

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