



September 2, 2014

Centers for Medicare and Medicaid Services (CMS)
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 Academy of General Dentistry (AGD) is the world's second largest dental professional organization, representing over 39,000 dentists. A stated mission of the AGD is "to foster continued proficiency of general dentists through quality continuing dental education in order to better serve the public."

CMS has proposed the rescission of §403.904(g) from the "Open Payments (Sunshine Act)" program, with consideration of two alternatives: 1) expanding the list of organizations in §403.904(g)(1) *by name*, or 2) expanding the list of organizations in §403.904(g)(1) *by articulating the specific accreditation or certification standards that would warrant the exemption*. According to the Federal Register, the reason for considering rescission of §403.904(g) is that "CMS' apparent endorsement or support to organizations sponsoring continuing education events [in §403.904(g)(1)] was an unintended consequence of the final rule."

Conversely, the *intended* consequences of the final rule are stated clearly by CMS in that, "if an applicable manufacturer conveys 'full discretion' to the continuing education provider, those payments are outside the scope of the rule (78 FR 9492). In contrast, when an applicable manufacturer conditions its financial sponsorship of a continuing education event on the participation of *particular covered recipients*, or *pays a covered recipient directly* for speaking at such an event, those payments are subject to disclosure." *Emphasis added.*

The AGD supports these *intended consequences* of the final rule as stated by CMS.

CMS identified §403.904(i)(1) as meeting its intent. However, §403.904(i)(1) does not meet CMS' intent. The reason is as follows. If a manufacturer conveys full discretion to the continuing education provider, does not select the speaker, and does not directly pay the speaker, the event nonetheless fails to meet the criteria for exemption under §403.904(i)(1) if the manufacturer learns of the application of its payment to a speaker after the event, for example, by coming across a publication of the organization that held the event.

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The AGD offers an alternative solution that has yet to be considered by CMS, and which appears to meet CMS' intended consequences while avoiding the appearance of the stated unintended consequence. The alternative solution would be to revise §403.904(i)(1) as follows, concurrent with the deletion of §403.904(g):

~~Indirect payments or other transfers of value (as defined in §403.902), where the applicable manufacturer has not selected the covered recipient speaker or provided the third party (such as a continuing education vendor) with a distinct identifiable set of individuals to be considered as speakers for the continuing education program. is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in §403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.~~

If §403.904(i)(1) is not revised as shown above, then §403.904(g) cannot be deleted. Moreover, if §403.904(i)(1) is not revised as shown above, then the AGD would only support either of the alternatives stated by CMS in the Federal Register - 1) expanding the list of organizations in §403.904(g)(1) *by name*, or 2) expanding the list of organizations in §403.904(g)(1) by articulating the specific accreditation or certification standards that would warrant the exemption – on the condition that said expansion include the Academy of General Dentistry, or the AGD's Program Approval for Continuing Education (PACE), respectively, depending upon the alternative chosen.

AGD began approving continuing dental education providers in 1988. Known first as the AGD National Sponsor Approval Program (NSAP), the AGD changed the program's name in 2000 to Program Approval for Continuing Education (PACE) to better describe its goal. AGD PACE reviews and approves providers of continuing dental education based on demonstrated compliance with thirteen Approval Standards. The principles of the AGD PACE Program support transparency in continuing dental education. Standard XII of the AGD PACE Standards requires PACE approved providers of continuing education to disclose any commercial support received for continuing education activities. Standard XII also requires individual instructors, authors and CE planners to disclose any potential commercial conflicts to potential audiences.

For additional information, please contact Ms. Lynda Lipske, Manager, AGD PACE, at 312-440-4335 or lynda.lipske@agd.org

Sincerely,



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Cc: John A. Thorner, JD, CAE, Executive Director/CEO, AGD

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