

February 15, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5060-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests"; 42 CFR Parts 402 and 403 [CMS-5060-P] RIN 0938-AR33

Dear Acting Administrator Tavenner:

On behalf of our more than 13,000 physicians, scientists, and other health professionals, the American Society of Nephrology (ASN) thanks you for the opportunity to provide comments on the proposed rule, "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests"; 42 CFR Parts 402 and 403 [CMS-5060-P] RIN 0938-AR33.

ASN is a not-for-profit organization providing the highest quality education for kidney professionals worldwide. Approximately 14,000 professionals attend ASN Kidney Week, the premier kidney meeting in the world. The society also produces myriad educational opportunities and publishes the two most widely read peer-reviewed journals in kidney medicine. ASN supports educational and scientific objectivity and institutional integrity through disclosure, evaluation, standardization, and transparency.

ASN appreciates CMS's efforts to bring greater transparency to transfers of value from drug, biologic, and medical device manufacturers to physicians. ASN is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education (CME) for physicians.

For the purposes of this letter, it is important to clarify the difference between Accredited CME and Certified CME. "Accredited CME" refers to CME activities that meet the requirements and standards of a CME accrediting body, such as the ACCME. "Certified CME" refers to CME activities for which medical professionals may claim CME credit, which is offered by the American Medical Association and two other organizations.

On page 78750 of the proposed rule, CMS proposes that there should be no differentiation between faculty speaking at CME-accredited educational activities and faculty speaking at other types of events, including those organized by a Medical Education Program. ASN strongly recommends that CMS reconsider this proposal. ACCME Standards for Commercial Support mandate that CME providers ensure that all CME planning decisions—including faculty

selection—are made independently from any commercial interest, and that commercial interests cannot take the role of an accredited partner in a joint sponsorship relationship.

Faculty speakers in Accredited and Certified CME programs are selected, and financially supported for their time, exclusively by the certified CME provider. None of these speakers has any relationship with any applicable manufacturer (even if a manufacturer is supporting the CME activity through an educational grant to the CME Provider). In contrast, faculty speaking at a Medical Education Program are selected by and receive direct financial support from the applicable manufacturer sponsoring the program. This is an important difference, and ASN urges the agency to make this distinction in the final rule.

On page 78750 of the proposed rule, CMS proposes that “Any payment or other transfer of value...must be reported, if the applicable manufacturer is aware of the covered recipients’ identity.” ASN agrees with CMS that in instances where the applicable manufacturer is not aware of the covered recipient’s identity, it is not necessary for the applicable manufacturer to report the payment to the CME provider. When a manufacturer makes an educational grant to a CME provider, a relationship is established only between the manufacturer and that CME provider; it does not establish any relationship between the eventual faculty and participants in the CME activity.

To summarize, ASN concurs with CMS that support from applicable manufacturers to CME Providers for Accredited and Certified CME activities does not constitute an indirect transfer of value to faculty or individuals who may participate in the CME activity in the future (but who are unknown at the time of the transfer to the CME provider). Therefore, the final rule should specify that payments to the CME Providers should not be reported as indirect transfers of value to the CME participants.

ASN appreciates the opportunity to provide CMS comments on the proposed Physician Payments Sunshine Act rule and welcomes the opportunity to discuss them further. To discuss this letter or ASN’s comments on the proposed rule, please contact ASN Manager of Policy and Government Affairs Rachel Shaffer at (202) 640-4659 or rshaffer@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald J. Falk". The signature is fluid and cursive, with the first name "Ronald" and last name "Falk" clearly distinguishable.

Ronald J. Falk, MD, FASN
President

cc: Rachel Shaffer