Submission to the Senate Special Committee on Aging
Roundtable on Sunshine Act Implementation
Senate Dirksen Office Building 562

September 12, 2012

Dear Chairman Kohl and Senator Corker:

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 implementation of 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 opinion that, unless CME-related support payments are exempted from the Sunshine Act's reporting rules, the Act will bring about a devastating, albeit unintended, effect on the professional training and education of medical professionals, and ultimately, patient care.

I. Introduction

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 interpreted to include coverage of these CME support payments, 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 Federal Government 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.

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.

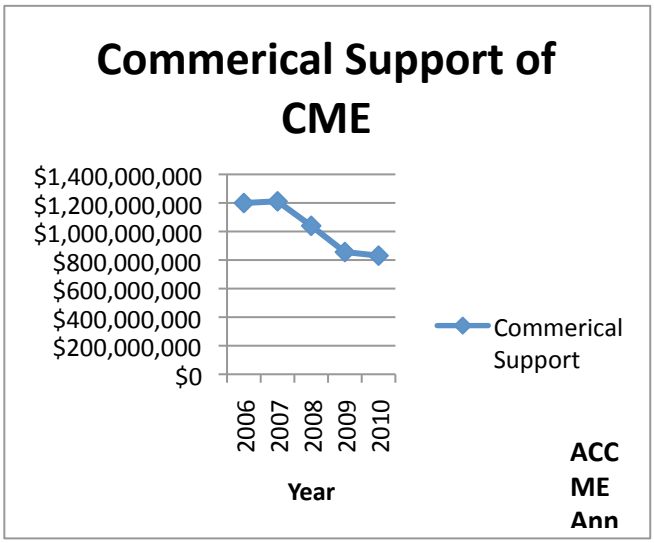
Graduation from medical school and completion of residency training are the first steps in a career-long educational process for physicians. To take advantage of the growing array of diagnostic and treatment options, physicians must continually update their technical knowledge and practice skills. CME 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.

[1] Lew Morris Testimony Senate Finance Committee

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 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:

[2] ACCME Annual Report Data 2010 (Published August 2011)
[3] Medlinx Survey 2011
[4] ACCME Annual Report Data 2010 (Publishes August 2011)

- 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.

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 last 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

[5] SACME-AAMC Harrison Survey 2010 (Published June 2011)
[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

"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 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. Further, 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

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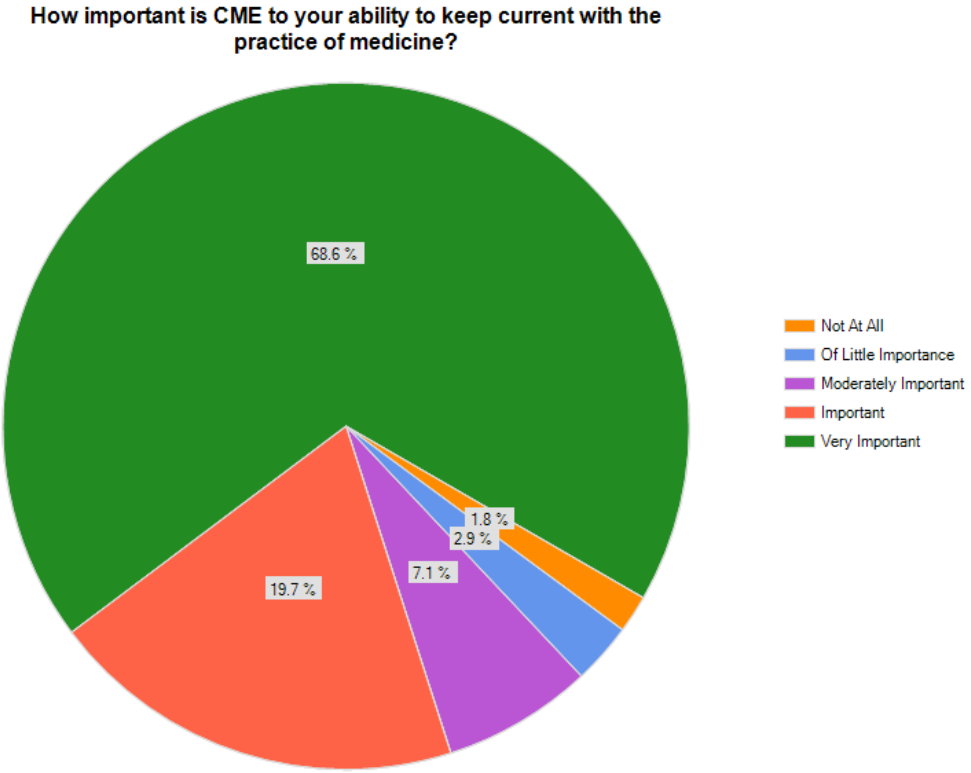
[9] *Improving COPD Patient Outcomes: Breaking Down the Barriers to Optimal Care.* American College of Chest Physicians annual meeting Chest 2010 in Vancouver, British Columbia.
[10] Drexel, C. et al. *J Clin Hypertens* (Greenwich). 2011 Feb;13(2):97-105
[11] Kiessling, A. et al. *Annals of Family Medicine* 9:211-218 (2011).

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.

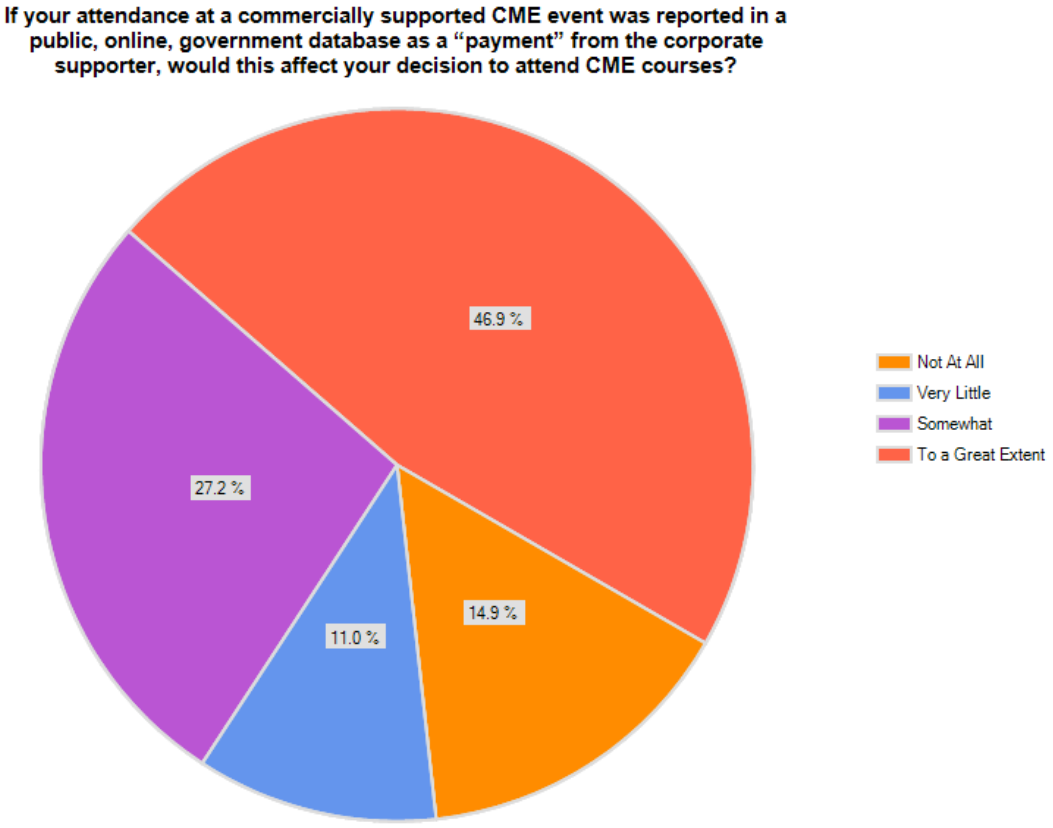
IV. CME Coalition Survey of Physicians

In a recent survey of 467 physicians conducted by the CME Coalition, respondents testified overwhelmingly to both their reliance on CME to improve patient outcomes, and to the importance of commercial support in making these programs financially viable. According to the report, 94 percent of doctors have attended accredited CME events in the last year, and over half of those polled had attended four or more events. Further, physicians clearly recognize the positive impact that accredited CME can have on their ability to improve health care outcomes for their patients. When it comes to both '[keeping] current with the practice of medicine' and '[improving] patient outcomes,' over 95 percent of those polled said that CME was *at least* 'moderately important' – with over two-thirds reporting that CME is 'very important' in keeping up with the latest innovations in their industry.



But despite their recognition that continued medical education increases their capacity to improve the quality of care that they provide, many health care professionals indicate that the reporting requirements mandated by the proposed rule implementing the Sunshine Act will chill their participation in such courses. A significant majority of physicians fear that having their information cataloged in a publicly available database as having received 'payment' from corporate supporters of CME programs will create the stigma that there is bias in these courses, and that their participation is somehow inappropriate. When asked if "attendance at a commercially supported CME event was reported in a public, online, government database as a 'payment' from the corporate supporter, would this affect [the] decision to attend CME courses," 75 percent of doctors responded that it would *at least* affect their decision 'somewhat,' and 47 percent said that their decision would be affected 'to a great extent.'

Moreover, results seem to similarly indicate that significantly fewer physicians would be willing to take leadership at CME events under CMS' proposed rule for the Sunshine Act, as 47 percent responded that their decision to participate as a panelist or presenter would be affected 'to a great extent' under the proposed rule. Additionally, health care providers recognize the important role of companies in providing the financial support – which would not be otherwise available – that is necessary to put on CME events. Among those surveyed, 89 percent of physicians agreed that health care companies should be *at least* 'somewhat' encouraged to provide financial support to underwrite accredited continuing medical education programming and online resources, two-thirds of which thought their financial support should be encouraged 'to a great extent.'



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

As you are aware, 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 Sunshine Act rules as proposed, 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.

VI. 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 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

[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.
[15] SCS Standard 1

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, 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

[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
[25] Standard 3.13
[26] ACCME Standard 4.1

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 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

[27] ACCME Standard 4.2
[28] ACCME Standard 4.3
[29] ACCME Standard 5.1
[30] ACCME Standard 5.2
[31] ACCME Standard 6.1
[32] ACCME Standard 6.2

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]

VII. Including Payments to Support CME under the Sunshine Act 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.

In its Proposed Rule, CMS provided 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

[33] ACCME Standard 6.3
[34] ACCME Standard 6.5

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.

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 sufficient 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.

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.

We worry that each supporter or booth purchaser that becomes aware of a program's presenters' identities might 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.

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 Sunshine Act reporting requirements will cause many medical professionals to forego CME.

VIII. 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, both online and in person, 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.

If it is extended to CME support payments, we believe that the Sunshine Act could 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 their reporting.

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 position that the negative impact on CME providers and those who depend upon CME outweigh any potential gain publishing such payments will accomplish.

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

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