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September 2, 2014

Ms. Marilyn B. Tavenner, Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Re: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2015; CMS-1612-P

Dear Ms. Tavenner:

On behalf of 4,000 practicing neurosurgeons in the United States, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate the opportunity to comment on the proposal to eliminate the exemption for continuing medical education (CME) from Open Payments reporting, which was included in the above referenced Notice of Proposed Rulemaking (NPRM). We have submitted comments related to the quality and payment provisions in separate comment letters.

The AANS and CNS strongly oppose the elimination of the Open Payments CME exemption. Whether the exemption is duplicative or not, the proposed elimination represents a complete reversal of a policy that was included in the Sunshine Act final rule, which had been thoroughly reviewed and vetted by all stakeholders. If your proposal is adopted, it would have a chilling effect on *appropriate* and *vital* industry support of CME, and would expose physicians and physician organizations to additional unnecessary administrative hassles associated with the Open Payments reporting and verification system.

As members of the Council of Medical Specialty Societies (CMSS), we fully endorse the comments that CMSS submitted to CMS and would like to take this opportunity to highlight the following points:

- **Accrediting Organizations.** CMS states that it has been asked by several groups to be recognized as accrediting organizations. This could be easily done by CMS and would in no way imply an endorsement by the agency. Such is the case in other instances where Medicare recognizes the organizations who set standards for various health care stakeholders, including the Joint Commission (hospitals), state medical licensing boards (physicians) and the Accreditation Council for Graduate Medical Education (residency training programs). Recognizing groups that accredit and certify continuing medical organization is no

different. It is imperative that CMS recognize the distinction between accredited and certified CME offered by healthcare professional organizations for the improvement and maintenance of knowledge and skills, as opposed to those programs promoted directly by industry. The elimination of the CME exemption would actually blur the lines, rather than bolster accredited CME conducted under the Accreditation Council for Continuing Medical Education's (ACCME) *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*. Should CMS wish to consider other accreditors or other equivalent standards, a mechanism exists to do so. An inter-professional coalition of accreditors of continuing education in the health professions called, *Joint Accreditation*, has been convened since 2009 and is a collaboration of ACCME, the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC). This is the function of professional self-regulation, does not require additional governmental regulation, and could easily be recognized by CMS for the purposes of the Open Payments CMS exemption.

- **Duplicative policy.** We believe that the fact that other provisions in the Open Payments policy (i.e., indirect benefit policy) may recognize that CME payments are exempt from reporting is not a reason to scrap the CME exemption. Furthermore, it is not clear that such policies will appropriately exempt industry from its reporting requirements given the way accredited CME programs are developed and marketed. As you may know, CME programs are planned and promoted months, and sometimes years, in advance. Many CME programs are planned and promoted to their intended audiences far enough in advance that attainment of commercial support grants by the CME provider is incomplete. Moreover, as faculty are selected and identified during the activity planning process by the accredited CME provider, their names are promoted in the activity programming to the intended audience. It is not realistic, nor would it be perceived as transparent, if faculty names were hidden until the day of the program, nor would physicians attend such programs. As a result, over time during the planning process, even if the company does not request faculty names, companies providing commercial support to CME providers will potentially learn the names of the faculty, usually before the program, and certainly within two quarters after the program, through promotion of the program itself.

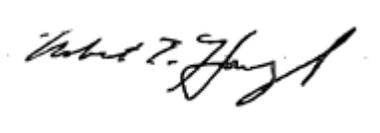
The current bright-line rule exempting industry support of certain CME programs from the Open Payments reporting requirements is well understood and more appropriate, regardless of the fact that CMS views this exemption as unnecessarily duplicative.

- **Compliance/Administrative burdens.** Physicians, physician specialty societies and industry have been operating under the current CME exemption for well over year. As mentioned above, CME programs are often planned years in advance. Thus, it is unreasonable for CMS to change the rules without adequate advanced notice to physicians and those groups planning and providing accredited CME. At a minimum, a change in the CME policy should be delayed until organizations and CMS can fully analyze the impact of the proposal to eliminate the current exemption. Furthermore, changing the policy will likely subject more physicians to the industry reporting requirements. This additional reporting and verification burden is unnecessary and will not result in any material benefit to patients.

The AANS and CNS appreciate the opportunity to comment on this proposed regulation. As always, we recognize the hard work and expertise of the individuals dedicated to Medicare policy. We recognize that many of the actions taken by the agency are mandated by law and we urge you to implement these mandates in the least burdensome way. In this vein, we therefore urge CMS to maintain the current Open Payments CME exemption.

Thank you for considering our comments. If you have any questions, or need additional information, please feel free to contact us.

Sincerely,



Robert E. Harbaugh, MD, President
American Association of Neurological Surgeons
Surgeons



Daniel K. Resnick, MD, President
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