

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

Re: 42 CFR Parts 403, 405, 410, et al. 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

The American Dental Association (ADA) is the world's oldest and largest dental professional organization, representing 157,000 dentists in the United States. The ADA is committed to the public's oral health, ethics, science and professional advancement and access to dental care for all Americans.

### **Continuing Education Exclusion (§ 403.904(g)(1))**

The ADA does not support removal of §403.904(g) from the "Open Payments (Sunshine Act)" program. The ADA believes that commercially supported continuing education activities should be exempt from reporting under Open Payments if the activities are offered by providers formally accredited or approved through programs with requirements for transparency and full disclosure, such as the American Dental Association's Continuing Education Recognition Program (ADA CERP), and the activities meet the criteria currently outlined in §403.904(g).

ADA CERP, established in 1993, reviews and approves providers of continuing dental education based on demonstrated compliance with fourteen Recognition Standards. The principles of the ADA's Continuing Education Recognition Program (CERP) support transparency in continuing dental education. Standard V of the ADA CERP Recognition Standards requires CERP approved providers of continuing education to disclose any commercial support received for continuing education activities. Standard V also requires individual instructors and CE planners to disclose relevant financial relationships they may have with commercial interests. CE providers are required to publish these disclosures. A copy of the CERP standards is attached.

The ADA is concerned that the indirect payment exemption, which CMS suggests will preserve the CE reporting exemption, would not protect accredited/certified continuing education. The indirect payment exemption will not apply to most accredited/certified CE because publicity materials for continuing education activities are typically published in advance of activities, so an applicable manufacturer providing funding for an activity would "know" (as defined in §403.902) the speaker's identity and would thus be required to report this as an indirect payment, even if the applicable manufacturer did not select or suggest the speakers to the continuing education provider.

The proposed change would likely, and perversely, incentivize manufacturers to offer unaccredited, non-certified CE classes and to select speakers for CE courses offered through a third party. Maintaining the CE exemption will benefit patients and the public in a number of ways. First, the exemption helps avoid the proliferation of innocuous and unhelpful information on the Open Payments website. Consumers may be confused when too much information is presented, and particularly by information that is not indicative of any potential conflict of interest or wrongdoing. As CMS points out in connection with proposed changes to the Physician Compare website, "Consumer testing has shown including too much information and/or measures that are not well understood by consumers on these pages can negatively impact a consumer's ability to make informed decisions."

Moreover, the proposed change would be confusing and disruptive. Speakers, manufacturers, and CE organizations would need to be re-informed about this reporting exemption when they are still

September 2, 2014  
Page 2

struggling to comprehend the existing regulatory scheme that was put in place only last year. Indeed, many have likely already made decisions based on the CE exemption for speaker compensation that, if the exemption is eliminated, would be reportable in upcoming years.

The ADA believes that any changes to Open Payments should be delayed for several years so that experience with the current system can be evaluated.

Whatever small increase in transparency that eliminating the exemption might engender, the marginal benefit would not outweigh the resulting negative impact it would have on the transfer of knowledge. The proposal would de-incentivize continuing education providers to the detriment of patients, and could have a chilling effect on doctors who would otherwise be willing to serve as faculty in accredited or certified CE programs. Since new scientific knowledge and new techniques and technologies are frequently communicated via accredited and certified continuing education, the proposed rule change could stymie the safe, effective adoption of new products and technologies that benefit patients and the public.

**Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models**  
**(Pages 40376-40378 of the Proposed Rule)**

CMS proposes that CMS and its contractors have access to identifiable patient data, regardless of payor, to conduct research for the Center for Medicare & Medicaid Innovation (the "Innovation Center"). However, CMS has not adequately articulated a rationale for requiring patient data in an identifiable format. The ADA believes that de-identified data would serve CMS's purpose equally as well, while not eroding patient privacy. To the extent that CMS has a need for identifiable patient data, this need does not outweigh the privacy risk to patients.

ADA urges CMS to develop technology to de-identify all patient data to HIPAA standards in order to protect patients from the real and potentially significant financial and reputational harm that could result from a breach or misuse of their individually identifiable patient information.

If CMS nevertheless collects identifiable patient data, ADA urges CMS to agree to (1) comply with all requirements that would be imposed on a HIPAA business associate and require that all agencies, contractors and individuals who have access to the patient data also be required to comply with such requirements, and (2) ensure that any identifiable or de-identified patient data is not used or disclosed for any purpose other than testing innovation payment and service delivery models by the Innovation Center.

For additional information please contact Dr. Frank A. Kyle, Jr., Manager, Legislative and Regulatory Policy, ADA Government and Public Affairs Division at 202-789-5175 or [kylef@ada.org](mailto:kylef@ada.org).

Sincerely,



Charles H. Norman, D.D.S.  
President



Kathleen T. O'Loughlin, D.M.D. M.P.H.  
Executive Director

Attachment: ADA Continuing Education Recognition Program (CERP) – Recognition Standards and Procedures, May 2014