

December 3, 2018

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Verma:

The undersigned physician organizations representing both national medical societies and state medical societies are writing in response to the Centers for Medicare & Medicaid Services (CMS) request for feedback about the reporting requirements under the Open Payments Program for educational materials, such as peer-reviewed journals, journal reprints and abstracts, and medical textbooks, as well as continuing medical education (CME) programs. We have long believed that the Agency's decision to include educational materials and CME programs as reportable transfers of value is contrary to both the statute and congressional intent and has harmed patient care by impeding ongoing efforts to improve the quality of care through timely medical education. Our concerns, which have been well documented in previous correspondence and discussions with Agency officials, are summarized below.

**CMS' decision to require reporting of medical textbooks and journal reprints make it more difficult for busy physicians to stay abreast of the latest advances in medical care.**

The Sunshine Act excludes several types of "payments" from the reporting requirements, 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, and abstracts of these articles are not directly beneficial to patients, nor are they intended for patient use. This conclusion is not consistent with the reality of clinical practice where patients benefit directly from improved physician medical knowledge and is not supported by the statutory language on its face or congressional intent.

Independent, peer reviewed medical textbooks and journal article supplements and 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. The exclusion for items that directly benefit patients was designed with medical textbooks and scientific medical journal supplements and reprints in mind since these clinical tools are often used side-by-side with a patient as a first resource to help diagnose and treat unfamiliar medical issues. The inclusion of these resources as reportable transfers of value 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) noted the "important public health and policy justification supporting dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications."<sup>1</sup> FDA guidelines 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. CMS decision not to exclude

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<sup>1</sup> Good Reprint Practices for the Distribution of Medical Journal and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. FDA, 2009.

medical textbooks or journal reprints has not only made doctors less likely to accept these materials but also, according to medical societies that develop many of these educational materials, has made industry less likely to distribute these materials due to the reporting burden. We believe the Sunshine Act was designed to support the dissemination of this type of educational material without unnecessary reporting. We recommend that CMS update its interpretation to include educational materials, such as peer-reviewed journals, journal reprints and abstracts, and medical textbooks as “educational materials that directly benefit patients” and, therefore, these items should not be reported under the Open Payments program.

**The reporting guidance pertaining to CME continues to be misinterpreted with many manufacturers overreporting.**

The November 2014 final rule implementing the Sunshine Act correctly excluded independent CME from reporting in the Open Payment System. Unfortunately, what followed was several months of confusing and contradictory subregulatory guidance from CMS. Not until April 2015 did CMS issue clear subregulatory guidance that correctly stated that reporting for independent CME is not triggered unless the manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient.

Our hope was that the new guidance would clear the way for our industry partners to continue to play a critical role in helping to meet the educational needs of physicians. Unfortunately, it appears that the reporting requirements are being inconsistently interpreted as some manufacturers view Open Payments Reporting as a compliance risk that leads to overreporting. This has resulted in perverse outcomes where physicians curtail participation in independent CME for fear that it is subject to reporting. This has also led to changes in how industry funds CME activities. As an example, industry has largely shifted its focus away from funding independent satellite symposia at medical society meetings and towards funding more promotional sessions where the reporting requirements are clear. A common reporting methodology, including a common set of definitions on what is reportable, would help to insure more consistency in how industry reports payments and mitigate some of the downstream consequences of overreporting. We urge CMS to make this a priority by engaging more proactively with stakeholders on this issue.

**The Agency’s positions on educational materials and CME have prevented the timely distribution of rigorous scientifically reviewed medical information to clinicians, thereby undermining efforts to improve the quality of care.** As clinicians, patients and providers of health care we know that these resources are critical for patient care and we request that you remove the reporting requirements limiting their use.

Sincerely,

American Medical Association  
Advocacy Council of ACAAI  
American Academy of Allergy, Asthma & Immunology  
American Academy of Facial Plastic and Reconstructive Surgery  
American Academy of Family Physicians  
American Academy of Otolaryngology—Head and Neck Surgery  
American Academy of Physical Medicine and Rehabilitation  
American Association of Clinical Endocrinologists  
American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons

American College of Allergy, Asthma and Immunology  
American College of Mohs Surgery  
American College of Osteopathic Internists  
American College of Osteopathic Surgeons  
American Osteopathic Association  
American Psychiatric Association  
American Society for Clinical Pathology  
American Society for Dermatologic Surgery Association  
American Society for Gastrointestinal Endoscopy  
American Society for Radiation Oncology  
American Society of Anesthesiologists  
American Society of Cataract and Refractive Surgery  
American Society of Clinical Oncology  
American Society of Hematology  
American Society of Plastic Surgeons  
American Thoracic Society  
American Urological Association  
College of American Pathologists  
Congress of Neurological Surgeons  
Endocrine Society  
Heart Rhythm Society  
Infectious Diseases Society of America  
Medical Group Management Association  
North American Spine Society  
Society for Cardiovascular Angiography and Interventions  
Society of Hospital Medicine  
The Society of Thoracic Surgeons

Medical Association of the State of Alabama  
Arizona Medical Association  
Arkansas Medical Society  
California Medical Association  
Connecticut State Medical Society  
Medical Society of Delaware  
Medical Society of the District of Columbia  
Florida Medical Association Inc  
Medical Association of Georgia  
Hawaii Medical Association  
Idaho Medical Association  
Illinois State Medical Society  
Iowa Medical Society  
Kansas Medical Society  
Kentucky Medical Association  
Louisiana State Medical Society  
Maine Medical Association  
MedChi, The Maryland State Medical Society  
Massachusetts Medical Society  
Michigan State Medical Society

Mississippi State Medical Association  
Missouri State Medical Association  
Montana Medical Association  
Nebraska Medical Association  
Nevada State Medical Association  
Medical Society of New Jersey  
New Mexico Medical Society  
Medical Society of the State of New York  
North Carolina Medical Society  
North Dakota Medical Association  
Ohio State Medical Association  
Oklahoma State Medical Association  
Oregon Medical Association  
Pennsylvania Medical Society  
Rhode Island Medical Society  
South Carolina Medical Association  
South Dakota State Medical Association  
Tennessee Medical Association  
Texas Medical Association  
Utah Medical Association  
Medical Society of Virginia  
Washington State Medical Association  
West Virginia State Medical Association  
Wyoming Medical Society