



Administrator  
Washington, DC 20201

DEC 23 2013

The Honorable Phil Roe  
U.S. House of Representatives  
Washington, DC 20515

Dear Representative Roe:

Thank you for your letter to the Centers for Medicare & Medicaid Services (CMS) regarding the February 2013 final rule implementing the Physician Payments Sunshine Act, now known as Open Payments (Affordable Care Act Section 6002).

In your letter, you expressed concerns with how the rule defines medical textbooks and the reprints of medical journal articles, as reportable to the Secretary of Health and Human Services. You also discussed your concern that having these items reported would prevent the timely distribution of the information to clinicians. You asked CMS specifically to place textbooks and scientific peer-reviewed medical journal materials among the items excluded from Open Payments reporting requirements.

We agree that scientific peer-reviewed journal reprints, supplements, and medical textbooks are educational to physicians. We also appreciate the importance of reprints, supplements, and medical textbooks in potentially improving quality of patient care. However, we do not believe these materials fall within the statutory exclusion. Section 1128G(e)(10)(B)(iii) of the Social Security Act allows applicable manufacturers to exclude from the reporting requirements payments or other transfers of value in the form of educational materials that *directly benefit patients or are intended for patient use*. As stated in the preamble to the final rule, "Although these items may have downstream benefits for a patient, we believe they are not directly beneficial to patients nor are they intended for patient use..." as required by the statutory exclusion. However, education materials, such as wall models and anatomical models that are intended to be used with the patient—and therefore directly benefit the patient—are excluded from Open Payments reporting requirements.

As discussed in our final rule, the mere existence of a financial relationship between the industry and physicians does not necessarily signify an inappropriate relationship. Disclosure alone is not sufficient to differentiate beneficial financial relationships from those that potentially create conflicts of interest. Nor, for that matter, should the inclusion of any particular type of payment or transaction on Open Payments be interpreted as any comment by the federal government on the societal value or appropriateness of a particular type of payment. Rather, Open Payments provides broad transparency to the nature and extent of relationships, providing consumers with the information needed to ask questions and to make more informed decisions. The Open Payments program is not meant to encourage or discourage any particular transaction or type of transaction; it simply reports the information in a neutral and non-judgmental way for the use of physicians, patients, researchers, or any other member of the public.

Applicable manufacturers reporting payments or other transfers of value are required to select the nature of payment category they believe most accurately describes a payment or other transfer of value. One nature of payment category available is the "education" category. CMS has clarified in sub-regulatory guidance that this category generally includes payments or other transfers of value that involve the imparting or acquiring of particular knowledge or skills, which can include medical textbooks and journal reprints provided to physicians. Another nature of payment category available is the "gift" category, depending on the circumstances of the transfer of value.

We are continuously examining this and other issues to ensure policy is aligned with the vision and intention of the Affordable Care Act section 6002, Transparency Reports and Reporting of Physician Ownership or Investment Interest.

Again, thank you for your continued interest in this program. Our response has been sent to each of the co-signers. Please do not hesitate to contact me with any further thoughts or concerns.

Sincerely,

A handwritten signature in cursive script that reads "Marilyn Tavenner". The signature is written in black ink and is positioned to the right of the word "Sincerely,".

Marilyn Tavenner