February 16, 2012

Marilyn Tavenner
Acting Administrator/COO
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Tavenner:

Comments re: Physician Payments Sunshine Act (PPSA)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

REFERENCE: File code CMS-5060-P; RIN 0938-AR33 Proposed Rule: Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests

Federal Register Vol. 76, No. 243, Dec. 19, 2011, pages 78742-78773; FR Doc No: 2011-32244

It is our pleasure to submit these comments on behalf of the CME Coalition (www.cmecoalition.org), an advocacy organization comprised of and representing continuing medical education (CME) providers, supporters and beneficiaries, regarding the proposed regulations to implement Section 6002 of the Patient Protection and Affordable Care Act (PPACA)—also known as the Physician Payment Sunshine Act (Sunshine Act). We appreciate the opportunity to express our views concerning our profound opinion that, as written, the proposed regulations will have a terribly detrimental, albeit unintended, effect on the professional training and education of medical professionals, and ultimately, patient care. For purposes of this document the term "supporter" refers to the manufacturer who provides financial support for the program and the term "sponsor" means the accredited entity that oversees the CME activity.

I. Introductory Summary

The CME Coalition both appreciates and endorses the manifest goals of the Physician Sunshine Act; namely, the public reporting of direct payments from manufacturers of medical products to the medical professionals who use them. For a host of reasons, we recognize the public interest in knowing whether physicians are financially benefiting from the same companies that produce the medicines they prescribe and the devices that they use.

We firmly believe, however, that it was never the intent of Congress to expand the public reporting requirements to include transactions related to the provision of continuing medical education when such payments are made from commercial interests to CME providers without allowing for the supporting entity to enjoy any control regarding either the presenters, the curriculum, or the attendees of a given educational program.

If left unaddressed, the Sunshine Act reporting requirements will create the erroneous impression that CME instructors have an inappropriate relationship with the commercial organizations that support the programs that include them through grants and other means. It will also foster the impression that attendees of commercially supported CME programs are inappropriately benefiting from these commercial companies. These misimpressions, and the stigma that attaches to them, will severely chill participation in educational programming among leading practitioners and academics, and will undermine the credibility and integrity of all accredited CME. Additionally, as our comments will attest, it will be virtually impossible to effectively meet the reporting requirements of the Sunshine Act in the CME context without making it practicably unworkable for the private sector supporters of CME to continue to participate.

As health care and educational professionals who value the importance of enhancing the continuing education of the country's physicians, we are troubled by the notion that the Department would not be seeking ways to encourage, rather than impede, this important practice. As our comments will indicate, we believe that the multitude of current accrediting standards and regulations that govern the medical community are more than adequate to ensure that CME is provided without supporter bias of any kind. We, therefore, respectfully request that the Proposed Rule be amended to exclude indirect payments for accredited CME programming.

II. Background on CME Coalition

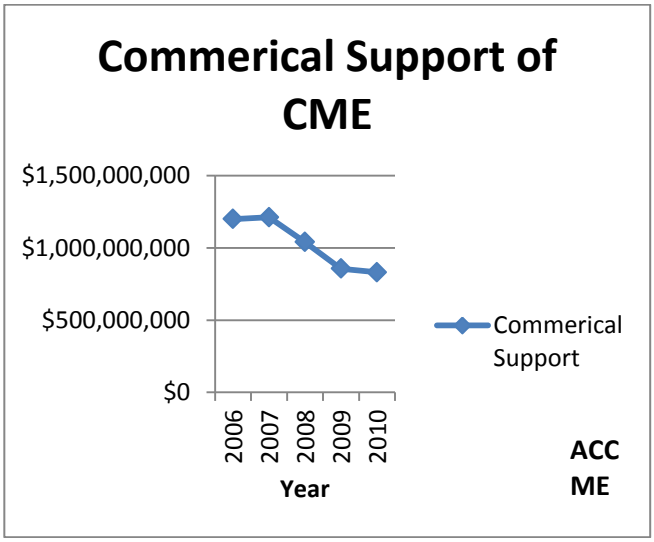
The CME Coalition represents a collection of continuing medical education provider companies, in addition to other supporters of CME and the vital role it plays in our health care system. Our member organizations manage and support development of healthcare continuing education programs that impact more 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. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their technical knowledge and practice skills. CME is a mainstay for such learning. Most State licensing authorities require physicians to complete a certain number of hours of accredited CME within prescribed timeframes to maintain their medical licenses. Hospitals and other institutions may impose additional CME requirements upon physicians who practice at their facilities.

The Accreditation Council for Continuing Medical Education (ACCME) is the principal CME accrediting authority in the United States and "plays a pivotal role in ensuring the integrity of CME by determining whether providers qualify to offer accredited CME programs and by providing ongoing oversight of the CME industry."[1] Once a CME provider gains ACCME accreditation, the provider may offer programs as accredited CME activities without seeking ACCME review or approval of the topic, content, faculty, or format of the individual activity. 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.

Current State of CME

For a variety of reasons, commercial support of CME funding has declined $297 million or 31.4 percent since 2007.[2]



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

[1] Lew Morris Testimony Senate Finance Committee
[2] ACCME Annual Report Data 2010 (Published August 2011)

soon face significant challenges accessing the appropriate, high quality CME necessary to stay current with innovations in the practice of medicine. In fact, 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. [3]

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).[4]

The number of ACCME-accredited providers grew steadily until 2007. The ACCME lost 42 national providers (6%) since 2007, including 13 providers (2%) between 2009 and 2010. The number of accredited providers now is at its lowest level since 2002. Most of the loss has been from the following provider types:

- Nonprofit physician membership organizations,
- Publishing/education companies, and
- Hospital/health care delivery systems.

A Biannual survey conducted by the Society for Academic CME (SACME) Research Committee and the Association of American Medical Colleges (AAMC) also found decreased access to high quality or appropriate CME.[5] The Biennial Survey of CME units at medical schools in the U.S. and Canada showed a drop in CME units over the past three years. Specifically:

- In 2010, over 130 courses on a yearly basis vs. 147 in 2008
- In 2010, approximately 1,363 credits vs. over 3,000 credits in 2008
- In 2010, attendance of 7,500 physicians vs. 9,000 physicians in 2008
- In 2010, attendance of 4,000 non-physicians vs. 4,600 non-physician participants in 2008

There was also a drop in CME units who provide credit for regularly scheduled conferences, series or rounds (RSS):

- Specifically, in 2010, there were 58 regularly scheduled series with 1,600 credits vs. 83 in 2008 2,274 credits in 2008.

[3] Medlinx Survey 2011
[4] ACCME Annual Report Data 2010 (Publishes August 2011)
[5] SACME-AAMC Harrison Survey 2010 (Published June 2011)

In addition, the numbers of asynchronous audio, video, and online courses also decreased.

- Specifically, in 2010, there were 52 courses used video with over 230 credits, audio vs. 170 courses and 266 credits in 2008.
- In 2010, these attracted 4,000 documented physician users vs. 6,895 in 2008.

More concerning is that over 25% of doctors found CME quality decreasing.[6]

Moreover, health professionals will also face challenges accessing appropriate, high quality CME because the economic climate, coupled with decreased commercial support, has affected state-accredited CME providers, universities, and even the federal government. For example, at least one medical school[7] and the Department of Defense (DOD) closed their continuing education offices this past year, and the number of CE providers accredited by state medical societies fell by 18.7% to 1,450 between 2003 and 2010.[8] AMA's Council on Medical Education noted that unabated, this trend could "impede the delivery of cost-effective, quality, accessible certified CME" dealing with local health issues.

III. CME and its Role in 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.[9] 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.[10] 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."[11]

Moreover, when industry is unable to support CME providers, academic institutions, , physicians will lose a valuable source of information and scientific evidence about new treatments and therapies. CME is necessary because new drugs are complex chemical products that require a close understanding, and because research and development often involve the creation of new products. However, the creation of new products will

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[6] Medlinx Survey 2011
[7] http://www.policymed.com/2011/10/cme-and-the-health-care-economy-hospitals-and-universities-cutting-back.html
[8] ACCME Annual Report Data 2010 Ammendum
[9] *Improving COPD Patient Outcomes: Breaking Down the Barriers to Optimal Care.* American College of Chest Physicians annual meeting Chest 2010 in Vancouver, British Columbia.
[10] Drexel, C. et al. *J Clin Hypertens* (Greenwich). 2011 Feb;13(2):97-105
[11] Kiessling, A. et al. *Annals of Family Medicine* 9:211-218 (2011).

produce enduring social gains only if physicians are properly trained and educated about them.

Pharmaceutical and Device manufactures provide grants to CME providers, CME providers to offer objective and independent CME programs, which follow the ACCME SCS. Producers of pharmaceutical products and medical devices ought to have an ability to support education that is unbiased, such as CME, to continue supporting the education of health care providers. CME also provides the function of making sure doctors are aware that new therapies, indications or treatments are actually on the market.

Today's CME providers have the experience, expertise, and long-term commitment to manage the challenges posed by an increasingly complex healthcare environment. Additionally, many stakeholders that comprise the CME enterprise have taken significant steps toward quality improvement. CME programs with commercial support are no different from non-supported CME programs because the content has to be vetted to ensure lack of any commercial bias. CME programs are not provided to "naïve audiences." Commercially supported CME programs speak to physicians who face their own reputational and liability risks when they prescribe drugs or devices and consonant of risk and cautious before changing the way they practice medicine In most of these sessions, physician questioning plays a prominent role, and there is little reason or incentive to think that a commercially supported CME program would push improper risk-making claims given the risk the provider could have of losing its accreditation or other legal sanctions from the FDA, ACCME, HHS OIG, or DOJ.

Physicians overwhelmingly value industry-supported CME and attendees overwhelmingly assert that industry-supported CME programs provide up-to-date, timely, useful, and reliable information about medications to treat particular conditions, and knowledge or skills helpful in their practice. In a recent survey of physicians, 89% of participants valued commercially provided grants to support CME. According to the survey, 76% of participants said they attended an industry supported education program. About 9 in 10 attendees said information provided at educational programs is up-to-date and timely, useful, and reliable. More than half of attendees said they often gain knowledge or skills helpful in their practice and those who practiced in rural areas (86%) were especially likely to attend.

94% said CME was very useful or somewhat useful to stay informed about medications to treat particular conditions. With respect to the educational value of industry supported programs:

- 59% of attendees always or usually gain improved clinical knowledge
- 63% of attendees always or usually learn about potential side effects of medicines
- 54% of attendees always or usually gain knowledge of new uses for medicines

- 58% of attendees always or usually improve knowledge of the range of treatment options
- 54% of attendees always or usually add knowledge about emerging drug risks
- 50% of attendees always or usually strengthen ability to care for patients

CME and FDA's Risk Evaluation Management Strategies (REMS)

The Food and Drug Administration Amendments Act of 2007 (FDAAA) created new section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which authorizes FDA to require a risk evaluation and mitigation strategy (REMS) when necessary to ensure that the benefits of a drug outweigh the risks. FDA may now 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.

Section 505-1 also authorizes FDA to require holders of covered applications approved without a REMS to submit a proposed REMS if the FDA becomes aware of new safety information as defined in 505-1(b)(3) and determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug. Once the holder of an approved covered application is notified by FDA that a REMS is necessary, the holder must submit a proposed REMS within 120 days, or within such other reasonable time as FDA requires to protect the public health (section 505-1(a)(2)(B)). Once approved, the REMS create an enforceable obligation for the manufacturer and the FDA. Proposed REMS may contain any of the following elements:

- **Medication Guide –** Document written for patients highlighting important safety information about the drug; this document must be distributed by the pharmacist to every patient receiving the drug.
- **Communication Plan –** Plan to educate healthcare professionals on the safe and appropriate use of the drug and consists of tools and materials that will be disseminated to the appropriate stakeholders.
- **Elements to Assure Safe Use (EASU) –** These are strictly controlled systems or requirements put into place to enforce the appropriate use of a drug. Examples of EASUs include physician certification requirements in order to prescribe the drug, patient enrollment in a central registry, distribution of the drug restricted to certain specialty pharmacies, etc.
- **Implementation Plan –** A description of how certain EASUs will be implemented.
- **Timetable for Submission of Assessments –** The frequency of assessment of the REMS performance with regard to meeting the goal(s) and objective(s). FDA requires that assessments be conducted at 18 months, 3 years, and 7 years post-launch, at a minimum. Results of these evaluations must be reported to the FDA and will

determine whether additional actions or modifications to the REMS program are required.

A drug's REMS program may not require the provision of all the components above, as the specific components a REMS program employs will vary based on the severity of the risks, the population likely to be exposed, and other factors. Most common REMS only require the provision of a medication guide. While REMS components are not uniform, some do and will contain new provisions and requirements for physicians and other certified health care providers.

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. The central component of the Opioid REMS program is an education program for prescribers (*e.g.*, physicians, nurse practitioners, physician assistants) and patients. The REMS notification letter expressed FDA's expectation that the training would be conducted by accredited, independent continuing education providers. FDA later elaborated its vision for prescriber education stating that it expected the CE training to be provided without cost to the healthcare professionals and that supporters would offer unrestricted grants to accredited CE providers to develop CE for the appropriate prescriber groups. FDA Commissioner Margaret A. Hamburg, M.D. asserted that, "the prescriber education component of this opioid REMS balances the need for continued access to these medications with stronger measures to reduce their risks."

In the final Opioid REMS Blueprint, FDA provided an outline of the required prescriber education. The outline specified that the education must include information on weighing the risks and benefits of opioid therapy, choosing patients appropriately, managing and monitoring patients, and counseling patients on the safe use of these drugs. In addition, the education must include information on how to recognize evidence of, and the potential for, opioid misuse, abuse, and addiction. FDA's expectation is that the initial or basic REMS related CE that should be offered to all prescribers of long-acting and extended-release opioids should consist of a ''core'' content of about 2 to 3 hours.

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. However, concerns about improper influence or conflicts of interest in REMS programs should be misplaced, given the safeguards in place and the significant penalties companies can face. Failure to comply with FDA REMS can render the

company's drug misbranded. Penalties can range from $250,000 to $1 million cap per violation; $1 million to $10 million cap per proceeding.

U.S. Senate Finance Report on Use of Educational Grants by Manufacturers

In 2007, the U.S. Senate Finance Committee published a report regarding industry-supported scientific and educational activities. The report was based on information submitted to the company by 23 pharmaceutical companies who funded educational grants. The Committee report found that, "the pharmaceutical industry is paying increased attention to educational grants and its compliance with fraud and abuse laws," and that "major drug companies have limited the direct involvement of field sales representatives and sales and marketing departments in the educational grant-making process."

The Committee staff found "some promising trends in pharmaceutical manufacturers' use of educational grants," such as companies adopting "corporate policies that, on their face, do not allow educational grants to be awarded for unlawful purposes." Moreover, the report found that, the overwhelming majority of companies are not "overtly giving educational grants to provide kickbacks to individual physicians or physician group practices" who attend educational programs and that this practice "has decreased over time." The report recognized that, "major pharmaceutical companies now conduct their educational grants activities in a way that is less likely to involve the direct transfer of remuneration from the company to physicians."

Private sector spending to provide continuing education to doctors in important areas of great innovation was significant. In 2003, 2004, and 2005, oncology was the therapeutic area that received the most grant funding, followed by cardiovascular disease and then neurology/psychology. The companies reported that for 2005 they had budgeted approximately $218 million in total grant funding for oncology, $112 million for cardiovascular disease, and $104 million for neurology/psychology. Total grant spending on these three therapeutic areas was even higher in 2004, with approximately $230 million spent on oncology, $186 million on cardiovascular disease, and $182 million on neurology/ psychology.

While this spending on educational grants, which has declined tremendously over the past seven years, may seem significant, we have seen great improvements in CVD and cancer. For example, since 1970, the death rate from heart disease has dropped nearly 60%; Deaths from stroke are down 70% since 1970; and the death rate from cancer has dropped 16% since 1990. If it were not for the declines in death rates from heart disease and stroke, one million more Americans would die every year. In addition, the 5-year survival rates for cancer have risen by 26% just since 1984. Based on these values, health economists are able to show that every $1 spent on statin therapy for heart attack survivors produced as much as $9.44 in health gains; and the routine use of beta-blockers

for acute heart attack sufferers produced up to $38.44 in health gains. Without the educational funding made available by these commercial supporters, it is highly likely that we would not have the same improvements because doctors would never have awareness of the new treatments, research and breakthroughs in these areas.

Ultimately, in the five years that have passed since this report publication, significant changes in the CME industry have continued to ensure that supporters follow appropriate rules and standards to prevent any influence or impropriety. Therefore, we strongly hold that CMS should change the proposed regulations to exempt accredited CME providers as the commitment to quality, unbiased, independent scientific programs has been demonstrated and may be endangered otherwise..

IV. Accredited CME Already Abides by Strict Standards to Avoid Potential Conflicts

CME today is vastly different from CME of the 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.

The combined efforts of these organizations have worked. In fact, studies demonstrate concerns about commercial support of CE are misplaced. In 2010, three large studies conducted independently by the Cleveland Clinic,[12] Medscape,[13] and the University of California, San Francisco,[14] were published in peer-reviewed journals. These studies produced substantial data that provide evidence there is a complete lack of commercial bias in industry-supported CME. Given the large amount of well-established CME regulations and guidance already in place, coupled with the results from these very large studies, additional regulations are unnecessary, duplicative, and burdensome.

ACCME Standards for Commercial Support

In 2004, the ACCME adopted its first set of Standards for Commercial Support (SCS) to provide guidelines and rules for CME providers who receive commercial support. The Standards were updated in 2006 and again in 2007. Under the SCS, CME providers must ensure that the following decisions are made free of any control of a commercial

[12] Kawczak S, Carey W, Lopez R, Jackman D. The effect of industry support on participants' perceptions of bias in continuing medical education. *Acad Med*. 2010;85(1):80-84.
[13] Ellison JA, Hennekens CH, Wang J, etal. Low rates of reporting commercial bias by physicians in online continuing medical education activities. *Am J Med*. 2009;122:875-878.
[14] Steinman MA, Boscardin CK, Aguayo L, Baron RB. Commercial influence and learner-perceived bias in continuing medical education. *Acad Med.* 2010;85(1):74-79.

supporter: (a) Identification of CME needs; (b) Determination of educational objectives; (c) Selection and presentation of content; (d) Selection of all persons and organizations that will be in a position to control the content of the CME; (e) Selection of educational methods; (f) Evaluation of the activity.[15]

Providers must also show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the provider. The ACCME defines "relevant" financial relationships" as financial relationships in any amount occurring within the past 12 months that creates the perception of a conflict of interest.[16] An individual who refuses to disclose relevant financial relationships must be disqualified from being a planning committee member, a teacher, or an author of CME, and cannot have control of, or responsibility for, the development, management, presentation or evaluation of the CME activity.[17] CME providers must implement a mechanism to identify and resolve all conflicts of interest prior to the education activity being developed and delivered to learners.[18]

Providers must make all decisions regarding the disposition and disbursement of commercial support[19] and cannot be required by a commercial interest to accept advice or services concerning teachers, authors, or participants or other education matters, including content, from a commercial interest as a condition of contributing funds or services.[20] CME providers must have a written agreement that documents the terms, conditions, and purposes of the commercial support that binds the provider and its educational partner(s).

CME providers must also have written policies and procedures governing honoraria and reimbursement of out-of-pocket expenses for planners, teachers and authors.[21] Moreover, CME providers, the joint sponsors, or designated educational partners must pay directly any teacher or author honoraria or reimbursement of out-of–pocket expenses in compliance with the provider's written policies and procedures.[22] This means that an applicable manufacturer can never pay a faculty member directly nor can they make any other payment to the director of the activity, planning committee members, teachers or authors, joint sponsor, or any others involved with the supported activity.[23] Additionally, CME providers are prohibited from using commercial support to pay for travel, lodging, honoraria, or personal expenses for non-teacher or non-author participants of a CME activity.[24] The provider may use commercial support to pay for travel, lodging, honoraria,

[15] SCS Standard 1
[16] Standard 2.1
[17] Standard 2.2
[18] Standard 2.3
[19] Standard 3.1
[20] Standard 3.2
[21] Standard 3.7
[22] Standard 3.8
[23] Standard 3.9
[24] Standard 3.12

or personal expenses for bona fide employees and volunteers of the provider, joint sponsor or educational partner. CME providers must produce accurate documentation detailing the receipt and expenditure of the commercial support.[25]

Arrangements for commercial exhibits or advertisements cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.[26] Product-promotion material or product-specific advertisement of any type is prohibited in or during CME activities. The juxtaposition of editorial and advertising material on the same products or subjects must be avoided. Live (staffed exhibits, presentations) or enduring (printed or electronic advertisements) promotional activities must be kept separate from CME.[27] Educational materials that are part of a CME activity, such as slides, abstracts and handouts, cannot contain any advertising, trade name or a product-group message:[28]

- For *print*, advertisements and promotional materials may not be interleafed within the pages of the CME content. Advertisements and promotional materials may face the first or last pages of printed CME content as long as these materials are not related to the CME content they face and are not paid for by the commercial supporters of the CME activity.

- For *computer based*, advertisements and promotional materials may not be visible on the screen at the same time as the CME content and not interleafed between computer 'windows' or screens of the CME content.

- For *audio and video recording*, advertisements and promotional materials may not be included within the CME. There will be no 'commercial breaks.'

- For *live, face-to-face CME*, advertisements and promotional materials cannot be displayed or distributed in the educational space immediately before, during, or after a CME activity. Providers cannot allow representatives of commercial interests to engage in sales or promotional activities while in the space or place of the CME activity.

The content or format of a CME activity or its related materials must promote improvements or quality in healthcare and not a specific proprietary business interest of a commercial interest.[29] Presentations must give a balanced view of therapeutic options, and the use of generic names is encouraged in order to contribute to this impartiality. If the CME educational material or content includes trade names, where available, trade

[25] Standard 3.13
[26] ACCME Standard 4.1
[27] ACCME Standard 4.2
[28] ACCME Standard 4.3
[29] ACCME Standard 5.1

names from several companies should be used, not just trade names from a single company.[30]

Individual faculty or CME presenters must disclose to learners any relevant financial relationship(s). This disclosure must include (1) the name of the individual; (2) the name of the commercial interest(s); (3) The nature of the relationship the person has with each commercial interest.[31] For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.[32] Moreover, the source of all support from commercial interests must be disclosed to learners. When commercial support is "in-kind" the nature of the support must be disclosed to learners.[33] Provider must disclose the above information to learners prior to the beginning of the educational activity.[34]

American Medical Association - Opinion 8.061 - Gifts to Physicians from Industry

In addition to the ACCME SCS, the American Medical Association (AMA) also has several ethical rules relevant to CME. For example, the AMA Council on Ethical and Judicial Affairs (CEJA) defines a legitimate "conference" or "meeting" as any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented. An appropriate disclosure of financial support or potential conflict of interest should be made.

AMA recognizes that "subsidies to underwrite the costs of CME conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible." Since the giving of a subsidy directly to a physician by a company's representative may create a relationship that could influence the use of the company's products, AMA recommends that any subsidy should be accepted by the conference's sponsor, who in turn can use the money to reduce the conference's registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by the physicians attending the conference."

Furthermore, AMA asserts that, "[s]ubsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians' time. Subsidies for hospitality should not be accepted

[30] ACCME Standard 5.2
[31] ACCME Standard 6.1
[32] ACCME Standard 6.2
[33] ACCME Standard 6.3
[34] ACCME Standard 6.5

outside of modest meals or social events held as a part of a conference or meeting." AMA maintains that, "it is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging, and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging, and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging, and other out-of-pocket expenses."

Scholarship or other special funds to permit medical students, residents, and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents, or fellows who will receive the funds is made by the academic or training institution. Carefully selected educational conferences are generally defined as the major educational, scientific or policy-making meetings of national, regional, or specialty medical associations. AMA also maintains that, "when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conferences or lectures."[35]

American Medical Association Opinion 9.011 - Continuing Medical Education[36]

AMA states that, the physician choosing among CME activities should assess their educational value and select only those activities which are of high quality and appropriate for the physician's educational needs. When selecting formal CME activities, the physician should, at a minimum, choose only those activities that (a) are offered by sponsors accredited by ACCME, the American Academy of Family Physicians (AAFP), or a state medical society; (b) contain information on subjects relevant to the physician's needs; (c) are responsibly conducted by qualified faculty; and (d) conform to Opinion 8.061.

The educational value of the CME conference or activity must be the primary consideration in the physician's decision to attend or participate. Though amenities unrelated to the educational purpose of the activity may play a role in the physician's decision to participate, this role should be secondary to the educational content of the conference. Physicians should claim credit commensurate with only the actual time spent attending a CME activity or in studying a CME enduring material.[37]

With respect to CME faculty, AMA requires physicians serving as presenters, moderators, or other faculty at a CME conference to ensure that (a) research findings and

[35] Report: Issued June 1992 based on the report "Gifts to Physicians from Industry," adopted December 1990 (JAMA. 1991; 265: 501); Updated June 1996 and June 1998.
[36] Report: Issued December 1993; Updated June 1996
[37] (3)

therapeutic recommendations are based on scientifically accurate, up-to-date information and are presented in a balanced, objective manner; and (b) the content of their presentation is not modified or influenced by representatives of industry or other financial contributors, and they do not employ materials whose content is shaped by industry. Faculty may, however, use scientific data generated from industry-supported research material.

AMA requires that all conflicts of interest or biases, such as a financial connection to a particular commercial firm or product, be disclosed by faculty members to the activity's supporter and to the audience. Faculty may accept reasonable honoraria and reimbursement for expenses in accordance with Opinion 8.061.

With respect to commercial support of CME activities, AMA Guidelines require physicians involved in the commercial support of CME activities to ensure that (a) the program is balanced, with faculty members presenting a broad range of scientifically supportable viewpoints related to the topic at hand and (b) representatives of industry or other financial contributors do not exert control over the choice of moderators, presenters, or other faculty, or modify the content of faculty presentations. Funding from industry or others may be accepted in accordance with Opinion 8.061.

Commercial supporters cannot promote CME activities in a way that encourages attendees to violate CEJA guidelines, including Opinion 8.061, or the principles established for the AMA's Physician Recognition Award. CME activities should be developed and promoted consistent with guideline 2 for attendees and the program, content, duration, and ancillary activities should be consistent with the ideals of the AMA CME program.

AdvaMed - Supporting Third-Party Educational Conferences

AdvaMed, the leading trade association for the medical device industry has determined that *bona fide* independent, educational, scientific, and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. The AdvaMed Code states that companies may provide a grant to the conference sponsor to reduce conference costs. They may also provide grants to a training institution or the conference sponsor to allow attendance by medical students, residents, fellows, and others who are Health Care Professionals in training.

Companies may provide grants when: (1) the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse; and (2) the training institution or the conference sponsor selects the attending Health Care Professionals who are in training. Such grants should be paid only to organizations with a genuine educational function and may be used to reimburse only the legitimate expenses for *bona fide* educational activities. Such grants also should be consistent with

applicable standards established by the conference sponsor and anybody accrediting the educational activity. The conference sponsor should independently control and be responsible for the selection of program content, faculty, educational methods, and materials.

Under the Advamed Code, companies may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees. Also, companies themselves may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are provided: (1) to all Health Care Professional attendees (with the limited exception noted below), and (2) in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity. Any meals and refreshments should be modest in value, subordinate in time and focus to the purpose of the conference, and clearly separate from the continuing medical education portion of the conference.

Companies may also make grants to conference sponsors for reasonable honoraria, travel, lodging, and modest meals for Health Care Professionals who are *bona fide* conference faculty members.

PhRMA Code

The pharmaceutical industry, as represented by PhRMA, has long recognized the importance of commercial support for CME within strict rules to limit the appearance of conflict. Continuing medical education (CME), also known as independent medical education (IME), helps physicians and other medical professionals to obtain information and insights that can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. Such financial support for CME is intended to support education on a full range of treatment options and not to promote a particular medicine. Accordingly, PhRMA requires a member company to separate its CME grant-making functions from its sales and marketing departments. In addition, requires member companies to develop objective criteria for making CME grant decisions to ensure that the program funded by the company is a *bona fide* educational program and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.

According to PhRMA, third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care, and therefore, financial support from companies is appropriate. A conference or meeting is any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentation(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented (adopting AMA 8.061).

The PhRMA Code requires any financial support be given to the CME provider or meeting/conference sponsor directly, which, in turn, can use the money to reduce the overall CME registration fee for all participants." The company should respect the independent judgment of the CME provider or meeting/conference sponsor and should follow standard ACCME SCS. The PhRMA Code clearly maintains that, "[w]hen companies underwrite CME or meetings/conferences, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines. The company should not provide any advice or guidance to the CME provider or meeting/conference sponsor, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company."

The PhRMA Code prohibits financial support for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME, either directly to the individuals participating in the event or indirectly to the event's sponsor. Similarly, funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event. A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for a CME event to provide meals for all participants.

Department of Health and Human Services (HHS) Office of the Inspector General (OIG)

In its 2003 Compliance Program Guidance for Pharmaceutical Manufacturers (CPG), OIG noted that, "educational funding can provide valuable information to the medical and health care industry." Moreover, OIG recognized that, "absent unusual circumstances, "grants or support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse, provided that the grant or support is not restricted or conditioned with respect to content or faculty."

OIG raised concerns however, about potential kickback issues. OIG noted that, "funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate. Furthermore, to the extent the manufacturer has any influence over the substance of an educational program or the presenter, there is a risk that the educational program may be used for inappropriate marketing purposes."

To reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, OIG recommended that manufacturers separate their grant making functions from their sales and marketing functions to insure that grant funding is not inappropriately influenced by sales or marketing motivations and

that the educational purposes of the grant are legitimate. PhRMA and AdvaMed subsequently incorporated this recommendation into their codes.

OIG also recommended that manufacturers establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient and that serve to ensure that the funded activities are bona fide. The manufacturer should have no control over the speaker or content of the educational presentation. Compliance with such procedures should be documented and regularly monitored. All of these recommendations are requirements in the ACCME SCS and present in the FDA Guidance and industry codes.

OIG recognized "that many grant-funded activities are legitimate and beneficial," and recommended that manufacturers review educational and research grants to physicians similarly to educational and research grants to purchasers. When evaluating educational or research grants provided by manufacturers to physicians, OIG recommended that the manufacturer determine whether the funding is for *bona fide* educational or research purposes. In addition, the manufacturer must determine if the funding is based, in any way, expressly or implicitly, on the physician's referral of the manufacturer's product. If so, the funding plainly implicates the anti-kickback statute, which prohibits the knowing and willful offer or payment of anything of value to induce referrals to the Federal health care programs. For example, when a pharmaceutical manufacturer rewards a high-prescribing physician by directing a CME provider to pay (or overpay) that physician to be CME faculty, that payment may be considered a kickback.

OIG recommended that, "manufacturers take steps to ensure that neither they, nor their representatives, are using these activities to channel improper remuneration to physicians or others in a position to generate business for the manufacturer or to influence or control the content of the program." In addition, OIG recommended that manufacturers and sponsors of educational programs, "be mindful of the relevant rules and regulations of FDA," and noted that, "[c]odes of conduct promulgated by the CME industry may provide a useful starting point for manufacturers when reviewing their CME arrangements."

Although OIG recommended elimination of industry sponsorship by funders who have a significant financial interest in physicians' clinical decisions, the office recognized that CME providers would need to identify alternative sources of funds to maintain the availability of CME. Recognizing the difficulties CME providers would face without commercial support, OIG recommended several measures that would "allow continued access to industry funding for CME, but limit industry's ability to influence how that money is used and what messages physicians receive." Morris' recommendations merely reiterated the 2003 CPG and recognized ACCME, PhRMA and AdvaMed for incorporating many of OIG's recommendations into their standards and rules.

FDA Guidance

The FDCA requires the FDA to regulate drugs and devices based on their "intended use." The term "intended use" is broadly defined to capture the manner in which a company characterizes its product in the marketplace. FDA thus must examine the various means by which manufacturers and their representatives provide information about their products to health care professionals and consumers, including statements and materials presented at industry-supported scientific and educational activities, to determine whether the products are being improperly promoted, and therefore misbranded or adulterated.

Oral statements and materials presented at industry-supported scientific and educational activities may provide evidence of a product's intended use. The "intended" use of a drug or device refers to the objective intent of the persons legally responsible for the labeling of the product. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. (21 CFR 201.128 and 801.4); see e.g., Coyne Beahm, Inc., et al. v. United States Food and Drug Administration, et al., 958 F. Supp. 1060 (M.D.N.C. 1997).

Accordingly, oral statements and materials presented at industry-supported scientific and educational activities may provide evidence of a product's intended use. If these statements or materials promote a use that is inconsistent with the product's approved labeling, the product is misbranded under section 502(f)(1) of FDCA for failure to bear labeling with adequate directions for all intended uses. If it is a device, it is also adulterated because the listing of unapproved uses in the labeling or advertising of an approved device results in an adulterated medical device under section 501(f) of the act, and misbranded under section 502(o) of the act because premarket notification was not provided as required under section 510(k) of the act (21 CFR 201.5; Alberty Food Products Co. v. United States, 185 F.2d 321 (9th Cir. 1950)).

FDA also finds support for its policy of examining a broad array of information disseminated by companies in the general grant of authority over labeling and advertisements. Section 201(m) of the act defines the term "labeling" to include all "written, printed, or graphic" materials "accompanying" a regulated product.[38]

On December 3, 1997, FDA issued its Final Guidance on Industry-Supported Scientific and Educational Activities. The guidance, which accommodated industry's need for predictability in these activities, provides a policy statement on what factors the agency will consider in determining whether an industry-supported activity is independent of the

[38] The Supreme Court has agreed with the agency that this definition is not limited to materials that physically accompany a product. If the material supplements, explains, or is otherwise textually related to a product, it is deemed to accompany the product for purposes of section 201(m) of the act. (See Kordel v. United States, 335 U.S. 345 (1948).

promotional influence of the supporting company and therefore not subject to regulation. FDA stated that its factors "are provided to furnish guidance on the design and conduct of such activities, so that they will be educational and non-promotional in nature." In determining whether an activity is independent of the substantive influence of a company, FDA examines whether and to what extent the company is in a position to influence the presentation of information related to its products or otherwise transform an ostensibly independent program into a promotional vehicle.

As explained in the guidance, FDA has not regulated and does not intend to regulate industry-supported scientific and educational activities that are independent of the promotional influence of the supporting company. This distinction is important because in addition to following ACCME SCS, accredited CME providers must also ensure that all programs meet the definitions and factors FDA proscribed for an industry-supported activity to be "independent." If CME providers do not follow FDA's guidance, there is potential for the CME provider's activity to be deemed promotional and to fall under FDA's jurisdiction with risk of penalties for any improper promotional materials or statements. Given FDA's decision not to regulate independent industry-supported activities, we would encourage CMS to similarly avoid promulgating Sunshine rules that will have the impact of regulating the nature of reporting and payments involving independent CME providers and faculty.

Although health care professionals at industry-supported scientific and educational activities must determine whether the information presented is scientifically sound for themselves, FDA recognized "that most industry-supported scientific and educational activities are not inherently misleading." Moreover, FDA stated its intent to "work with major accrediting organizations to monitor company-supported educational activities conducted by their accredited providers," and recognized that "the primary responsibility for overseeing the process of postgraduate and continuing professional education and scientific exchange lies with the scientific and health care communities and accrediting organizations." Further, FDA recognized "the importance of avoiding undue Government interference in postgraduate and continuing education for health care professionals."

We have recently seen this recognition of the important role of CME through the Opioid REMS, discussed above. Furthermore, as discussed below, accredited CME providers and manufacturers face significant penalties and fines under the FDCA for not following FDA's guidance because if a CME program is not "independent" within FDA's criteria, it could be considered promotional and any product being discussed could be considered "misbranded."

The FDA guidance includes a number of suggestions on the design and conduct of industry-supported scientific and educational activities so that they will be free from the promotional influence of the supporting company and not misleading. First, FDA

emphasized the importance of provider "sole responsibility," giving the provider full control over the design and content of the program and selection of speakers. FDA clearly recognized that it will not infer any bad intent by a manufacturer to influence content of a program when "a *provider* independently selects a presenter." The guidance also maintained that the supporting company should provide limited technical support only in response to an unsolicited request for assistance from either the provider or a presenter and should not engage in activities that could influence the presentation's content such as scripting and targeting points for emphasis.

With respect to the focus of a CME program, FDA said it will look at whether "the central theme [of the program] is based on a single product marketed by the company or a competing product, except when existing treatment options are so limited as to preclude any meaningful discussion of alternative therapies." FDA recommended that, "emphasis on a newer or, in the view of the presenter, more beneficial treatment modality should be provided in the context of a discussion of all reasonable and relevant options." This guidance should address CMS' concern that CME programs promote new, more expensive brand name products.

Second, FDA stated that the provider ensure meaningful disclosure to the audience, at the time of the program, to the audience of: (1) the company's funding of the program; (2) any significant relationship between the provider (an entity, other than a regulated company, that produces the activity or program), presenters or moderators, and the supporting company (e.g., employee, grant recipient, owner of significant interest or stock); and (3) whether any unapproved uses of products will be discussed. FDA defined "meaningful disclosure" as "disclosure that is reasonably calculated to reach the relevant audience in a manner that will alert them to potential biases" and to ensure that the audience is in a position to fully evaluate the information presented, in order to avoid being misled, confused, or deceived." FDA defined "significant relationships" as "relationships that may give rise to actual or perceived conflicts of interest." Where there is a question as to whether a relationship is significant, FDA recommended that providers, presenters, and supporting companies disclose the existence of the relationship. FDA specifically asserted that, "the provider should determine how to ensure that disclosure is meaningful."

We believe that CMS' proposed regulations should follow FDA's preference for allowing the CME providers to "determine how to ensure that disclosure is meaningful" to the audience, rather than attempting to publish payments on CME faculty and providers. Furthermore, FDA envisioned that any potential conflict of interest risk could "be satisfied by disclosing the existence of and characterizing significant relationships, and need not include further detail such as the amount of compensation or funding received." Moreover, FDA clearly recognized that "disclosure should impose only a minimal burden on providers, presenters, and supporting companies." In addition, FDA's assertion that disclosure "of any significant relationship between the provider, supporting company, and

presenters or moderators would be sufficient," suggests that further disclosure from CMS would be unnecessary, duplicative and burdensome.

We suggest, therefore, that the Department should follow FDA's recognition that the amount of compensation or funding received is unnecessary for disclosure at CME activities. Moreover, we implore the Department to adopt FDA's reasoning, which noted that disclosure for CME activities "should impose only a minimal burden on providers, presenters, and supporting companies." As we have noted throughout our comment, the Sunshine Regulations as drafted, would impose a significant and unnecessary burden on providers, presenters, supporters and participants.

FDA also recognized the difficulty a supporting company and provider may have documenting the dates, times, and locations of all presentations in advance, and eliminated this disclosure requirement from its guidance. Accordingly, CMS should similarly acknowledge the difficulty manufacturers and CME providers would have documenting the dates, times, and locations of all presentations, especially given the nature of grand rounds CME, regional and local conferences, and hospital or community health centered activities. While multiple presentations of the same program may raise promotional concerns, providers already will have significant firewalls to prevent any such promotion through FDA's guidance as well as ACCME SCS.

Finally, FDA asserted that sales or marketing departments of the supporting company should avoid involvement in audience selection decisions. These changes have been implemented in the PhRMA, AdvaMed and ACCME rules and standards. FDA also stated that providers should not have any promotional activities in the meeting room, a rule that has similarly been incorporated in the previously referenced standards. Ultimately, FDA recognized that, "industry-supported scientific and educational activities that are designed and carried out in this manner are less likely to result in the dissemination of false, misleading, or biased information that can adversely affect public health."

V. In the Context of CME, the Sunshine Act Proposed Rule is Unworkable for Many Reasons

Definition of "Awareness" is Problematic

We believe that requiring applicable manufacturers to report payments to third parties, such as CME providers, when they are "aware" of the identity of a covered recipient who

will receive payment indirectly from the third party is impossible to implement in any practical sense.

Section 1128G(e)(10)(A) of the Act excludes the reporting of payments or other transfers of value that an applicable manufacturer makes indirectly to a covered recipient through a third party when the applicable manufacturer is *unaware* of the identity of the covered recipient. The Coalition believes that the vague meaning of this provision will create significant uncertainty for CME supporters, providers and participants. Under the proposed interpretation, for example, if a CME provider (who is not a covered recipient) receives an educational grant from an applicable manufacturer, and either 1.) the CME provider included the names of faculty in a CME proposal or 2.) the applicable manufacturer subsequently learned of the faculty's participation at some point, the applicable manufacturer would have to report the payment as if it were made directly to the faculty.

CMS provides no explicit guidance as to what point during the process a CME grant is awarded, an applicable manufacturer to be considered "aware" of the covered recipient's identity. For example, a typical scenario is where a CME provider applies for a CME grant without designating faculty, no faculty have been hired or reached out to, and only the CME scientific staff have worked on the proposal. In this case, if the CME provider is awarded a grant at this stage, the applicable manufacturer has awarded an educational grant in which they were "unaware" of the identity of a covered recipient.

The Coalition believes that if a grant is awarded under such circumstances, and the manufacturer somehow later becomes "aware" of the identity of a covered recipient, this payment should be exempt because the manufacturer had no involvement in choosing the faculty (even though such is banned by ACCME, FDA, PhRMA, OIG) and the recipient's identity played no role in the manufacturer's grant awarding decision. Essentially, if an applicable manufacturer is unaware of a covered recipient's identity at the time they are awarding a grant, there is no need to publish these payments because the grant was awarded based on the educational and practice gaps and the scientific evidence contained in the proposal.

Under the Proposed Rules, we are concerned as to what happens in the case in which a supporter's final payment for services to a provider does not occur until after the program has been completed and the identities of the presenters have been disclosed? Does this now become a reportable transaction?

Furthermore, we are also uncertain as to what the impact will be on CME program attendees whose identity becomes known to a program supporter. Will their subsidized attendance qualify as a payment that must be reported? If so, is it not misleading to the public to create the impression that these attendees are receiving payment from health care manufacturers?

In the case of accredited CME, however, the above circumstances are moot. Manufacturers can never have any say in choosing faculty for any CME program, which is why we believe the concern for publishing payments made to faculty through CME providers is unnecessary. There are significant rules and regulations in place that CME providers follow to choose faculty, which we discussed in detail above. While the Coalition supports the goal of the Sunshine Act for promoting transparency and reducing potential conflicts of interests, the CME industry and CME providers already have significant mechanisms and regulations in place to mitigate and manage such risks.

Moreover, we believe that requiring the public reporting of payments made from manufacturers indirectly to CME faculty is improper and misleading. 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. CMS cannot, thus, directly attribute a manufacturer's payment to CME faculty when the accredited provider receives the payment, and the faculty never receives payment from the company/grantor. Publishing payments as if the faculty received the payment directly from the applicable manufacturer calls into question the independence of an accredited CME program, which FDA, OIG, ACCME, PhRMA and AdvaMed standards and rules were designed to preserve. Thus, CMS' interpretation runs counter to significant rules and standards that ensure independence in industry-supported CME programs.

Furthermore, because applicable manufacturers must report any product or service associated with the payment, publishing a payment to a CME faculty member would create an association between the CME program and promotion of a particular company's product. Juxtaposing a CME faculty member's name and payment for a CME program, with a manufacturer's product manifests a direct violation of the ACCME SCS and puts the accredited CME provider into non-compliance with the ACCME's mandates. It is also improper to link CME faculty to an applicable manufacturer in the context of accredited CME programs because many of these individuals will have no contact or association with the company, other than knowing the names of companies that are supporting the program with an educational grant.

ACCME SCS's prohibit inappropriate relationships between faculty and a manufacturer and therefore, publishing such payments would again put a CME provider in non-compliance with ACCME requirements. In addition, imposition of these requirements will also enable the breach of independence of CME providers from applicable manufacturers by suggesting that these manufactures may dictate the amount and the nature of payment by the CME provider to a faculty who is also a covered recipient.

Additionally, the disclosure of CME faculty members to applicable manufacturers could reduce the independence accredited CME provides have in producing independent

programs. Under FDA and OIG Guidance, ACCME SCS, and PhRMA/AdvaMed Codes, an applicable manufacturer can only provide educational grant funding to an accredited provider. Applicable manufacturers have no say in what faculty is utilized or how much honoraria and related payments the accredited provider gives to the faculty. The accredited provider is not obligated to disclose any specific information to the supporting applicable manufacturer on payments made to individual faculty.

Accurately Dividing the Payments Among Presenters Would be Close to Impossible

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.

As the Proposed Rules are written, we believe that 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.

Such an outcome creates an impossible tracking and attribution role for the CME provider companies that are tasked with coordinating these events. Further, the absence of any certainty in this regard, coupled with the sizable fines for corporations that fail to make accurate reports, will have the added impact of dissuading many commercial supporters from even taking the risk of supporting CME activity going forward. If commercial support were to further erode from CME, it would put tremendous strain on our current means of providing our medical practitioners with the continuing education they desperately need.

Complying Would be Overly Burdensome and Contrary to Executive Order 13563

CMS has not calculated the regulatory burden on CE providers if it were to include indirect payments from CE providers and other groups. Moreover, the proposed CMS Regulations are contrary to Executive Order 13563 by burdensome regulations on CME providers

The impact of tracking, recording, reporting systems and hours on CME providers were not accounted for in the CMS financial impact assessment of the proposed rules. CMS has not evaluated a) allowing CME providers 45 days to review the accuracy of such payments if they are to be posted by applicable manufacturers b) the time, staff, costs, and resources on CME providers and other groups to communicate with applicable

manufacturers about the nature and magnitude of such payments c) the adverse impact publishing faculty payments will have on the integrity, accountability, and independence in CME programs; and d) the burden this will place on recruiting faculty for CME programs.

As noted above, CME providers will now have to track all payments or other transfers of value for faculty including but not limited to, honorarium, food, travel, and incidentals, in addition to NPI numbers. CME providers will also have to track attendees, if the list is published or available (department and annual meetings). This will decrease attendance while increasing administrative burdens.

Moreover, CMS' proposed regulations are contrary to Executive Order 13563, dated January 18, 2011. The Order reiterated Executive Order 12866 of September 30, 1993, which noted that each agency must, among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

CMS' proposed interpretation of awareness, which will adversely affect CME providers, did not determine how the benefits of imposing such regulations on CME providers justify the costs. Moreover, CMS' inclusion of CME providers does not suggest any careful tailoring because it imposes a significant burden on CME providers. In addition, it appears as though CMS did not consider any alternatives to including CME providers because had they reviewed all of the rules, regulations and standards we summarized above from FDA, HHS OIG, ACCME, PhRMA and AdvaMed, they would have realized that direct regulation of accredited CME payments is unnecessary. Similarly, CMS in promulgating the proposed regulations on "awareness," CMS did not consider "regulatory approaches that reduce burdens and maintain flexibility" for CME providers and stakeholders.

The Executive Order also recognized that, "Some sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent, or overlapping" and that, "Greater coordination across agencies could reduce these requirements, thus reducing costs and simplifying and harmonizing rules." The

accredited CME industry, as described above, already faces a significant number of regulatory requirements and standards. Implementing CMS' proposed regulations to include CME providers do not promote innovation. Instead, we believe it stifles innovation by requiring accredited CME providers to take resources they would be using to create new and innovative educational programs and materials, and diverts them to tracking payments.

Educational Materials Exception

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.

CMS created an exception for "educational materials that directly benefit patients or are intended for patient use." The implication is that other educational materials that 1) do not directly benefit patients or 2) are not intended for patient use, must be reported, such as CME program materials. CMS states that the exception is limited to "materials" (including written and electronic materials), but excludes "services or other items." The Coalition maintains that CME materials given to participants should be exempt from reporting because CME materials, presentations and curricula *directly* benefit patients by improving the knowledge, competency, training and education of health care professionals, enabling them to render care that is more effective and to improve patient outcomes.

Creates Unfair Misimpression and Stigma, Leading to Reduction in CME Participation

As strong advocates for CME, we see the education of medical practitioners as an indispensible ingredient in the expansion of health care innovations and improvements in patient outcomes. A robust commitment to CME requires adequate resources from across the health care system. It also requires the participation from expert practitioners and academics who will take the time to share their knowledge with other medical professionals. We harbor great concern that the requirement that such indirect payments be reported will cause many leaders in their field to forego participation in CME rather than have to answer questions related to the so-called commercial payments they were reported to have received.

Additionally, while all agree that we should be encouraging physicians to take on as much education as they can, we fear that the Proposed Rules would require the reporting of CME support payments as though they were direct payments to CME program attendees if a supporter was ever found to be "aware" of a physician's attendance. For the same reasons related to stigma associated with commercial support, we believe that this would cause many medical professionals to forego CME.

Estimate of Economic Burden on Compliance for CME Providers

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).

In 2010, commercial interests reportedly provided $830,849,917 in grants in support of CME programs. 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. This would cause an enormously destructive economic impact on CME activities designed to educate physicians.

We must assume, as most CME supporters would assume, that given the uncertain nature of the "awareness" definition, coupled with the very significant penalties for failure to report, any payment to support CME could trigger the law's reporting requirement.

We reach these estimates through the following methodology:

- There are 16,503 courses held each year with support of industry. A total of 2,267,764 physician participants attend these courses throughout the year.[39] 547 (79%) of the 694 nationally accredited providers accept commercial support.

- There are 1450 State accredited providers of CME. These providers supply CME to physicians in their state including local community hospitals and state chapters of national organizations. Of those, approximately 725 (50%) receive commercial support for their CME activities.

- As a result, the rule as written would require an additional 1,272 organizations to report payments or transfers of value to physicians.

- In addition, many nationally accredited providers offer credit to additional institutions that can no longer keep up with the immense paperwork associated with CME accreditation. This would add approximately 1,000 additional entities.

- Based on the estimate of 2,272 organizations, with 1,000 attendees per organization, this would amount to CME providers keeping track of 2,267,764 physician participants. If there were three commercial supporters per activity (conservatively accounting that these events range from one to 50 supporters including booth rentals), we estimate this to come to six transactions/per

[39] ACCME Annual Report Data Addendum 2010
http://www.accme.org/sites/default/files/null/606_2010_Annual_Report_Addendum_20110915.pdf

participant/activity, which would be the equivalent of 13,606,584 transactions. Because CME providers would have no way of knowing if the physician was near the reporting threshold, they would be required to report every transaction.

- A full time employee (FTE) can accurately track 20 transactions/hour. We calculate it would thus require 680,329 hours of recording time and data entry time. Using the Bureau of Labor Statistics Occupational Employment Statistics reported compensation for Management Occupations at General Medical and Surgical Hospitals, the hourly average rate for Management Occupations is $44.88 or $65.01/hour when fringe and overhead costs are applied. Physicians are already reviewing their information online, but for the CME activities, a physician FTE could review perhaps six times as fast or 18% of the time to review transactions from hospitals and other CME providers. This would amount to 113,388 hours by physicians prior to reporting to the covered manufacturer, supplier or GPO.

- For review of the CME data, we estimate that it will require 113,388 hours or 80 transactions to review per/hour. This is based on an average hourly rate of $54.53 for healthcare practitioners and technical occupations in physician offices, which rises to $72.52 with 33% fringe benefits and overhead costs. This average includes physicians who account for about ½ the employment in this category.

- In addition to the costs listed, there will also be costs for aggregate spend computer tracking systems at over 2,272 entities, which will include staff training and coordination with other systems within the hospitals, medical societies and other CME providers. If each system with training costs just $5,000, which is lower than actually expected, this would add another additional $11,360,000.

- We also believe there will be significant additional time required to track down the physicians' NPINPI numbers and other relevant information for widely attended events such as grand rounds, state meetings, internet courses and other activities. Because we have no idea what this will require, these numbers are not included in our estimates. One Coalition member however, noted that this could require significantly more time than the time needed to simply enter the data.

Estimated Compliance Costs for CME Providers (Year 1)

	Estimated Entities Reporting (CME providers and joint sponsors)	Estimated Entries	Estimated hours	Hourly Rate	Average Total Cost Per Entity	Total Burden

CME Providers Entry	2,272	13,606,584	680,329	$65.01	$19,466	$44,228,201
CME Review (physicians)	334,500	13,606,584	113,388	$75.52	$25.57	$8,563,070
Computer Software and Training	2272				$5,000	$11,360,000
CME Total		13,606,584	793,717			$64,151,271

For years 2-3, we estimate that some of the administrative burden will be similar as the number of entries may become less, the staffing requirements will still be significant.

Estimate Compliance Costs for CME Providers (Year 2-3/year)

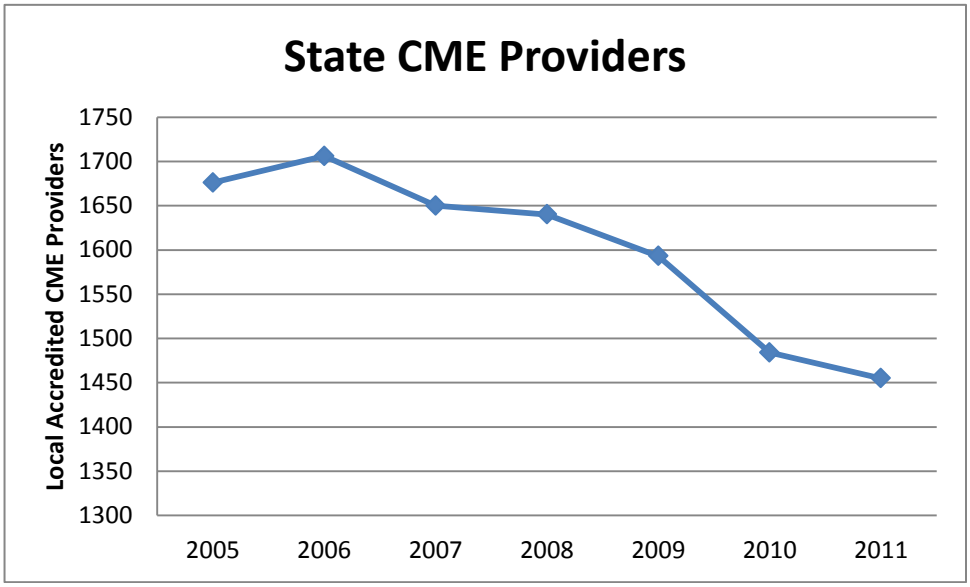
	Estimated Entities Reporting (CME providers and joint sponsors)	**Estimated Entries**	**Estimated hours**	**Hourly Rate**	**Average Total Cost Per Entity**	**Total Burden**
CME Providers Entry	2,272	13,606,584	680,329	$65.01	$19,466	$44,228,201
CME Review (physicians)	334,500	13,606,584	113,388	$75.52	$25.57	$8,563,070
CME Total		13,606,584	793,717			$52,791,271

Estimated Total 3 Year Cost for CME Providers Implementation

Year	Cost
Year 1	$64,151,271
Year 2	52,791,271
Year 3	52,791,271
Three Year Cost for CME providers	$169,733,813

State Level Providers

Since 2005, the number of state level CME providers has dropped 13.1%. We believe the proposed new accounting requirements will only add to the administrative burden of these providers and cause a mass exodus of CME providers on the local level. This trend will only contribute to the increasing challenges we face in keeping our physician work force current with state-of-the-art medicine.



VI. Conclusion

Since the first academic-industry-physician alliances helped produce insulin over eighty years ago, American's have enjoyed a high standard of living, including their state of health and the medical discoveries and treatments that have steadily improved it. This active partnership between science and commerce has created a wide-ranging and productive exchange of knowledge and information. For the last century, physicians have worked hand-in-hand with industry to create some of the most revolutionary advances in medicine and healthcare. Today, it would seem impossible for a physician to be competent in medicine without the information, tools, treatments, data, and other resources industry provides. As a practical matter, commercially supported CME serves an irreplaceable role in disseminating this information to doctors.

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. Medicine features landmark breakthroughs, such as the discovery and testing of a new therapeutic agent. Changes in medicine often are revolutionary. 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.

Although unintended, we believe that CMS' proposed regulations will adversely affect CME providers and deny society the benefits of the knowledge that highly regarded and well-motivated professionals possess. Since 1945, we have had the benefit of these collaborations without having seen any sign of the systematic abuse that could justify the reporting CMS is proposing.

Ultimately, payments made to CME providers for education fall outside of the Sunshine Act's intentions because CME providers are not covered recipients. If CMS believes that CME providers should be treated as covered third parties, then we would suggest that payments to CME providers should be exempted from reporting because of the ACCME's Standards of Commercial Support or the safeguards, firewalls, and transparency protections already required for certified CME. Otherwise, publication of such grants and payments would be detrimental to CME providers in many ways, such as finding sufficient subject-matter expert faculty, planning and budgeting high cost and high quality CME, and soliciting funding. We urge you to consider our belief that the negative impact on CME providers and those who depend upon CME outweigh any potential gain CMS believes publishing such payments will accomplish.

We thank you very much for this opportunity to share our comments.