



**Joint Council of Allergy,
Asthma & Immunology**

ACAAI
**American College
of Allergy, Asthma
& Immunology**

August 13, 2014

Submitted to www.regulations.gov

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, Maryland

Re: Revisions to the Sunshine Act Under the Medicare Physician Fee Schedule for CY 2015, CMS-1612-P

Dear Administrator Tavenner:

The American College of Allergy, Asthma & Immunology (ACAAI) and the Joint Council of Allergy, Asthma and Immunology (JCAAI) appreciate the opportunity to submit these joint comments on the Centers for Medicare and Medicaid Services' (CMS') proposed changes to the Open Payments System, otherwise known as the Sunshine Act, recently published in the CY 2015 Physician Fee Schedule (PFS) proposed rule. The ACAAI and the JCAAI members include approximately 3,000 physicians who are board-certified or board-eligible in Allergy and Immunology. Our organizations support the goals of the Sunshine Act to promote transparency with respect to relationships between physicians and drug and device manufacturers. However, the ACAAI and the JCAAI have serious concerns about CMS' proposed removal of the exemption for Continuing Medical Education (CME) payments made by manufacturers to support speakers or faculty at CME programs. The ACAAI and the JCAAI also share continued concerns about CMS' interpretation of the educational materials exception under the Sunshine Act and the short timeline and complicated process for physicians to register in the open payments system and dispute a manufacturer's reported payment.

1. Proposed Removal of the CME Exemption to the Reporting Requirements

Current regulations at 42 CFR § 403.904(g) allow for an exemption to the reporting requirements for manufacturer payments or transfers of value for speakers or faculty at CME events provided (1) the CME program meets the requirements of one of five accreditation or certification organizations approved by CMS; (2) the manufacturer does not pay the speaker or faculty directly; and (3) the manufacturer does not select the speaker or faculty or provide a list of

approved speakers or faculty to the CME organization. Our organizations have structured our CME programs and relationships with manufacturers to meet this exemption.

CMS proposes removing this exemption from the rule implementing the Sunshine Act on the grounds that it is redundant with the exemption for indirect payments to physicians under 42 C.F.R. § 403.904(i)(1). In the alternative, CMS has requested comments on whether it should add to the list of approved accreditation and certification organizations under the exemption at 42 C.F.R. § 403.904(g) *or* expand this list of organizations by articulating criteria for accredited CME groups as opposed to listing specific groups in the regulation. These later two proposals are largely in response to criticisms that CMS has tacitly endorsed certain CME providers by listing only a pre-approved number of organizations in the regulation.

The ACAAI and the JCAAI have concerns about CMS' proposed removal of the CME exemption. The indirect payment exemption at § 403.904(i)(1) only exempts indirect payments or transfers of value when the manufacturer is unaware of the identity of the ultimate covered recipient and remains unaware of the recipient's identity during the reporting year and for two quarters thereafter. We do not believe the availability of the CME exemption should hinge on whether or not the manufacturer happens to learn of the identity of the speaker either before or after the event has taken place. The important thing is that the manufacturer did not select or influence the selection of the speaker. CME programs, including the list of speakers or faculty, are broadly publicized and could easily be received by manufacturers through promotional brochures and mailings. In addition, manufacturer representatives might attend a CME event. Further, a speaker or the organization sponsoring the CME would have no way of knowing whether a manufacturer learned of and is therefore required to report a payment.

For these reasons, we urge that the existing CME exemption in 42 CFR § 403.904(g) be retained as is. Alternatively, the ACAAI and the JCAAI propose that CMS clarify the scope of the indirect compensation exemption by (1) adding language to 42 C.F.R. § 403.904(i)(1) that explicitly states that CME is in fact covered by the indirect payment exemption and (2) also clarify that a manufacturer need only report CME sponsorship payments if they select or influence the selection of the speakers or faculty. We would also suggest that CME providers have at least six months to implement this change before it takes effect.

2. CMS' interpretation of educational materials under the statute

The Sunshine Act excludes payments or transfers of value made by manufacturers for “[e]ducational materials that directly benefit patients or are intended for patient use” at 42 U.S.C. § 1320a-7h(e)(10)(iii). CMS continues to interpret this rule to exclude payments for medical textbooks, scientific journal reprints, and other educational resources for physicians. We believe these materials have a direct benefit for patients because they are used by physicians to improve patient care. ACAAI and the JCAAI believe that this interpretation is inconsistent with Congressional intent and we urge CMS to reconsider its interpretation of the educational materials exemption to include medical education textbooks and scientific journal reprints or any other materials related to physician education.

3. Lack of clarity and time as to registration and dispute resolution processes

The timelines for physician registration in the open payments system, aggregation of individual physician data, and the dispute resolution process are too short, particularly given the lack of notice, clarity and guidance on these systems. In addition, physicians must complete separate registrations in the Enterprise Identification Management system and the open payments system, and they have not received enough notification and clarification as to the steps involved in this process for all of them to complete registration in time for this year's dispute resolution period.

There are also many steps involved in the dispute resolution process and physicians must resolve any concerns over reported payment or transfers of value data by working directly with manufacturers, which is not always the most efficient means of addressing disputes. For these reasons, the ACAAI and the JCAAI recommend that CMS and the Office of Management and Budget (OMB) delay publication of payments data for six months.

4. Unilateral authority of manufacturers to dismiss disputes

The ACAAI and the JCAAI are concerned about the level of authority given to manufacturers in the dispute resolution process. Specifically, CMS statements have indicated that manufacturers can unilaterally dismiss a dispute or ask a physician to withdraw a dispute after reviewing the disputed data. While CMS has stated publically that manufacturers do not have unilateral authority to dismiss disputes but must instead work with physicians to achieve a mutually agreed upon resolution, the ACAAI and JCAAI recommend that CMS publish guidance clarifying this process to be made available to all stakeholders, physicians and manufacturers.

We appreciate this opportunity to comment on the Open Payments System in the proposed rule for the CY 2015 Physician Fee Schedule. If you have any questions, please feel free to contact our Washington representative, Rebecca Burke, at 202-872-6751.

Sincerely,



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President, ACAAI



Allen Meadows, MD
President, JCAAI