Organizations Submitted Comments to CMS to Request CME Be Excluded from Proposed Physician Payment Sunshine Rules

Accreditation Council for Continuing Medical Education
Advanced Medical Technology Association (AdvaMed)
Alliance for Continuing Education in the Health Professions
American Academy of Allergy, Asthma & Immunology
American Academy of CME
American Academy of Dermatology
American Academy of Family Physicians (AAFP)
American Academy of Hospice and Palliative Medicine
American Academy of Laser Dentistry
American Academy of Neurology (AAN)
American Academy of Ophthalmology (AAO)
American Academy of Orthopedic Surgeons (AAOS)
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Pediatrics (AAP)
American Academy of Physical Medicine and Rehabilitation
American Association for the Study of Liver Disease (AASLD)
American Association of Clinical Endocrinologists (AACE)
American Association of Family Physicians (AAFP)
American Association of Medical Colleges (AAMC)
American College of Cardiology (ACC)
American College of Chest Physicians (ACCP)
American College of Emergency Physicians (ACEP)
American College of Medical Genetics (ACMG)
American College of Obstetricians & Gynecologists (ACOG)
American College of Occupational and Environmental Medicine
American College of Physicians (ACP)
American College of Preventive Medicine (ACPM)
American College of Radiology (ACR)
American College of Rheumatology (ACR)
American College of Surgeons (ACS)
American Geriatrics Society (AGS)
American Medical Association (AMA)
American Medical Informatics Association (AMIM)
American Society for Clinical Pathology (ASCP)
American Society for Reproductive Medicine (ASRM)
American Society of Clinical Oncology (ASCO)
American Society of Clinical Pathologists (ASCP)
American Society of Colon and Rectal Surgeons (ASCRS)
American Society for Echocardiography (ASE)
American Society of Hematology (ASH)
American Society of Nephrology (ASN)
American Society of Nuclear Cardiology (ASNC)
American Society of Plastic Surgeons (ASPS)
American Society of Transplant Surgeons (ASTS)
American Thoracic Society (ATA)
American Urological Association (AUA)
Annenberg Center for Health Sciences at Eisenhower
Association for Hospital Medical Education
Association of Black Cardiologists (ABC)
Association of Clinical Research Organizations (ACRO)
Association of Clinical Researchers and Educators (ACRE)
Association of Health Systems Pharmacists (ASHP)
BIO
California Academy of Family Physicians
Clinical Patient Educators Association
CME Outfitters
Coalition for Healthcare Communications
Continuing Medical Education (CME) Coalition
Council for Medical Specialty Societies (CMSS)
Endocrine Society
Federation of State Medical Boards
Genentech
Global Education Group
Healthcare Institute of New Jersey
Heart Rhythm Society
Illinois State Medical Society
Imedex
Life Science Alley (Minnesota)
Medical College of Wisconsin
Medical Communication Media
Medical Society of New Jersey
Meeting Resources Unlimited
Mercy Hospitals
Millennium Medical Education Resources
Missouri Association of Osteopathic Physicians and Surgeons
National Association of Medical Education Companies
National Comprehensive Cancer Network
National Jewish Health
National Medical Association (NMA)
New York State Dental Association
North American Spine Society (NASS)
Massachusetts General (Harvard)
Oklahoma State Medical Association
Pennsylvania Dental Association
Pfizer
PhRMA
PRIME Oncology
PriMed
Rockpointe, Inc.
Society of Academic Continuing Medical Education (SACME)
Society of Critical Care Medicine
Society of Critical Care Medicine (SCCM)
Society of Hospital Medicine (SHM)
Society of Neurological Surgeons (SNS)
Society of Nuclear Medicine (SNM)
Society of Thoracic Surgeons (STS)
Southern Medical Association
Texas Alliance for CME
University of Kansas
University of North Texas Health Science Center
University of Virginia
Washington University in St. Louis

CME COALITION

THOUGHTS ON IMPLEMENTATION OF THE PHYSICIAN PAYMENT SUNSHINE ACT

PRESENTED TO OMB

JANUARY 17, 2013

An Introduction to CME

- The CME Coalition represents a collection of continuing medical education provider companies, in addition to other supporters of CME and the vital role it plays in our health care system.
- Our member organizations manage and support development of healthcare continuing education programs that impact more than 500,000 physicians, nurses and pharmacists annually.
- Graduation from medical school and completion of residency training are the first steps in a career-long educational process for physicians. Most State licensing authorities require physicians to complete a certain number of hours of accredited CME within prescribed timeframes to maintain their medical licenses.
- The Accreditation Council for Continuing Medical Education (ACCME) is the principal CME accrediting authority in the United States
- Generally, physicians can use only accredited CME to satisfy licensure and hospital privileging requirements. According to the most recent report, ACCME has 694 nationally accredited CME providers.

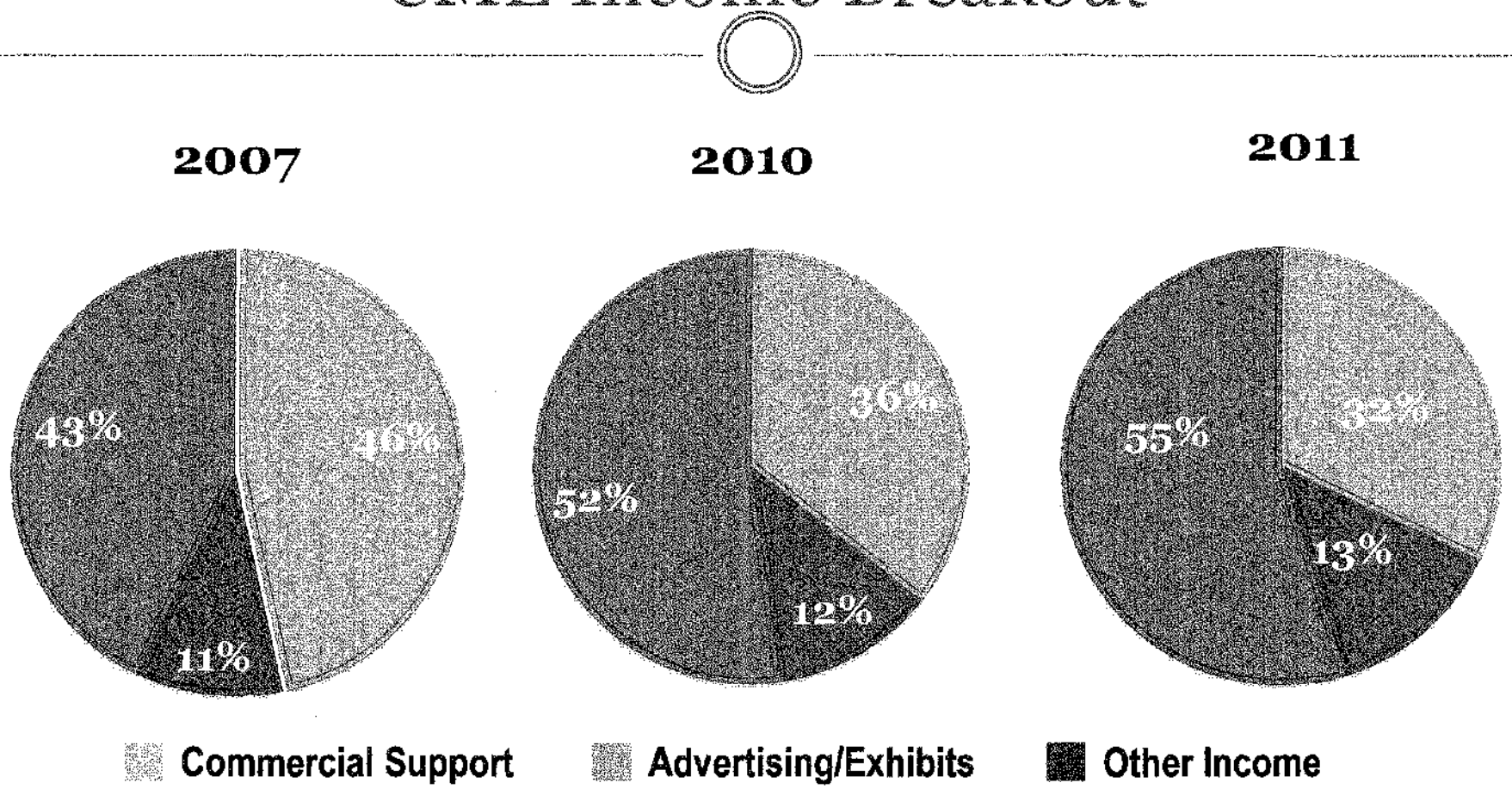
Introductory Remarks on Sunshine Act

- We support the public reporting of direct payments from manufacturers of medical products to the medical professionals who use them.
- We firmly believe, however, that it was never the intent of Congress to expand the public reporting requirements to include indirect commercial support for continuing medical education.
- If left unaddressed, the Sunshine Act reporting requirements will create the false impression that CME instructors and attendees have an inappropriate relationship with the commercial organizations that support the programs.
- Additionally, it will be virtually impossible to meet the reporting requirements of the Act without making it practicably unworkable for private sector supporters of CME to continue to participate.

The Current State of CME

- For a variety of reasons, commercial support of CME funding has declined $297 million or 31.4 percent since 2007. It now accounts for approximately one-third of CME spending annually.
- Without a reversal of this trend, or an infusion of government funding, health professionals will soon face significant challenges accessing the appropriate, high quality CME necessary to stay current with innovations in the practice of medicine.
- A recent survey revealed that 52.2% of physician respondents said they have lately had to spend more time and effort locating appropriate CME and 64.1% said they have had to pay more for the cost of CME for themselves or staff.
- In 2010, accredited providers produced more than 81,000 activities, a 14.2% decrease of activities from 2009, and a 27.8% decrease in activities since 2007. Also in 2010 there were over 660,000 hours of instruction, which is 29,000 (4.2%) fewer hours than in 2009. In 2010, 1.5 million physicians participated in live courses this is down from 1.6 million in 2009 (representing an 8% reduction).

Commercial Support is Indispensible: CME Income Breakout



Physicians Recognize the Value of CME

- In a 2012 survey of 515 physicians conducted by the CME Coalition, health care providers testified to their reliance on CME to improve patient outcomes.
  - 95 percent of physicians said that CME was at least 'moderately important' in effecting their ability to improve patient outcomes.
  - 89 percent of physicians agreed that health care companies should be at least 'somewhat' encouraged to provide financial support to underwrite accredited CME activities.

Improving Patient Outcomes

- According to a recent study, physicians who attended an industry-supported educational activity were 50% more likely to provide evidence-based care for COPD than nonparticipants were.
- Another program showed that the patients of physicians who attended an industry supported educational activity were 52% more likely to receive evidence-based hypertension care than those seen by health care providers than nonparticipants were.
- In addition, the results of a recent study showed that "heart disease patients whose general practitioners participated in an interactive, case-based CME program had a significantly reduced risk of death over 10 years compared with those whose doctors didn't receive the education."

Improving Patient Outcomes

- FDA may require REMS for any New Drug Application (NDA), Abbreviated New Drug Application (ANDA), or Biologic License Application (BLA) at any stage of the product lifecycle when the FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks.
- The strong connection between FDA, manufacturers and CME providers is clearly demonstrated by REMS. In fact, recently, FDA began requiring companies to fund CME for REMS education in long acting opioids.
- Under the proposed rules, however, funds given to CME providers to produce REMS-mandated CME would constitute a transfer of value and would have to be reported. This could be a huge disincentive to participate in a REMS program because many physicians would not want to appear on lists for attending such programs. Moreover, the publication of payments made by manufacturers to CME providers who are providing the FDA mandated REMS would suggest impropriety and brings into question the objectivity of the program, despite the fact that FDA has mandated the specific educational components.

Existing Accredited CME Standards

- CME today is vastly different from CME of decades past.
- New standards of commercial support create a principled firewall that prevents undue industry influence.
- CME providers that accept commercial support are committed to transparency, accountability, and independence in producing CME programs and strictly follow all of the rules, standards and regulations cited above to eliminate any kind of potential bias or "conflict of interest."
- Even more recently, the Coalition published a CME Code of Conduct to bring clarity to the rules governing CME.

Review of Existing Accredited CME Standards

- ACCME
- AMA
  - Gifts to physicians
  - CME
- ADVAMED
- PhRMA
- HHS OIG
- FDA

CME and the ACA

- CME Activities: Metrics from October 2011 - October 31st 2012
  - 111,703 US members have participated in one or more ACA and EHR activities
  - 13 CME programs posted
  - 50,556 participants have earned CME credit
  - 76% of participants are active in direct patient care, with the majority (66%) in primary care
  - >30% of participants were MDs
  - 72% of health care providers were nurse/advanced practice nurses
- 5 Healthcare Advisories: Metrics from June 2011 – June 2012
  - 1,333,897 emails delivered; 13.6% open rate
  - 515,831 informed members – email, desktop and mobile

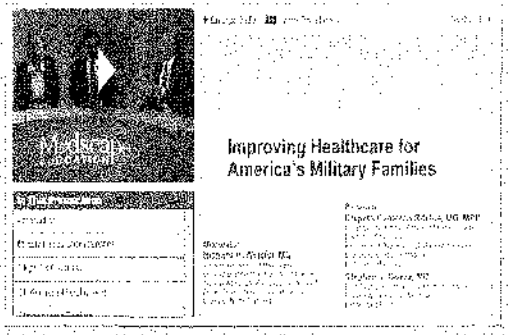
Other Government Programs

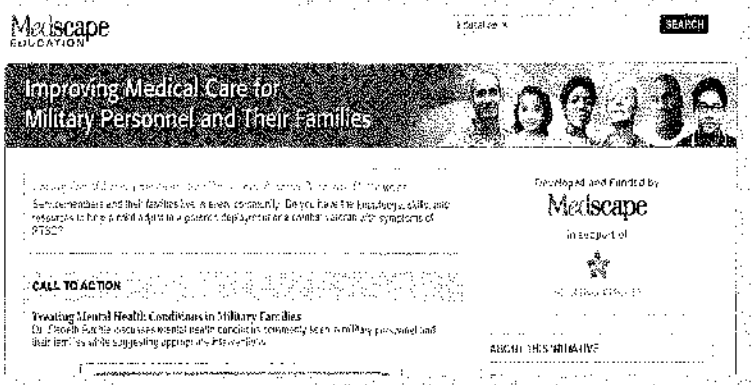
- CMS – ICD 10
  - 3 programs posted 6/28/12 – *21,889 participants*
- CMS – HIV Prevention and Care
  - 3 programs posted 7/20/12 – *3641 participants*
- NIDA – Prescribing Pain Medication Safely
  - 2 programs posted 9/26/12 - *59,256 participants*
- CDC – CFS and Unsafe Injection Practices
  - 2 programs posted – *82,402 participants*
- Office for Civil Rights – HIPAA
  - 2 programs posted 6/28/12 – *14,542 participants*
- Others – AHRQ, National Child and Maternal Health Program
  - 2 programs posted – *11,241participants*

192,971 participants; 87,468 earned credit

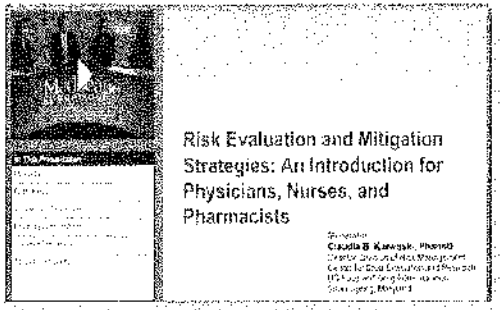
Medscape Supported Programs

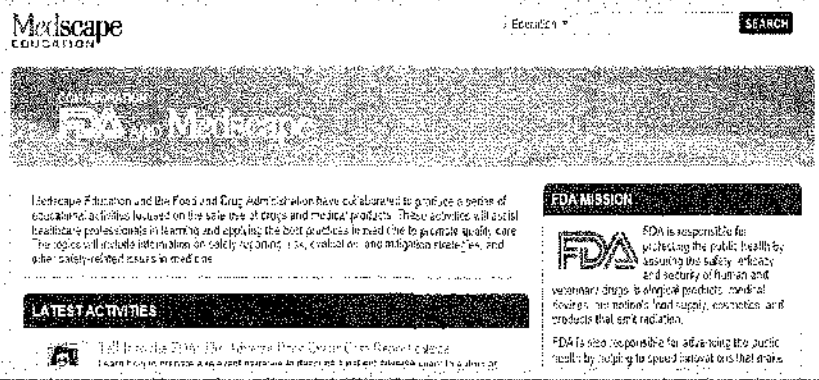
- **Joining Forces Initiative**
  - 10 CME programs posted since June 2011 – ***155,826 learners; 81,680 earned credits***





- **Food and Drug Administration**
  - 5 CME programs posted since November 2011 – ***94,543 learners; 39,181 earned credits***





Proposed Rule is Unworkable

- **Definition of "Awareness"**
  - Vagueness concerns
  - Timing of "awareness" and supporter payments for CME
  - Internet-based CME involves over 80 million physician interactions
  - CME faculty, who are typically physicians and thus "covered recipients," are never paid directly from an applicable manufacturer for an accredited CME program; they are paid through the accredited CME provider.

- **Dividing attribution/payments**
  - Many CME programs involve numerous presenters as well as a multitude of official supporters. Many more companies help to underwrite the cost of educational programming by purchasing booths and displays.
  - Each supporter or booth purchaser that becomes aware of a program's presenters' identities would have to find a way to calculate what amount of their payment was attributable to a given presenter and report it as such. Additionally, once a CME supporter became aware of the identity of an attendee, it might have to report some portion of its payment as though it were made to that individual as well.

Unintended Consequences

- **Creation of stigma**
  - We believe that this would cause many medical professionals to forego CME.
- **Economic burden**
  - We estimate that this regulation could cost hospitals, associations and other CME providers a total of $169,733,813 for three years ($64,151,271 for the first year, and $53,791,271 for years two and three). The economic impact of reporting the educational "transfers of value" to participants would thus constitute approximately 7.7% of the total commercial support currently spent on CME.

Conclusions

- The Need for CME has Never Been Greater
  - More than 400,000 medical journal articles are published each year, making the practice of medicine very dynamic. The sheer volume of new scientific data and changes in medicine requires as many appropriate avenues for funding certified CME as possible.
  - In addition, the changes to practice in medicine occur rapidly. The nature of medicine involves constant advancement, testing, and application. Patients and society demand that our physicians receive information instantaneously, and that updates in treatment, diagnosis, and prevention are disseminated to physicians as soon as practically possible.
  - Without CME, health care practitioners cannot get the most recent and up to date advances. Such advances are pivotal in allowing physicians to begin implementing new breakthroughs sooner and improve patient outcomes before it is too late.
- Rigorous protections already exist to protect the scientific validity of accredited CME and prevent supporter bias
- Educational Materials Exception Seems Applicable
  - We applaud CMS's proposal to exclude "educational materials that directly benefit patients" from the reporting requirements and suggest that accredited CME programs should be treated the same way.