



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

August 27, 2014

Dear Ms. Tavenner:

The National Comprehensive Cancer Network (NCCN), an alliance of 25 of the world’s leading cancer centers, welcomes the opportunity to comment on 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”, as published in the July 11, 2014 Federal Register notice.

Continuing medical education (CME) is a vital component of our health care system because it allows health care providers the opportunity to keep current with and remain proficient in scientific and treatment advances. Accredited CME is the gold standard of continuing medical education. Because of the importance of CME to the medical and scientific community, NCCN strongly disagrees with CMS’s proposal to delete the “Continuing Education Exclusion” found in 42 CFR 403.904(g) in its entirety.

CMS 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, we do not believe they are 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*, whereas Section 403.904(g) states that an applicable manufacturer is unaware of the identity of the covered recipient if the manufacturer does not know the identity of the covered recipient *prior to the payment or transfer of value*. Ensuring that an applicable manufacturer remains unaware of speakers in the timeframe suggested in 403.904(i)(1) is nearly impossible. Applicable manufacturers can learn the identities of speakers through brochures, programs, and other publications, or through their employees’ attendance at the CME activities. Since the applicable manufacturer is unable to influence the content, speakers, or attendees of an accredited CME event, then it is irrelevant whether the applicable manufacturer becomes aware of the identity of any covered recipient(s).

The CME exemption of Section 403.904(g) is also important for CME attendees. CME providers such as NCCN who receive commercial support for education programs may provide educational items, such as handouts, slides, and abstracts to enhance and solidify the participant

Fred & Pamela Buffett Cancer Center at The Nebraska Medical Center

City of Hope Comprehensive Cancer Center

Dana-Farber/Brigham and Women’s Cancer Center | Massachusetts General Hospital Cancer Center

Duke Cancer Institute

Fox Chase Cancer Center

Huntsman Cancer Institute at the University of Utah

Fred Hutchinson Cancer Research Center/ Seattle Cancer Care Alliance

The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

Robert H. Lurie Comprehensive Cancer Center of Northwestern University

Mayo Clinic Cancer Center

Memorial Sloan Kettering Cancer Center

Moffitt Cancer Center

The Ohio State University Comprehensive Cancer Center - James Cancer Hospital and Solove Research Institute

Roswell Park Cancer Institute

Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine

St. Jude Children’s Research Hospital/ The University of Tennessee Health Science Center

Stanford Cancer Institute

University of Alabama at Birmingham Comprehensive Cancer Center

UC San Diego Moores Cancer Center

UCSF Helen Diller Family Comprehensive Cancer Center

University of Colorado Cancer Center

University of Michigan Comprehensive Cancer Center

The University of Texas MD Anderson Cancer Center

Vanderbilt-Ingram Cancer Center

Yale Cancer Center/Smilow Cancer Hospital

educational experience. Currently, the CME exemption of Section 403.904(g) excludes reporting of these items. Absent that specific exemption, potential attendees are likely to be less willing to participate in those programs if they believe their identity and attendance may be become known to the commercial supporters and the value of the educational materials may thus be reported.

If CMS removes Section 403.904(g) in its entirety, we recommend that Section 402.904(i)(1) be modified to include the following language: “the exemption applies when an applicable manufacturer provides funding to a CME provider, but does not select or pay the covered recipient speaker directly nor provide the CME provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CME program.” However, it should be noted that NCCN supports the current CMS exclusions for CME programs accredited by ACCME and other agreed-upon accrediting organizations; we do not share the concern expressed by CMS that including a short list of acceptable accrediting organizations by name could imply CMS’s endorsement of the named continuing education providers over others.

NCCN is concerned about and disagrees with CMS’ proposed sudden and significant policy change to the Open Payments program. The proposed change would increase disruptions to appropriate and beneficial relationships between the medical community and the drug and device industries. We urge CMS to maintain the current system and to avoid hastily discarding the CME exemption, which was carefully considered before it was enacted and which remains critical to the education of healthcare providers and, consequently, patient health. We believe that if the proposed changes are finalized, they will create an inadvertent and unnecessary barrier to the development and delivery of high quality, accredited CME. The health of the public would ultimately be negatively affected.

We appreciate the opportunity to comment on the proposed changes. Please do not hesitate to contact Jessica DeMartino, PhD, Manager of Health Policy Programs at (215)690-0245 or demartino@nccn.org with any clarifying questions or comments. At your request, NCCN would welcome the opportunity to meet with CMS colleagues to discuss our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert Carlson", written in a cursive style.

Robert Carlson, MD  
Chief Executive Officer