

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