August 5, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Tavenner:

The undersigned medical associations and medical specialty societies are writing to register serious concerns with implementation of the Physician Payments Sunshine Act (Sunshine Act) and to request an expanded timeframe to allow recipients to register, review, and dispute their data in the Open Payments System before publication. Our organizations represent physicians who are directly impacted as covered recipients in the Open Payments System or indirectly impacted through their affiliation with teaching hospitals. Many of our organizations supported passage of the Sunshine Act and, fundamentally, we have no issue with efforts to increase transparency in the interactions between physicians and industry. However, we have a number of serious concerns regarding how the Open Payments System has been implemented.

Significant Expansion of Reporting Requirement – Educational Activities

In the proposed Medicare Physician Fee Schedule for 2015, the Centers for Medicare and Medicaid Services (CMS) has proposed revoking the existing Sunshine Act reporting exclusion for continuing medical education (CME) activities, due in large part to requests from other accrediting bodies that they be added to the list of exempt organizations covered by the exclusion. Instead, the proposal would exempt third party transfers to Continuing Education (CE) only where an industry donor is unaware of the recipients/beneficiaries before and after the funds are transferred. Our organizations believe that this raises concerns as industry could learn the identities of speakers/faculty and potentially participants after the funds have been transferred through brochures, programs, and other publications, or through their physician-employees' participation in CE activities (either as speakers/faculty or attendees). Our organizations are concerned that this would have a significant, chilling impact on CE, which runs contrary to the public interest. **We therefore recommend strongly that the CMS slightly modify the proposal to add the language that the exemption applies under section 403.904(i)(1) when an applicable manufacturer provides funding to a CE provider, but does not select or pay the covered recipient speaker/faculty directly, or provide the CE provider with a distinct, identifiable set of covered recipients to be considered as speakers/faculty for the CE program. The agency can include the guidance in the regulation or preamble that the foregoing is achieved where the industry donor is unaware of the speakers/faculty and other participants before committing to fund the activity under section 403.904(i)(1). This accomplishes CMS' goal while eliminating the potential for negatively impacting CE. To allow CE providers time to ensure that their processes comply with the modified exemption, we urge CMS to make this change effective six months after the final rule is issued.**

In addition, when it passed the Sunshine Act Congress outlined 12 specific exclusions from the reporting requirement, including "[e]ducational materials that directly benefit patients or are intended for patient use." In an overbroad interpretation of the statute, CMS concluded that medical textbooks, reprints of peer reviewed scientific clinical journal articles, and other services used to educate physicians were not covered by this exclusion even though these clearly have a direct benefit to patients and their medical care.

The importance of up-to-date, peer reviewed scientific medical information as the foundation for good medical care is well documented. 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 Agency's decision to not cover these materials under the educational materials exclusion 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. **Our organizations urge the Agency to reconsider its decision not to cover medical textbooks, journal article supplements, and reprints within the existing statutory exclusion for educational materials that directly benefit patients.**

Physician Registration Impeded by Condensed Timeframe

There are widespread concerns that the implementation of this new system for data collection—without minimally a six month period to upload the data, process registrations, generate aggregated individualized reports, and manage the dispute communications and updates—will not be ready and will likely lead to the release of inaccurate, misleading, and false information. The Agency has not provided effective notification to the vast majority of physicians nor provided a reasonable amount of time for the undersigned organizations to engage and educate physicians on the registration and dispute process. Early in the regulatory process, medicine informed CMS that a minimum of six months would be needed to ensure an adequate amount of time for outreach on registration and the dispute process. As soon as our organizations learned the date that physicians could begin registering for each phase, a concerted communications campaign was launched. The content had to be developed after the abbreviated period for registration began and with limited opportunity to develop materials because of the compressed period for registration and dispute in advance of publication. Thus, we know that it is extremely likely that many physicians impacted by the Sunshine Act reporting are not aware of the registration requirement and based on feedback thus far certainly will not have adequate time to register prior to the deadline for flagging inaccurate data in the public database. Accordingly, **our organizations strongly urge CMS and the Office of Management and Budget (OMB) to postpone for six months, until March 31, 2015, the publication of the information collected in the Open Payments System, to compensate for this year's six months delay in providing the opportunity for physicians to register, contrary to Agency communications throughout 2013 representing that physicians would be permitted to do so beginning January 1.**

Complicated and Incomplete Guidance Exacerbates Condensed Registration Timeframe

Perhaps most troubling, many physicians are expressing frustration at an overly complex registration process which, combined with the condensed timeframe, makes the task of reviewing and disputing reports by August 27 effectively impossible for the Agency's estimated 224,000 covered physician recipients. We have previously stated that CMS' number is likely an extremely low estimate of impacted physicians. CMS has suggested that it will take 30-45 minutes to complete the 5-step process of registering in the Open Payments system. Our own analysis suggests a substantially more complex 11-step registration process, which does not include the pre-registration step of verifying identity in Medicare's Enterprise Identity Management (EIDM) System. Moreover, when the post-registration time it takes to review and dispute data is factored in, there are an additional 5 steps layered on top of the already cumbersome registration process. This process must be streamlined and physicians must be given adequate time to review and dispute their reports. Thus, **we repeat our request that CMS and OMB delay for six months the publication of the information collected in the Open Payments System until March 31, 2015.**

Moreover, our organizations have serious concerns that Agency guidance gives manufacturers the power to unilaterally dismiss disputes that were initiated by physicians or teaching hospitals. These concerns are the result of language that was buried in the supplementary documents of a May 5th Federal Register Notice, stating that manufacturers "after reviewing the disputed information, if they determine that no change is required to the data, may dismiss the dispute or request that physician or teaching hospital who initiated the dispute to withdraw it." The February 2013 Final Rule does not authorize manufacturers or group purchasing organizations (GPOs) to dismiss disputes without both parties agreeing that the dispute is resolved. If no resolution is reached, the manufacturer's or GPO's reported data will be flagged as disputed in the public database until resolution has been reached between the parties. In a June 24th meeting with AMA and specialty society staff, CMS officials stated their intent to issue clarifying guidance that manufacturers and GPOs are not authorized by the agency to unilaterally dismiss disputes. While Agency officials have indicated that they have clarified the guidance to manufacturers, requests from our organizations to see the written changes have gone unanswered. **We request that the Agency provide the clarifying guidance to physicians/teaching hospitals, to manufacturers/GPOs, and to our organizations.**

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 Child & Adolescent Psychiatry
American Academy of Dermatology Association
American Academy of Disability Evaluating Physicians
American Academy of Emergency 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 for Geriatric Psychiatry
American Association of Clinical Endocrinologists
American Association of Neuromuscular and Electrodiagnostic Medicine
American Association of Orthopaedic Surgeons
American Clinical Neurophysiology Society
American College of Cardiology
American College of Chest Physicians
American College of Emergency Physicians
American College of Medical Genetics
American College of Occupational and Environmental Medicine
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Phlebology
American College of Radiology
American College of Rheumatology
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Psychiatric Association
American Society for Aesthetic Plastic Surgery
American Society for Clinical Pathology

American Society for Dermatologic Surgery Association
American Society for Radiation Oncology
American Society for Reproductive Medicine
American Society for Surgery of the Hand
American Society of Anesthesiologists
American Society of Bariatric Physicians
American Society of Cataract & Refractive Surgery
American Society of Dermatopathology
American Society of Hematology
American Society of Neuroradiology
American Society of Nuclear Cardiology
American Society of Transplant Surgeons
American Thoracic Society
American Urological Association
American Women's Association
American Society of Echocardiography
College of American Pathologists
Digestive Health Physicians Association
Infectious Diseases Society of America
Large Urology Group Practice Association
Medical Group Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Critical Care Medicine
Society of Hospital Medicine
Society of Interventional Radiology
Society of Thoracic Surgeons
The Endocrine Society

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
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 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