



August 19, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
PO 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

On behalf of the North Carolina Academy of Family Physicians (AAFP), which represents 3,600 family physicians and medical students across our state, we would like to reiterate the comments of the American Academy of Family Physicians 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 NCAFP 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 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.

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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 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.

In addition to preserving the CME exemption, the NCAFP 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.

In conclusion, the NCAFP remains 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.

With best regards,



William A. Dennis, MD
NCAFP President