



August 26, 2014

Marilyn Tavenner, BSN, MHA  
Administrator  
Center for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, Maryland 21244-1850

Re: Open Payments Reporting Requirements Related to CME

Dear Ms. Tavenner:

**Subject:** Open Payments Reporting Requirements Related to CME

As the president of the Postgraduate Institute for Medicine (PIM), a company that employs 19 individuals and is dedicated to helping physicians improve the health care of patients by providing independent, certified CME, I am writing to express my deep concern for a recently proposed CMS policy that I fear would effectively eliminate the Sunshine Act reporting exemption for certified continuing medical education (CME). My organization is accredited by the Accreditation Council for Continuing Medical Education (ACCME) and the American Dental Association CERP, as well as by the American Nurses Credentialing Center Commission of Accreditation and the American Psychological Association. The vast majority of the 800 plus CME activities PIM provides yearly have physicians (using the term broadly, as defined in the statute) as faculty or as participants.

Continuing medical education is a vital component of our healthcare system and allows our nation's doctors and healthcare providers to remain up to date with the latest in medical science. Accredited CME is the gold standard of continuing medical education. By incorporating strong criteria that ensure that the education being provided to learners is based firmly in science, accredited CME guarantees that any supporter bias - be it commercial or otherwise - is eliminated from the curriculum. PIM, like every other accredited provider, is held accountable for assuring full compliance with standards for independence, such as the *ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities*.

My concern is that the proposed changes in the final rule could diminish participation by physicians in CME, both as faculty and learners. I strongly urge CMS to appreciate the need to promote physician participation in CME as being in our national interest.

In CMS' February 2013 Final Rule on Sunshine Act implementation, your agency wisely created a bright line "CME exemption" that made it clear to physician participants that they could present at, and attend, accredited continuing education programs without risking the stigma and reputational impact that is likely to be the result of listing in the Open Payments system, if the example of release of data on Medicare payments to physicians is any example.

It is my understanding that your stated goal is actually to expand the definition of "Sunshine exempt" CME to take into account programs that may be accredited for nurses, optometrists, pharmacists, and others. If this is so, I wholeheartedly endorse this goal.

However, I am concerned that your recent proposal of July 3rd would instead eliminate the current CME "safe harbor" from reporting by redefining CME payments as "indirect payments" which may be reportable.

I support the CME Coalition's position of altering of the wording of § 403.902 (Definitions) to add "**accredited or certified continuing education program**":

*A. An educational activity designed, sponsored or hosted by a third party organization that is accredited or certified by an accrediting body or organization that is recognized by a state or federal government. The accrediting body or organization must:*

- a. Have standards regarding the acceptance and use of payments or other transfers of value from applicable manufacturers;*
- b. Enforce compliance with these standards through audit, inspection, complaints, or otherwise;*
- c. Have the authority to impose penalties for non-compliance with such standards, including loss of status or ability to offer credits to physicians;*
- d. Require the third party organization to certify compliance with such standards on a regularly scheduled basis (e.g., bi-annually); and*
- e. Not be owned or controlled, in whole or in part, by an applicable manufacturer*

*B. The educational activity can be in-person, online, or through other educational platforms.*

*C. The educational activity includes the value of the tuition or attendance fees, as well as any educational materials or items associated with the program (e.g., slides or handouts) as long as (i) the content is related to the educational activity; and (ii) the funds used for the materials came from the same financial support.*

AND, the retention and revision of section "g" to include:

*(A) Payments or other transfers of value provided indirectly to physician speakers, faculty, or attendees at an **accredited or certified continuing education program** (as defined above) are not required to be reported if all of the following conditions are met. The applicable manufacturer must not:*

- a. Select or pay the covered recipient speaker directly;*
- b. Provide the CE/CME provider with a distinct, identifiable set of covered recipients to be considered as speakers; and*

*c. Influence, invite or select the covered recipient-attendees or otherwise condition its financial sponsorship on the participation of particular covered recipients.*  
*(B) The awareness standard (as defined in § 403.902) shall not apply to physician speakers, faculty, or attendees at an accredited or certified continuing education program.*

I implore you to ensure that indirect commercial support for CME programs, where the accredited provider exercise complete discretion on the selection of planners/ faculty and content, remains exempted from reporting under the Open Payments system. It is vital to America's patients that their healthcare providers remain well educated and informed on the latest medical science in their field, and therefore, we must encourage, rather than discourage, participation in CME.

Sincerely,



Michael R. Lemon, MBA, FACEHP  
President, Postgraduate Institute for Medicine

The Postgraduate Institute for Medicine has been awarded **Accreditation with Commendation** (2012-2018) by the Accreditation Council for Continuing Medical Education (ACCME®) and **Accreditation with Distinction** (2014-2018) by the American Nurses Credentialing Center Commission on Accreditation (ANCC)