

n behalf of the California Academy of Family Physicians (CAFP), representing more than 8,700 California family physicians and medical students, 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.

CAFP supports the American Academy of Family Physicians? (AAFP) comments dated August 1, 2014. As an Accreditation Council for Continuing Medical Education (ACCME)-accredited organization with a long history of developing continuing medical education (CME) programming we submit comments independent of AAFP.

The CAFP strongly disagrees with the CMS proposal to delete the ?Continuing Education Exclusion? in 42 CFR 403.904(g); the deletion of Section 403.904(g) would create confusion and have the unintended and unwanted consequence of discouraging the development of and participation in CME programming. CMS made the right policy decision in its February 2013 Final Rule on Sunshine Act implementation when it recognized that indirect payments made to faculty at CME activities are not payments or transfers of value for the purposes of the Open Payment program and therefore do not need to be reported. CMS wisely created a bright line ?CME exemption? making it clear to physician participants that they could present at and attend accredited CME/CE programs without risking the stigma and reputational impact that accompanies listing in the Open Payments system. The 2013 Final Rule recognized the propriety of industry support for accredited/certified CME and of encouraging physician participation in accredited/certified CME programming; it acknowledged the standards met by accredited providers in protecting all content from any industry influence or bias.

The parameters of the CME exemption in Section 403.904(g) are clear and unambiguous; stakeholders have relied on them in planning, developing, offering, attending and documenting CME programs over the past 18 months since the final rule was published.

CMS now proposes to delete 42 CFR 403.904(g), in part, because the agency considers it redundant with the exclusion in 42 CFR 403.904(i)(1). In CAFP?s view, these sections are not the same. Section 403.904(i)(1) excludes ?indirect payments? or other transfers of value where the applicable manufacturer is ?unaware? of the covered recipient?s identity during the reporting year and for two quarters thereafter. Stakeholders have struggled to interpret Section 403.904(i)(1)?s terms and what is required of them thereunder and CMS?s guidance has not provided clarity. Section 403.904(i)(1) alone cannot provide the certainty and clarity needed to ensure the continued delivery of properly accredited and certified CME to the physician workforce.

The CME exemption of Section 403.904 (g) is important for CME attendees. CME providers such as CAFP receive commercial support for educational programming. Absent the specific exemption in 403.904(g), attendees may be less willing to participate in those programs ? even if the industry support for the program was completely independent and conflict-free ? if they believe their identity and attendance may become known to the commercial supporters and the value of the CME may thus be reported against them. The deletion of Section 403.904(g) may chill participation in valuable CME activities and hinder the adoption and spread of important new therapies and medical information, which in turn may negatively affect patients. The integration of new technologies, updated guidelines and change tools for practice behavior might also be affected should these recommendations be enacted.

CAFP appreciates and strongly supports CMS's insistence on having safeguards to ensure the ethical and independent production of CME. CAFP adheres to the Standards for Commercial Support (SCS): ACCME's Standards to Ensure the Independence of CME Activities. Compliance with those standards is a requirement for accreditation. CAFP also adheres to the CMSS Code for Interactions with Companies ? another gold standard for producing conflict-free, quality CME.

In conclusion, CAFP appreciates the opportunity to comment on the proposed rule; we are greatly concerned by this sudden and significant policy change to the Open Payments program, and we urge CMS to maintain the sound policy evidenced in Section 403.904(g) at this early stage in the implementation of Open Payments and to avoid hastily discarding the CME exemption.

We are happy to address any questions you might have. Please contact Deputy Executive Vice President Shelly B. Rodrigues, CAE (415) 345-8667, [srodrigues@familydocs.org](mailto:srodrigues@familydocs.org).