while not available at the time the Letter of Agreement is signed between the CME organization and the Industry supporter, it is often freely available well before a CME activity takes place through various audience generation communications sent out by the CME organizations.

As such, we at Med-IQ respectfully submit for your consideration the following as a resolution to the Proposed Rule Changes:

1. We agree that the language in §403.904(g) should be removed because of redundancy with §403.904(i)(1).
2. We propose that language to §403.904(i)(I) be modified to add language that clarifies that exemption applies under section §403.904(i)(I) when an applicable commercial supporter provides funding or in-kind support to a CME provider but **does not**:
  - a. Know the identity of the covered recipient speaker/faculty at the time of execution of the Letter of Agreement between the commercial supporter and the CME provider
  - b. Select or pay the covered recipient speaker/faculty directly
  - c. Provide the CME provider with a list in any format of individuals to be considered as faculty/speakers
3. Additionally this guidance should specify under section §403.904(i)(I) that the CME provider must meet the accreditation or certification requirements and standards for continuing education and commercial support of their specific Accrediting Institution for which the activity is intended
4. Further, this guidance should clarify under section §403.904(i)(I) that if a commercial supporter becomes aware of the names of speakers/faculty after the commitment to support the activity was made, the activity would remain exempt.

Otherwise, it is our contention that the revised language would negate rather than expand the current exemption that is in place for accredited and certified CME. We are confident that this is not your intent.

I strongly urge you to consider these proposed modifications to ensure that indirect commercial support for accredited and certified CME activities, where the accredited provider exercises complete control over the content and speakers/faculty, remains exempt from reporting under the Open Payments system. It is vital to America’s patients that their healthcare providers remain well educated and informed on the latest medical science in their field and implement best

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medical practice based on current evidence-based science. Therefore, we must encourage and facilitate, rather than discourage, participation in CME.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Mencia", is positioned above the typed name.

William Mencia, MD, CCMEP  
Vice President, Education and Medical Affairs  
Medical Director  
Med-IQ

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