



August 22, 2014

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

Dear Administrator Tavenner:

On behalf of the more than 100,000 certified physician assistants (PAs) represented by the American Academy of Physician Assistants (AAPA), thank you for the opportunity to submit comments to CMS' proposal to eliminate the exclusion for accredited and certified continuing education (Section 403.904(g)) under the Open Payments program of the Sunshine Act. AAPA is very appreciative of CMS' recognition of the unintended consequences of the exclusion, as well as CMS' willingness to explore alternative ways to clarify that accredited continuing medical education is exempt from the Sunshine Act's reporting requirements.

As previously communicated, AAPA is very concerned with the impact of the current Open Payments program regulation's limited exclusion of continuing medical education (CME) and continuing education (CE) accredited by the five specified accrediting bodies. Although the Sunshine Act does not cover PAs, establishing a regulatory exemption for CME accredited by the five bodies created confusion regarding the reporting of CME provided by AAPA and AAPA affiliated organizations. Additionally, the guidance posed a threat to AAPA CME/CE independence from commercial influence. CMS' proposal to eliminate Section 403.904(g) should resolve the unintended consequences for AAPA and its affiliated organizations. However, if CMS re-evaluates the proposed regulatory change and determines the exclusion is necessary to distinguish accredited CME/CE activities from promotional education, AAPA strongly encourages CMS to add AAPA to the specified list of accreditors of CME and CE who are exempt from reporting through the Sunshine Act.

AAPA believes neither faculty nor attendees at certified and accredited CME should be subject to the reporting requirements of the Sunshine Act's Open Payments program. AAPA also believes a distinction should be made between accredited/certified CME and the promotional education of healthcare professionals offered by companies. Accordingly, AAPA recommends, in the absence of endorsing a list of accrediting bodies, CMS make clear that acceptable accrediting bodies must adhere to the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support: Standards to Ensure Independence in CME Activities* or equivalent standards. AAPA has endorsed the ACCME Standards for Commercial Support and applies them to our CME accreditation processes.

Additionally, AAPA is concerned with the ambiguity surrounding “awareness” of a company in knowing names of CME faculty, particularly in a time based rule. Reporting faculty information is often released as part of advance planning, promotion, and marketing of CME programs. Additionally, the reporting of faculty information is typically reported at the time of grant reconciliation, which occurs after the conclusion of the in-person CME activity, but could very well occur during the reporting year or by the end of the second quarter of the following reporting year. In lieu of reporting if a company knows names within two quarters after an event, AAPA again recommends CMS consider participation in certified or accredited CME that adheres to the ACCME Standards for Commercial Support or equivalent standards exempt from the reporting requirements of the Sunshine Act’s Open Payments program,

Again, thank you for your attempt to simplify the reporting requirements and address unintended consequences resulting from the CMS regulations regarding CME/CE activities through the Sunshine Act Open Payments program. AAPA appreciates the intent of the Sunshine Act to increase transparency of transfers of value from industry to physicians, which have the potential to create bias. Additionally, AAPA appreciates the monumental work accomplished by CMS in implementing the law. Please do not hesitate to have your staff contact Sandy Harding, AAPA senior director of federal advocacy, at sharding@aapa.org or 571-319-4338 for additional information.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John McGinnity". The signature is stylized and cursive, with a large initial "J" and "M".

John McGinnity, MS, PA-C, DFAAPA
President