

October 24, 2014

The Honorable Michael C. Burgess, MD
United States House of Representatives
2336 Rayburn House Office Building
Washington, DC 20515

Dear Dr. Burgess:

The undersigned physician organizations representing both national specialty medical societies and state medical societies are writing to express our strong support for H.R. 5539, which would clarify that certain applicable manufacturer transfers of value to support independent medical educational programs and materials are exempt from reporting under the Physician Payments Sunshine Act (Sunshine Act). Passage of this bill is urgently needed to remedy onerous and burdensome reporting obligations imposed by the Centers for Medicare and Medicaid Services (CMS) that have already chilled the dissemination of medical textbooks, peer-reviewed medical reprints and journals, and to avert a similar negative impact on access to independent certified and/or accredited continuing medical education (CME). H.R. 5539 would ensure that efforts to promote transparency do not undermine efforts to provide the most up-to-date independent medical knowledge, which improves the quality of care patients receive through timely dissemination of medical knowledge.

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 12 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. 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.

The Food and Drug Administration’s (FDA) 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.” H.R. 5539 clarifies that the Sunshine Act was designed to support the dissemination of this type of educational material.

More recently, CMS has issued a proposal to remove the current exemption applicable to certified and accredited CME that meets certain criteria demonstrating independence. The proposal is inconsistent with the legislative history of the Sunshine Act and will further erode support of independent medical

education. There is widespread consensus that the agency's proposal will harm the dissemination of clinically relevant and critical medical knowledge that improves and enhances patient care. We strongly support the provisions in H.R. 5539 which would clarify that CME that meets the standard for independence must be exempt from Sunshine Act reporting.

We strongly support passage of H.R. 5539 and commend your leadership on this issue. The Institute of Medicine and other major stakeholders have repeatedly expressed concern with the length of time required for clinically validated discovery to become part of regular clinical practice. The Sunshine Act was not passed to limit or construct additional barriers to the dissemination of new medical knowledge that improves patient health outcomes. H.R. 5539 is needed to ensure patients benefit from the most up-to-date and relevant medical knowledge.

Sincerely,

American Medical Association
AMDA-The Society for Post-Acute and Long-Term Care Medicine
American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
American Academy of Emergency Medicine
American Academy of Family Physicians
American Academy of Ophthalmology
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Neuromuscular & Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American Clinical Neurophysiology Society
American College of Allergy, Asthma and Immunology
American College of Cardiology
American College of Emergency Physicians
American College of Gastroenterology
American College of Osteopathic Emergency Physicians
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Phlebology
American College of Preventive Medicine
American College of Radiology
American College of Rheumatology
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
American Psychiatric Association

American Society for Aesthetic Plastic Surgery
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society for Reproductive Medicine
American Society of Anesthesiologists
American Society of Bariatric Physicians
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology
American Society of Dermatopathology
American Society of Dermatologic Surgery Association
American Society of Echocardiography
American Society of Hematology
American Society of Nephrology
American Society of Neuroradiology
American Society of Retina Specialists
American Urological Association
Endocrine Society
Infectious Diseases Society of America
Joint Council on Allergy, Asthma and Immunology
Medical Group Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Interventional Radiology

Medical Association of the State of Alabama
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
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
Indiana State Medical Association
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
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
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association