



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

DEC 23 2013

Administrator
Washington, DC 20201

The Honorable Tom Price
U.S. House of Representatives
Washington, DC 20515

Dear Representative Price:

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 black ink that reads "Marilyn Tavener". The signature is written in a cursive, flowing style with a large, sweeping flourish at the end.

Marilyn Tavener

Congress of the United States
Washington, DC 20515

November 22, 2013

Marilyn Taverner
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1454-P
P. O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Taverner:

The undersigned Members of Congress write to express our concerns with regulations recently promulgated by the Centers for Medicare and Medicaid Services (CMS) under the Sunshine Act and their impact on scientific peer reviewed medical journals and textbooks. We believe these regulations are contrary to congressional intent and will adversely impact patient care as well as ongoing medical education.

The Sunshine Act was designed to promote transparency for payments and other financial transfers of value between physicians and the medical product industry. As part of this provision, Congress outlined twelve specific exclusions from the reporting requirement, including ***“[e]ducational materials that directly benefit patients or are intended for patient use.”*** In its interpretation of the statute, CMS concluded that medical textbooks, reprints of peer-reviewed scientific clinical journal articles, journal supplements and abstracts of journal articles are “not directly beneficial to patients, nor are they intended for patient use.” This conclusion is inconsistent with the statutory language on its face, congressional intent, and the reality of clinical practice where patients benefit directly from improved physician medical knowledge.

The importance of up-to-date, peer-reviewed scientific medical information as the foundation for good medical care is well documented. Medical textbooks and scientific peer-reviewed journal supplements and reprints have long been considered essential tools for clinicians to remain informed about the latest in medical practice and patient care. Independent, peer-reviewed medical textbooks and journal article reprints represent the gold standard in evidence-based medical knowledge and provide a direct benefit to patients because better informed clinicians render better care to their patients. Moreover, Congress included a specific exclusion of items that directly benefit patients, such as reference materials that are often used side-by-side with a patient as a first resource when a patient brings an unfamiliar medical issue to a clinician. Many medical textbooks and scientific medical journal reprints are used in this way by physicians. The design of the reporting requirement presents a clear disincentive for clinicians to accept high quality, independent educational materials, an outcome that was unintended when the provision was passed into law.

The Food and Drug Administration (FDA)’s 2009 industry guidance titled “Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices” underscores the importance of this scientific peer reviewed information. The FDA

noted the “important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications.” FDA guidelines for reprints provide that medical reprints should be distributed separately from information that is promotional in nature, specifically because the reprints are designed to promote the science of medicine, are educational, and intended to benefit patients. We believe the Sunshine Act was designed to support the dissemination of this type of educational material.

We are concerned that the final regulations could inadvertently prevent the timely distribution of rigorous scientifically reviewed medical information to clinicians and patients and thereby undermine efforts to improve the quality of care provided to patients. This was not the intent of Congress when the Sunshine Act was passed, as evidenced by statutory language. We request a meeting with Dr. Jonathan Blum, Principal Deputy Administrator and Director, to discuss these matters, to urge the reversal of this policy, and specifically to place textbooks and scientific peer reviewed medical journal materials among the items excluded from the Sunshine Act’s reporting requirement. These materials are critical for patient care as intended by Congress.

Sincerely,



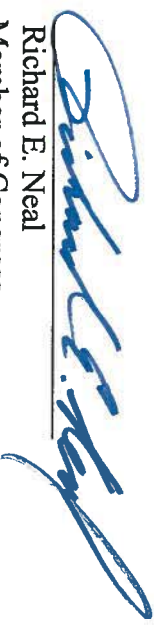
Robert E. Andrews
Member of Congress



Michael C. Burgess, M.D.
Member of Congress



Allyson F. Schwartz
Member of Congress



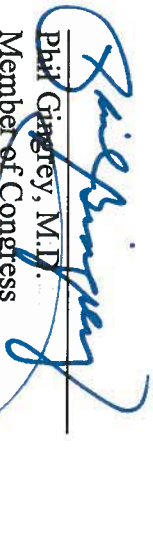
Richard E. Neal
Member of Congress



Pat Meehan
Member of Congress



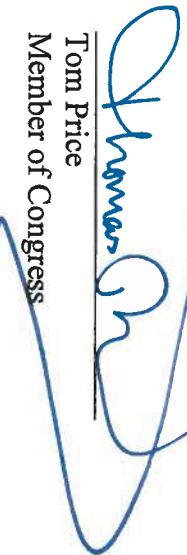
Andy Harris, M.D.
Member of Congress



Phil Gingrey, M.D.
Member of Congress



Paul Brown, M.D.
Member of Congress

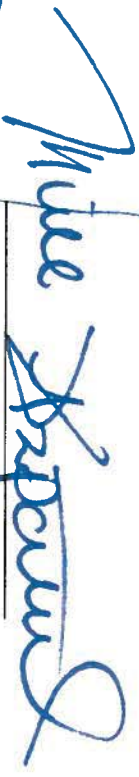



Tom Price
Member of Congress




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Member of Congress


Michael Turner
Member of Congress



Mike Fitzpatrick
Member of Congress



John F. Tierney
Member of Congress


Michael E. Caputo
Member of Congress


Marsha Blackburn
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Paul Gosar
Member of Congress

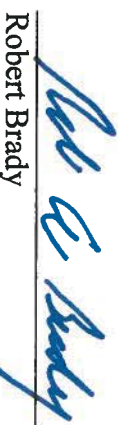

Charles W. Boustany, Jr., M.D.
Member of Congress

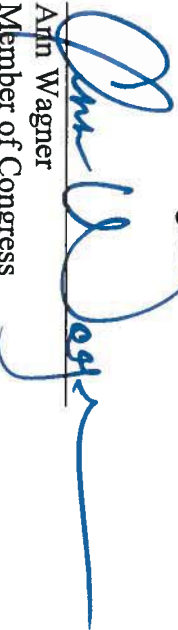

Charles Rangel
Member of Congress


Dan Benishek, M.D.
Member of Congress


Bill Johnson
Member of Congress


Kathy Castor
Member of Congress


Robert Brady
Member of Congress


Ann Wagner
Member of Congress

Cc:

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services

Dr. Jonathan Blum
Principal Deputy Administrator and Director
Centers for Medicare and Medicaid Services

Dr. Shantanu Agrawal
Office of Corporate Integrity