

October 28, 2013

Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

The undersigned physician organizations representing both national medical societies and state medical societies are writing to express our serious concerns about the Center for Medicare and Medicaid Services' (CMS) recently promulgated regulations to the Sunshine Act and their impact on scientific peer reviewed medical journals and textbooks. We believe the regulations in this regard are contrary to both the statute and congressional intent and will potentially harm patient care by impeding ongoing efforts to improve the quality of care through timely medical education.

The Sunshine Act was designed to promote transparency with regard to 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 and abstracts of these articles are "not directly beneficial to patients, nor are they intended for patient use." We believe 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. Scientific peer-reviewed journal reprints, supplements, and medical text books 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 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. 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 & scientific medical journal supplements and 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 they passed the Sunshine Act as evidenced by the statutory language. We request that you reverse this policy and place textbooks and scientific peer reviewed medical journal reprints, supplements, and abstracts among the items excluded from the Sunshine Act's reporting requirements. As clinicians, patients and providers of health care we know that these materials provide a direct benefit to patients and are critical for patient care.

Sincerely,

American Academy of Child and Adolescent Psychiatry
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Neurology
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons/ Congress of Neurological Surgeons
American Association of Orthopaedic Surgeons
American Association for Geriatric Psychiatry
American College of Cardiology
American College of Emergency Physicians
American College of Radiology
American College of Rheumatology
American Geriatrics Society
American Medical Association
American Medical Directors Association
American Podiatric Medical Association
American Psychiatric Association
American Society of Anesthesiologists
American Society for Clinical Oncology
American Society for Clinical Pathology
American Society for Dermatologic Surgery Association
American Society for Gastrointestinal Endoscopy
American Society of Nephrology
American Society of Nuclear Cardiology
American Thoracic Society
American Urological Association
Endocrine Society, The
Heart Rhythm Society
Infectious Diseases Society of America
International Society for the Advancement of Spine Surgery
Medical Group Management Association
Society for Vascular Surgery

Arizona Medical Association
California Medical Association

Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association
Medical Association of Georgia
Hawaii 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
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nebraska Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York
North Dakota Medical Association
Ohio State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Tennessee Medical Association
Texas Medical Association
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wyoming Medical Society

Cc: Marilyn Tavenner