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Submitted electronically via <http://www.regulations.gov>

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1612-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington DC 20201

RE: Comments on Physician Sunshine and the CE safe harbor in the Medicare Physician Fee Schedule Proposed Rule for CY 2015

Dear Ms. Tavenner:

Elsevier is pleased to submit comments on the proposed changes to the Physician Sunshine Act, section 6002 of the Patient Protection and Affordable Care Act (ACA), that the Centers for Medicare and Medicaid Services (CMS) proposes in the CY 2015 Medicare Physician Fee Schedule rule CMS 1612-P, which was published in the *Federal Register* on July 11, 2014.¹ Elsevier is the world's leading provider of scientific, technical and medical information and delivers a wide array of information and workflow tools that help researchers generate valuable insights in the advancement of scientific discovery and improve the productivity of research. Through our medical journals, books, major reference works, databases, and online information tools, which include well known titles such as *The Lancet* and *Gray's Anatomy*, Elsevier provides critical information and analysis that help its customers improve medical outcomes and enhance the efficiency of healthcare.

We are concerned that the proposed changes to the continuing education (CE) exception to the Physician Sunshine Act's reporting requirement further complicates an already complex area and does not serve the transparency intent that the Sunshine Act set out to achieve. We recommend that § 403.904(g) not be removed. Our detailed comments are provided below.

The CE Exclusion Should Remain as Finalized in the Sunshine Act Final Rule

The proposal to eliminate § 403.904(g) in its entirety is concerning. This change, along with other components of the proposal would make the reporting requirements surrounding CE exemptions more, not less, uncertain and difficult to

¹ This proposed rule, *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*, 79 Fed. Reg. 40,318 (July 11, 2014) is available at <http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-15948.pdf>.

understand. As currently finalized each of the following criteria for CE must be met in order to qualify for exclusion under the reporting requirement:

- The event at which the covered recipient is speaking must meet the accreditation or certification requirements and standards for continuing education for one of the following organizations: the Accreditation Council for Continuing Medical Education (ACCME) et al.;
- The applicable manufacturer does not pay the covered recipient speaker directly.
- The applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers or the continuing education program.

The proposal to remove this explicit exemption for CE and instead rely only on the more general exemption where the manufacturer is “unaware” of, that is, “does not know,” the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year,” is problematic. CMS further states “When an applicable manufacturer or applicable GPO provides funding to a continuing education provider, but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct, identifiable set of covered recipients to be considered as speakers for the continuing education program, CMS will consider those payments to be excluded from reporting under § 403.904(i)(1).” However, § 403.904(i)(1) itself does not include language describing those other conditions. Elsevier feels strongly that the original language in § 403.904(g) is much clearer and more formally defined.

Elsevier does not believe that § 403.904(g) is redundant with the exclusion in § 403.904(i)(1). To meet the criteria for exclusion under the reporting requirement, § 403.904(g) prohibits an applicable manufacturer from “selecting” the covered recipient speaker or from “providing” the third party with a distinct, identifiable set of individuals to be considered as speakers for the CE program. That is different from the awareness standard in § 403.904(i)(1), as remaining “unaware” is not the same as refraining from “selecting” a speaker or “providing” a list of recommended speakers.

Elsevier believes that reliance on the notion of “awareness” brings considerable ambiguity to the criteria required to meet the reporting exclusion. Moreover, the burden of remaining “unaware” may be practically unrealistic because presenters are always publicly listed prior to a CE event in meeting schedules and promotional materials, and speaker payments must be reported afterward. Hence, it would be very difficult for an applicable manufacturer to remain “unaware” both before and after a CE event.

Finally, eliminating § 403.904(g) in its entirety in deference to § 403.904(i)(1) creates uncertainty around the reporting burden for physician attendees who receive educational materials included in the tuition fees for an accredited or certified CE program which meets all three current exemption conditions. The current rule, supplemented by the FAQ below regarding items reportable for attendees, leaves no such ambiguity:

Lodging, travel and meals for speakers of an accredited or certified CME event meeting all three requirements in 42 CFR 403.904(g)(1) will be deemed to be included in the total speaker compensation and, therefore, exempt from reporting under Open Payments. However, travel, lodging and meals and all other natures of payments provided in conjunction with the accredited or certified CME event (with the exception of educational materials included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides) will need to be reported for physician attendees (who are not speakers).²

We feel that the language in § 403.904(g)(ii-iii) and its accompanying FAQ are appropriately clear and precise and that the proposed change would blur the currently defined boundaries which work well.

We strongly encourage CMS to ensure that indirect commercial support for CE programs, where the accredited CE provider exercises complete discretion on the content, remains exempted from reporting under the Open Payments system by keeping the existing criteria in § 403.904(g). We believe retaining the CE exclusion as originally written will further this goal. It is vital

² The CMS FAQ is available at <https://questions.cms.gov/faq.php?id=5005&faqId=8386>.

to America's patients that their healthcare providers remain well educated and informed on the latest medical science in their field. Therefore, we must encourage, not discourage, participation in CE programs.

Textbooks and Reprints

Additionally, Elsevier encourages CMS to fully recognize the importance and utility of medical journal reprints and medical textbooks as tools which are directly beneficial to patients and should therefore qualify for the educational exclusion under the Sunshine Act's reporting requirement. Peer-reviewed medical textbooks and journal reprints directly benefit patients. Clinicians consult these educational materials to address unfamiliar issues immediately and at the point of care with the patient beside them. The importance of up-to-date, peer-reviewed medical information as the foundation for good medical care is well documented, and peer-reviewed medical journals and textbooks meet the highest standards for research and review.

Medical journals, journal reprints, supplements and medical textbooks meet the definition of directly beneficial to patients because better informed physicians provide better care to patients.

CE programs, journal reprints and medical textbooks ensure new research and practice reach physicians in a timely fashion. A 2001 Agency for Healthcare Research & Quality factsheet noted that "[u]p to two decades may pass before the findings of original research becomes part of routine clinical practice."³ These vital tools are widely used to reduce that gap. The current final rule presents a clear disincentive for the distribution of educational journal reprints and medical textbooks, and we fear that this recent proposal to change the exclusion conditions for CE would do the same.

Elsevier appreciates the opportunity to submit comments for your consideration in an effort to cooperatively work toward improving access, consistency in policy, and continued quality in health services.

If you have any questions, please contact Adam Huftalen, Senior Manager of Federal Government Affairs, at (202) 857-4644 or adam.huftalen@reedelsevier.com.

Sincerely,



Karthik Krishnan
Senior Vice President & General Manager
Global Pharmaceuticals & eCommerce
Elsevier, Inc.

³ Healthcare 411. (2001, March 1). Retrieved August 29, 2014, from <http://www.ahrq.gov/research/findings/factsheets/translating/tripfac/index.html>