



AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

August 1, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Reports of payments or other transfers of value to covered recipients within the 2015 proposed Medicare physician fee schedule

Dear Administrator Tavenner:

On behalf of the American Academy of Family Physicians (AAFP), which represents 115,900 family physicians and medical students across the country, 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*. The AAFP looks forward to submitting an additional comment letter in response to other portions of the 2015 proposed Medicare physician fee schedule.

The AAFP strongly disagrees with the CMS proposal to delete the “Continuing Education Exclusion” found in 42 CFR 403.904(g) in its entirety. CMS suggests that the deletion of Section 403.904(g) would remove an unintended redundancy from the final rule and expand the range of educational events that are appropriately exempt from reporting. We believe the deletion of the section would do neither. Moreover, the suggested change would create more confusion and more unintended and unwanted consequences than it purports to resolve.

In issuing the final rule on February 1, 2013, CMS recognized that industry support for accredited or certified CME is a unique relationship that calls for a unique treatment. That remains unchanged today. Physicians must stay up to date on the latest medical research and medications so they can provide the most appropriate care to their patients. Each year, this research results in new treatment breakthroughs, medications, diagnostic procedures, and clinical guidelines. Communication between physicians, device manufacturers, and pharmaceutical companies is critical if physicians are to remain current with the latest research and provide state-of-the-art care that the public deserves. Industry-supported CME, which strictly adhere to the “Standards for Commercial Support (SCS): Standards to

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Ensure the Independence of continuing medical education (CME) Activities” of the Accreditation Council for Continuing Medical Education (ACCME), which outlines standards for relationships between Accredited and Certified CME Providers is a vitally important resource for physicians to learn new information as it becomes available.

In recognition of this reality, CMS made the right policy decision when it issued the final rule indicating that indirect payments made to faculty at CME activities are not indirect payments or otherwise transfers of value for the purposes of the Open Payment program and therefore do not need to be reported when all of the following conditions are met:

- The event at which the covered recipient is speaking meets the accreditation or certification requirements and standards for continuing education of one of the following:
 - The Accreditation Council for Continuing Medical Education (ACCME);
 - The American Academy of Family Physicians;
 - The American Dental Association’s Continuing Education Recognition Program;
 - The American Medical Association;
 - The American Osteopathic Association;
- The applicable manufacturer does not pay the covered recipient speaker directly.
- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.

The parameters of the CME exemption in Section 403.904(g) are clear and unambiguous, and stakeholders have relied upon them in planning, developing, offering, attending and documenting CME programs over the past eighteen 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). Although there may be overlap between the two sections, they 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. Nor can the imperfectly and inconsistently understood Section 403.904(i)(1) alone provide the certainty and clarity needed to ensure the continued delivery of properly accredited and certified CME to the physician workforce who needs it.

The CME exemption of Section 403.904(g) is important for CME attendees. CME providers such as the AAFP who receive commercial support for part of the educational program may provide educational items, such as handouts, slides and abstracts. Currently, the CME exemption of Section 403.904(g) excludes reporting of those items. But absent that specific exemption, 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.

To the extent that leaving both Sections 403.904(g) and 403.904(i)(1) in place creates some overlap or redundancy, no additional confusion or adverse consequences arise, but removing Section 403.904(g) in favor of 403.904(i)(1) would be trading the clearer and more certain provision for the murkier and more problematic one. That unnecessary and ill-advised trade 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 impact patients.

Further, CMS specified the five organizations in Section 403.904(g) not because of a drafting accident, but because those five organizations had proven track records for adherence to stringent standards to ensure integrity in providing CME by maintaining and guaranteeing the CME provider's discretion and independence from inappropriate industry control. As the nation's leading CME provider organization for one of the nation's largest physician member specialty societies, as well as one of the three national CME credit systems for physicians, the AAFP appreciates and strongly supports CMS' insistence on having safeguards in place to ensure CME independence, validity, and relevance. CMS recognized that the AAFP and others strictly adhere to the "Standards for Commercial Support (SCS): Standards to Ensure the Independence of continuing medical education (CME) Activities" of the Accreditation Council for Continuing Medical Education (ACCME), which outlines standards for relationships between Accredited and Certified CME Providers and the companies that may provide grants to those providers. Notably, under the SCS, faculty of certified and accredited CME programs must be selected, directed, reviewed, evaluated, and paid by the Accredited CME providers and must have no relationship with the manufacturers. The AAFP closely monitors its adherence to the SCS, and compliance with those standards is a requirement for our credit certification. The AAFP also adheres to the CMSS Code for Interactions with Companies – another gold standard for producing conflict-free, quality CME.

The AAFP urges CMS to specify that certified or accredited CME by the five organizations named in the final rule remain exempt in order to preserve the distinction between certified or accredited CME and other educational programming. Any additional bodies that are allowed to take advantage of the Section 403.904(g) CME exemption should comply with standards as stringent as the standards that govern the five accrediting bodies that are currently listed there. If, out of concern for seeming to favor these five organizations with proven compliance track records or for some other reason, CMS insists those five bodies must not be named in the rule, then at the very least the AAFP urges CMS to modify rather than eliminate Section 403.904(g) so that it exempts only CME activities that bear credit from a national credit system and/or are offered by an organization that strictly adheres to the SCS standards that ensure the independence of CME activities of the AACME but otherwise preserves the specific CME exemption.

Furthermore, as a provider of accredited CME, the AAFP continues to have substantial interactions with manufacturers that provide grants to fund accredited CME. We remain alarmed at the vastly inconsistent interpretations of the indirect transfer standards. While CMS in 403.904(i)(1) refers back to the definition of an indirect transfer in 403.902, in interpreting the rule, manufacturers often do not. Section 403.902 makes clear that indirect transfers of value made by an applicable manufacturer to a covered recipient are only reportable if the applicable manufacturer "requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s)." The AAFP believes manufacturers have taken a conservative approach to the

indirect payment language of the rule, often applying only the knowledge standard without consideration of whether the manufacturer required, instructed, or directed an indirect transfer to occur. This results in significant administrative burden and potential over-reporting of indirect transfers by third parties including accredited CME providers. To prevent burdensome over-reporting, the CME exemption should remain explicit.

In addition to preserving the CME exemption, the AAFP also urges CMS to simultaneously reduce the administrative burden and potential over-reporting of indirect transfers of value through excluding CME activities where the industry donor is unaware of the speakers and other participants before committing to fund the activity. This would accomplish CMS' goal of expanding the range of educational events that are appropriately exempt from reporting while simultaneously eliminating the potential for negatively impacting CME.

While we welcome this opportunity to provide comments, the AAFP is disappointed CMS would suggest making such a sudden and significant policy change to the Open Payments program, especially during its infancy, since the proposed change would needlessly increase disruptions to the valid relationships between the medical professional community and the drug and device industries. We urge CMS to stay its hand at this early stage in the implementation of Open Payments and to avoid hastily discarding the CME exemption, which was carefully considered before it was enacted and which remains critical to the education of our health care providers and consequently to the health of the public.

In conclusion the AAFP remains significantly concerned that the proposed change, if finalized, would create an inadvertent barrier to the development and delivery of high quality certified or accredited CME with the final result of negatively affecting care provided to patients. We appreciate the opportunity to provide these comments and make ourselves available for any questions you might have. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,

A handwritten signature in black ink, appearing to be 'J. Cain', with a long horizontal flourish extending to the right.

Jeffrey J. Cain, MD, FAAFP
Board Chair