

June 29, 2016

The Honorable John Barrasso, MD  
United States Senate  
307 Dirksen Senate Office Building  
Washington, DC 20510

Dear Dr. Barrasso:

On behalf of the undersigned organizations, we are writing to express our strong support for S. 2978, the “Protect Continuing Physician Education and Patient Care Act,” which would protect the dissemination of peer and independent third-party reviewed services and products that improve patient care. The uptake of evidence-based medical practice is facilitated by a practicing physician’s consideration of independent peer-reviewed journals, medical textbooks, and independent continuing medical education. When initially considering the Physician Payments Sunshine Act, Congress specifically intended to exclude such independent sources of clinical information so as to avoid chilling the dissemination of high quality and actionable clinical information that had undergone independent review. Your legislation clarifies 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 and 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). This legislation 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.

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 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.

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 physicians 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." This bill clarifies that the Sunshine Act was designed to support the dissemination of this type of independent educational material.

We also support language in the bill clarifying that CME that meets the standard for independence must be exempt from Sunshine Act reporting. This has become necessary due to contradictory guidance from CMS that required several revisions to subregulatory guidance. Adding to the concern, a recent New England Journal of Medicine article, which was co-authored by current and former CMS staff, says that "payments related to all accredited CME activities must be reported beginning in 2017." This statement only adds to the confusion surrounding the status of independent CME as it relates to Open Payments reporting.

We strongly support passage of the bill and commend your ongoing 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. This bill is needed to ensure patients benefit from the most up- to-date and relevant medical knowledge.

Sincerely,

American Medical Association  
Advocacy Council of the American College of Allergy, Asthma and Immunology  
Aerospace Medical Association  
AMDA – The Society for Post-Acute and Long-Term Care Medicine  
American Academy of Dermatology Association  
American Academy of Facial Plastic and Reconstructive Surgery  
American Academy of Family Physicians  
American Academy of Home Care Medicine  
American Academy of Hospice and Palliative Medicine  
American Academy of Neurology  
American Academy of Ophthalmology  
American Academy of Otolaryngology—Head and Neck Surgery  
American Academy of Pain Medicine  
American Academy of Physical Medicine and Rehabilitation  
American Association of Child & Adolescent Psychiatry  
American Association of Clinical Endocrinologists  
American Association of Clinical Urologists  
American Association of Hip and Knee Surgeons  
American Association of Neurological Surgeons

American Association of Neuromuscular & Electrodiagnostic Medicine  
American Association of Orthopaedic Surgeons  
American Clinical Neurophysiology Society  
American College of Cardiology  
American College of 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 College of Surgeons  
American Gastroenterological Association  
American Geriatrics Society  
American Osteopathic Association  
American Society for Clinical Pathology  
American Society for Dermatologic Surgery Association  
American Society for Gastrointestinal Endoscopy  
American Society for Radiation Oncology  
American Society for Surgery of the Hand  
American Society of Addiction Medicine  
American Society of Anesthesiologists  
American Society of Cataract and Refractive  
American Society of Echocardiography  
American Society of Hematology  
American Society of Plastic Surgeons  
American Society of Retina Specialists  
American Society of Transplant Surgeons  
American Urological Association  
Congress of Neurological Surgeons  
Endocrine Society  
International Society for the Advancement of Spine Surgery  
National Association of Medical Examiners  
Obesity Medicine Association  
Renal Physicians Association  
Society for Cardiovascular Angiography and Interventions  
Society for Vascular Surgery  
The Society of Thoracic Surgeons

Medical Association of the State of Alabama  
Alaska State Medical Association  
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  
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  
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  
Wyoming Medical Society