



1720 Eye Street, NW, Suite 400
Washington, DC 20006

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

August 29, 2014

Re: Revisions to the Sunshine Act Under the Medicare Physician Fee Schedule for CY 2015, CMS-1612-P

Dear Administrator Tavenner,

We are pleased to submit 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 changes to the February 8, 2013 Final Rule to implement Section 6002 of the Affordable Care Act (the Physician Payments Sunshine Act). Specifically, we have tailored our comments to address CMS’s proposal to remove § 403.904(g)(1), the “accredited-CME exclusion” from the Final Rule.

The CME Coalition actively participated in the regulatory process of the current Final Rule, has closely followed CMS’s guidance throughout Sunshine Act implementation, and has monitored manufacturers’ and physicians’ experiences with the first year of Open Payments reporting. We believe our experiences working daily with CME providers, as well as our extensive understanding of the nuances of the Sunshine Act, has put us in a unique position to anticipate the impact of your proposal and articulate our serious concerns that the proposed changes will have a detrimental, albeit unintended, effect on the professional training of medical professionals, and ultimately, on patient outcomes.

Whereas we support the objective outlined in CMS’s statement accompanying the proposed rule that “if an applicable manufacturer conveys ‘full discretion’ to the continuing education provider, those payments [should be] outside the scope of the rule,” and thus not reportable, we are very concerned that the actual language being proposed by CMS, could cause considerable confusion, as written, and instead *eliminate* the current reporting exemption for these programs for physician speakers, faculty, and attendees. Such an outcome would have devastating consequences for the practice of CME, and ultimately, for patients.

Therefore, in place of the proposed approach, we suggest that CMS:

- 1. Define “accredited or certified continuing education program”;**

2. **Extend the current Sunshine Act reporting exemption to all *bona fide* CME/CE programs, (as defined by specific criteria, herein), where the applicable manufacturer does not:**
 - a. Select or pay the covered recipient speaker or faculty directly;
 - b. Provide the CME provider with a distinct, identifiable set of covered recipients to be considered as speakers or faculty; or
 - c. **Influence, invite, or select the covered recipient-attendees or otherwise condition its financial sponsorship on the participation of particular covered recipients.**
3. **Clearly and explicitly exempt all *bona fide* CME/CE programs (as defined by specific criteria, herein) from the indirect payment awareness or knowledge standards.**

I. Introductory Summary

In February of 2013, the Centers for Medicare and Medicaid Services (CMS) released a Final Rule implementing the Physician Payments Sunshine Act that included an important reporting exemption for payments to speakers at accredited CME events. At the time, CMS acknowledged that “industry support for accredited or certified continuing education is a unique relationship,” and recognized that rigorous accreditation standards exist to ensure that all accredited or certified CME curricula is evidence-based and free of inappropriate bias. Specifically, CMS correctly recognized and acknowledged that accredited and “certified continuing education that complies with applicable standards of the accrediting and certifying entities generally includes safeguards designed to *reduce industry influence*.”¹ Further, CMS recognized that the “accrediting and certifying bodies, including ACCME, AOA, AMA, AAFP, and ADA CERP, and the industry standards for commercial support, *create important and necessary safeguards prohibiting the involvement of the sponsor in the educational activity*.”²

CMS’s clear and well-defined exemption sent a clear message to physician participants that they could present at, and attend, accredited or certified CME programs without later finding themselves publicly reported in the Open Payments system as recipients of payments or other transfers of value from applicable manufacturers. In fact, CMS recognized that the three conditions outlined in section 403.904(g) would “greatly reduce the number of payments to speakers at accredited or certified continuing education programs that must be reported.”³ Moreover, commercial supporters of CME could take comfort in knowing that their independent grants for CME programs would never necessitate tracking or reporting, so long as they followed the rules restricting their involvement and the applicable standards for commercial support.

¹ 78 Fed. Reg. 9480 (emphasis added).

² 78 Fed. Reg. 9480.

³ 78 Fed. Reg. 9492 (emphasis added).

However, as part of its recent proposed rule outlining the CY 2015 Medicare Physician Fee Schedule, CMS advanced a new proposal that would make changes to the treatment of CME under the Sunshine Act by eliminating section 403.904(g) in its entirety from the current final rule.

II. Our Analysis of the CMS Proposal

CMS states that its motivation in eliminating section 42 C.F.R. § 403.904(g) is to “create a more consistent reporting requirement” and avoid the “apparent endorsement or support to organizations sponsoring continuing education events.” Its remedy, according to CMS, would result in an outcome whereby “payments... where an applicable manufacturer conveys ‘full discretion’ to the continuing education provider... [would be] outside the scope of the rule.” Although this intended outcome seems to indicate CMS’s willingness to *expand* rather than *eliminate* the reporting exemption for CME payments, because the exemption would no longer be limited to programs accredited by the five enumerated bodies of section 403.904(g), we fear that instead, the opposite outcome could result. Indeed, unless CMS explicitly states otherwise, CMS’s proposal to replace the “CME exemption” with the “indirect payment” exemption at 42 C.F.R. § 403.904(i)(1) will subject CME payments to reporting should the commercial supporter (manufacturer) become aware of the identity of the program’s speakers, faculty, or attendees within 18 months of its indirect payment to the CME provider. Given the public nature of CME programs and the broad knowledge standard CMS has adopted, this is a virtual surety. Additionally, since CMS is proposing to implement this change in 2015, it could retroactively force commercial supporters to report indirect payments made as long ago as Q3 2013, which would be a massive administrative challenge and could even implicate constitutional concerns related to reasonable notice.

Thus, if allowed to stand without further clarification that specifically exempts these payments from the reporting requirement in the actual rule, rather than the preamble, we believe the decision to simply eliminate section 403.904(g) could have the following consequences:

Speakers/Faculty - Because CMS only states that indirect payments to speakers at continuing education events will be exempt from reporting in its proposed preamble, and not in the actual rule, it is unreliable from a legal standpoint and these payments could easily be interpreted instead as a reportable “indirect payment.” Indeed, CMS suggests that its intent is to consider these payments “indirect payments” in order to avoid redundancy. Under the current Final Rule, however, indirect payments must be reported if the applicable manufacturer becomes aware of the identity of the recipient of the payment within up to 18 months of the payment. Thus, because CME presenters are always publicly listed, and it is unreasonable to assume that a commercial supporter will remain unaware of their identity, as a practical matter these payments will always have to be reported, thus eliminating the current bright line reporting exemption that exists. Unless, however, CMS takes the position that manufacturers do not “require, instruct, direct, or otherwise cause” CME providers to make payments to physicians speakers or faculty, in which case the payment or transfer of value does not meet the definition of indirect payment, and thus would not be reportable. However, CMS has not offered such

explicit clarity in the preamble or elsewhere.

Attendees - Because current CMS guidance provides that physician-attendees at CME programs are only exempt from reporting for the educational value (or ancillary items) provided at accredited CME events per Section §403.904(g), the entire status of attendees is brought into question as a result of the proposal to eliminate this provision. Thus, the educational value that physicians receive from these programs may have to be considered and reported as indirect payments. As a result, CMS should clarify that this reporting exemption still exists for attendees or users of *bona fide* CME programming. Otherwise, it will be literally impossible for commercial supporters to attempt to accurately calculate, track or report the “value” of the educational experience for any given physician participant. Further, forcing manufacturers to require accredited CME providers to track and report to the manufacturer specific physician information about their participation or attendance is generally prohibited under current standards for commercial support and otherwise blurs the strong firewalls CME providers have in place to ensure the integrity of their programs.

Undermining the Stature of Accredited CME - By eliminating any distinction between accredited CME and other forms of education, CMS is proposing to eliminate any distinction between their treatment of accredited CME and other educational programming under the Sunshine Act. As an association of organizations that strive to make accreditation stand for something meaningful in terms of providing public assurance as to the scientific credibility of CME material, we believe this creates a damaging precedent from the perspective of both doctors and patients. Accredited CME is the Gold Standard of continuing education and is consistently relied upon by the federal government in the pursuit of public health objectives.

III. CME Coalition Proposal

If the goal is truly to find a way to exempt *bona fide* CME related payments when the applicable manufacturer is provided no opportunity to inappropriately influence the curriculum, presentation, or selection of physician participants or attendees, the CME Coalition has drafted specific language for CMS to consider in place of their proposal. While we are cognizant of the agency’s discomfort with serving in the role as “approver” of *bona fide* accreditors, we believe we have developed an approach that meets all of CMS’s needs.

First, we are proposing that CMS maintain an explicit definition in the Final Rule of “accredited or certified CME” in the definition section of the Final Rule. We appreciate CMS’s desire to avoid listing specific accrediting bodies. We have thus analyzed the requirements of accredited CME programs that receive commercial support to formulate a definition to include only *bona fide* accrediting bodies.

Revise §403.902 (Definitions) to add “accredited or certified continuing education program”:

- A. *An educational activity designed, sponsored, or hosted by a third party organization that is accredited or certified by an accrediting body or organization that is recognized by a state or federal government. The accrediting body or organization must:*
- 1. Have standards regarding the acceptance and use of payments or other transfers of value from applicable manufacturers;*
 - 2. Enforce compliance with these standards through audit, inspection, complaints, or otherwise;*
 - 3. Have the authority to impose penalties for non-compliance with such standards, including loss of status or ability to offer credits to physicians;*
 - 4. Require the third-party organization to certify compliance with such standards on a regularly scheduled basis (e.g., bi-annually); and*
 - 5. Not be owned or controlled, in whole or in part, by an applicable manufacturer.*
- B. *The educational activity can be in-person, online, or through other educational platforms.*
- C. *The educational activity includes the value of the tuition or attendance fees, as well as any educational materials or items associated with the program (e.g., slides or handouts) as long as (i) the content is related to the educational activity; and (ii) the funds used for the materials came from the same financial support.*

Second, understanding that the retrospective “awareness” standard becomes nearly impossible for accredited CME speakers, faculty and attendees to comply with, instead of removing Section 403.904(g), we would recommend revising it to state:

*(A) Payments or other transfers of value provided indirectly to physician speakers, faculty, or attendees at an **accredited or certified continuing education program** (as defined above) are not required to be reported if all of the following conditions are met. The applicable manufacturer must not:*

- 1. Select or pay the covered recipient speaker directly;*
- 2. Provide the CE/CME provider with a distinct, identifiable set of covered recipients to be considered as speakers; and*
- 3. Influence, invite, or select the covered recipient-attendees or otherwise condition its financial sponsorship on the participation of particular covered recipients.*

(B) The awareness standard (as defined in § 403.902) shall not apply to physician speakers, faculty, or attendees at an accredited or certified continuing education program.

Note: our revision to section 403.904(g) includes the two safeguards CMS already has in place: A(1) and A(2), but also includes an *additional* safeguard, A(3), which prohibits manufacturers from influencing the selection of physician-attendees. Furthermore, to be exempted from Sunshine reporting, CME providers must meet our definition of “accredited or certified continuing education program.” This provides for additional firewalls between manufacturers and CME providers.

While CMS may be concerned with implementation of this proposal, several factors strengthen the prospect and success of our proposal, while also ensuring that the spirit of the Sunshine Act and implementing regulations are not sacrificed.

First, the Coalition's proposal in no way alters CMS's ability to audit or inspect an applicable manufacturer for compliance with truthful and accurate reporting. That is, if CMS implements our proposal, the agency would continue to have the authority to audit or inspect a manufacturer to determine if the manufacturer correctly exempted from reporting CME payments. Should CMS determine that a manufacturer incorrectly withheld information (e.g., provided a grant to a CME provider that did not meet the conditions above), CMS could impose civil money penalties.

Likewise, manufacturers would continue to attest to the truthfulness and accuracy of their annual payment reports. Thus, CMS could continue to hold manufacturers accountable for any CME-related payments that should have been reported. Moreover, during the next reporting and attestation period, CMS could add additional language to the attestation form in which the manufacturer could acknowledge that they accurately reported (or exempted) CME-related payments.

Second, CMS could work closely with the CME Coalition, the ACCME, and related CME stakeholders to implement the ACCME's proposal to establish a voluntary system in which the ACCME would recognize additional accrediting or certifying bodies that meet the ACCME's Standards for Commercial Support (SCS). This voluntary system would remove CMS from the "approver" role and allow the agency to rely on established CME stakeholders to self-regulate CME providers with respect to commercial support from applicable manufacturers. CMS would not be responsible for creating a list of "Sunshine Exempt CME Accrediting Bodies" or otherwise be responsible for handling decisions about which accrediting or certifying bodies meet the ACCME SCS. This process would provide guidance to applicable manufacturers, CME stakeholders, and physicians regarding which CME providers would be exempt from reporting requirements. CMS could continue its oversight of manufacturers directly or indirectly through the ACCME's transparent process, without increasing any of its regulatory responsibilities.

In its comments to CMS, the ACCME proposed a two-step process be adopted for CME learners, planners, teachers, and authors in commercially supported accredited continuing professional education to earn exemption from reporting under the Sunshine Act. First, the accreditation system must *utilize the ACCME SCS exactly as written by the ACCME*. The SCS forms the basis for our definition of "accredited or certified continuing education." Second, the accreditation system must successfully complete an *ACCME verification process* to "ensure that it evaluates its continuing education providers for compliance with the ACCME SCS using the same rules, data sources, and interpretations as the ACCME." "Under the Standards, commercial interests are not allowed to pay speakers directly nor are they allowed to suggest or select speakers," ACCME's comment states. "In addition, the Standards safeguard independence by requiring the identification and resolution of conflict of interest; the appropriate management of funds derived from industry; the absolute separation of promotion from education; the freedom from commercial bias; and the full disclosure of relevant financial relationships, as well as of any commercial support."

By offering a transparent and public process – in the interests and spirit of the Sunshine Act – the ACCME would ensure that CME/CE programs have adequate safeguards to reduce any potential bias or conflict of interest. Given the ACCME’s expertise in evaluating compliance with its own SCS – which CMS has already acknowledged – the ACCME’s proposed framework coupled with the CME Coalition’s proposed regulatory language provide CMS with a workable solution. Furthermore, the ACCME has extensive monitoring and enforcement powers. If CME providers do not adhere to these rigorous standards, the ACCME will remove their accredited status and such providers will no longer enjoy exemption from Sunshine Act reporting.

The CME Coalition would welcome the opportunity to meet with CMS and help implement the ACCME and CME Coalition’s proposal to ensure that only those CME/CE providers meeting the highest standards maintain exemption from Sunshine Act reporting.

IV. CME and its Role in Improving Patient Outcomes

In order to appreciate the rationale for exempting CME-related payments from Sunshine Act reporting, it is necessary to have an appreciation for the intrinsic value of CME and the role it plays in our healthcare system.

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.

Several studies in the past few years have analyzed the impact of continuing medical education on improving patient care. The studies have repeatedly shown that physicians who are educated about the latest advances in evidence-based practice will make more informed treatment decisions, resulting in improved patient outcomes.

Some examples of recent studies include an industry-supported CME program for multiple sclerosis, which demonstrated “statistically significant changes in participant knowledge and competence across a broad range of patient-care topics.”⁴ Another study found that physicians who attended an industry-supported educational activity for chronic obstructive pulmonary disease were 50% more likely to provide evidence-based care than nonparticipants were.⁵ In addition, patients suffering from hypertension were 52% more likely to receive evidence-based hypertension care when they were seen by physicians who attended an industry-supported educational activity than those seen by nonparticipants.⁶ Yet another study showed that “heart disease patients whose general practitioners participated in an interactive, case-based CME

⁴ *Multiple Sclerosis CME/CE Live Intervention Demonstrates Improved Clinician Knowledge*, published by Med-IQ October 2, 2012

⁵ *Improving COPD Patient Outcomes: Breaking Down the Barriers to Optimal Care*. American College of Chest Physicians annual meeting Chest 2010 in Vancouver, British Columbia.

⁶ Drexel, C. et al. *J Clin Hypertens* (Greenwich). 2011 Feb;13(2):97-105

program had a significantly reduced risk of death over 10 years compared with those whose doctors didn't receive the education.”⁷

In addition, in a recent poll of 488 CME participants, 98.5% of the respondents stated that the knowledge they gained from the CME event was “practical, relevant, and/or helpful in [their] care of patients.”⁸ More than 97% also stated that they learned and/or adopted new diagnostic approaches and/or therapies that resulted in better patient outcomes.

Understanding the particular areas for which physicians need education remains a vital aspect of CME. A 2014 industry-supported study compared oncologists’ responses to treatment case studies with optimal answers based on National Comprehensive Cancer Network kidney-cancer guidelines and evidence-based opinions of two renal cell carcinoma experts.⁹ The findings revealed clinically relevant practice performance gaps that affect how oncologists deliver care to patients. The American Society of Clinical Oncology (ASCO) selected the study as one of eight “noteworthy studies among more than 500 abstracts” to be presented during their 2014 symposium.

The impacts of CME on patient well-being – including longer life, less pain, or less adverse side effects – are well-established. A 2014 study found that CME can also have significant *dollar savings* in patient care.¹⁰ The authors used an educational activity aimed at preventing bleeding-related complications from cardiac and thoracic surgeries for their analysis. The results suggest that even if only a small number of surgeons put into practice what they learned from CME, cost savings could be substantial. Savings would rise even further as more surgeons adopted practices they learned from CME.

In recent years, commercial funding for CME has dropped significantly, yet little has been written about how this might affect CME in fields such as oncology, where new drugs and advances emerge at a rapid pace. Commercial support represented 25.9% of total CME funding in 2013, down from 46% of total funding in 2007.¹¹

The *Journal of Cancer Education* published a study in April 2014 that surveyed close to 300 oncologists about the role of industry-supported CME in their professional development and patient care.¹² The study found that 90% of oncologists “agree” or “strongly agree” that commercial support may be more necessary for oncology than for other specialties due to the rate at which cancer therapies are introduced. Respondents indicated that commercial support plays an important role in providing this cutting-edge information. Three-quarters of the

⁷ Kiessling, A. et al. *Annals of Family Medicine* 9:211-218 (2011).

⁸ 2014 *Opinions about Elimination of the CME Exemption on the Sunshine Act*, Primary Care Network, Aug. 14, 2014

⁹ Rini, Brian et al. *Professional practice gaps and barriers to optimal care of renal cell carcinoma (RCC) among oncologists in the United States*, *J Clin Oncol* 32, 2014.

¹⁰ Ravyn, D, et al. *Estimating health care cost savings from an educational intervention to prevent bleeding-related complications: the outcomes impact analysis model*, *J Continuing Educ Health Prof* Spring 2014

¹¹ ACCME 2013 Annual Report

¹² Robinson, C et al. *The Consequences of Diminishing Industry Support on the Independent Education Landscape: An Evidence-Based Analysis of the Perceived and Realistic Impact on Professional Development and Patient Care Among Oncologists*, *J Cancer Educ.* 2014.

oncologists indicated that commercial support is a significant reason high-quality oncology CME is available. Furthermore, approximately 88% said it is “somewhat” to “very likely” that implementation of new or emerging therapies would be slower if commercial support is reduced, and 89% said implementation of evidence-based medicine would be slower. When asked about their concerns with removing commercial support, oncologists responded that the lack of commercial support for CME would negatively impact the cost of CME, the availability of professional development opportunities, and access to CME.

In summary, the creation of new products will produce enduring social gains only if physicians are properly trained and educated about these advances. Pharmaceutical companies invest billions of dollars in creating new treatments for patients every year. Patients count on doctors to be up to date with these latest medical breakthroughs, and CME provides doctors with that knowledge.

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

Our previous comment to CMS walked through the extensive barriers preventing the slightest industry influence from entering educational content. Many accreditors have directly adopted Standards for Commercial Support (SCS) as promulgated by the Accreditation Council for Continuing Medical Education (ACCME). In addition to the ACCME SCS, the American Medical Association (AMA) has several ethical rules relevant to CME¹³, manufacturers are bound by OIG guidelines and the AdvaMed and PhRMA Codes, and manufacturers have incorporated FDA’s Final Guidance on Industry-Supported Scientific and Educational Activities into their commercial support policies. Industry’s commercial support standards remain just as strong today as when we submitted our comments to the original Final Rule, and have in many cases expanded.

In preparation for submitting this comment, the CME Coalition analyzed the standards of more than a dozen accrediting bodies. Many accreditors have directly adopted the ACCME SCS and have monitoring activities and disciplinary procedures in place, including the ability to revoke a program’s accreditation status if that program fails to live up to their rigorous standards.

The ACCME SCS, and other similar standards of commercial support, create a principled firewall that prevents undue industry influence. As an overview, 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.¹⁴

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

¹³ American Medical Association - Opinion 8.061 - Gifts to Physicians from Industry; American Medical Association Opinion 9.011 - Continuing Medical Education

¹⁴ SCS Standard 1

to the provider.¹⁵ 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.¹⁶ 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.¹⁷

Providers must make all decisions regarding the disposition and disbursement of commercial support¹⁸ 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.¹⁹ 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.²⁰ Moreover, CME providers, the joint providers, 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.²¹ This means that an applicable manufacturer may 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 provider, or any others involved with the supported activity.²² In addition, 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.²³ 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 provider, or educational partner. CME providers must produce accurate documentation detailing the receipt and expenditure of the commercial support.²⁴

The ACCME SCS also extends into arrangements for commercial exhibits or advertisements. Exhibits and ads cannot influence planning or interfere with the presentation, nor can they be a condition of the provision of commercial support for CME activities.²⁵ 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.²⁶ Educational materials that are part of a

¹⁵ Standard 2.1

¹⁶ Standard 2.2

¹⁷ Standard 2.3

¹⁸ Standard 3.1

¹⁹ Standard 3.2

²⁰ Standard 3.7

²¹ Standard 3.8

²² Standard 3.9

²³ Standard 3.12

²⁴ Standard 3.13

²⁵ Standard 4.1

²⁶ Standard 4.2

CME activity, such as slides, abstracts, and handouts, cannot contain any advertising, trade names, or product-group messages.²⁷

Individual faculty or CME presenters must disclose to learners any relevant financial relationships. 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.²⁸ For an individual with no relevant financial relationship(s) the learners must be informed that no relevant financial relationship(s) exist.²⁹ 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.³⁰ The financial information must be disclosed to learners prior to the start of the educational activity.³¹

VI. Why is the Reporting Exemption so Important for CME?

As strong advocates for CME, we see the education of medical practitioners as an indispensable ingredient in the expansion of health care innovations and improvements in patient outcomes. A robust commitment to CME requires adequate resources from across the healthcare system. It also requires the participation from expert practitioners and academics who are willing to take the time to share their knowledge with other medical professionals.

We harbor great concern that the requirement for such indirect payments to 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.

In addition, while all agree that we should be encouraging physicians to take on as much education as they can, we fear that the Proposed Rule 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. Indeed, in a recent poll of 527 CME participants, almost 70% stated that the elimination of the CME exemption would discourage them from participating in industry-supported CME activities.³²

Furthermore, while the reporting obligations would be a great economic burden for manufacturers under the proposal, CME providers would also be forced to bear an unfair burden to collect data on every speaker and participant. Providers, though not “applicable manufacturers,” are directly harmed by this new proposal. We have examined the resources that companies would have to expend in the **Appendix section**.

VII. Conclusion

²⁷ Standard 4.3

²⁸ Standard 6.1

²⁹ Standard 6.2

³⁰ Standard 6.3

³¹ Standard 6.5

³² *2014 Opinions about Elimination of the CME Exemption on the Sunshine Act*, Primary Care Network, Aug. 14, 2014

In conclusion, in its proposed change to the Final Rule, CMS states that replacing the CME exemption with the indirect payment standard “is consistent with our discussion in the preamble to the final rule, in which we explained that if an applicable manufacturer conveys ‘full discretion’ to the continuing education provider, those payments are outside the scope of the rule.” However, as described above, we are concerned that if these payments are indeed to be covered under the rules governing “indirect payment,” they may, as a practical matter, *lose*, rather than *maintain*, their current reporting exemption.

We are passionate about accredited continuing medical education because we see the direct beneficial impact it has on physician excellence and patient outcomes. Forcing these indirect payments to be reported in the Open Payments system will have an unmistakable and chilling effect on physician, and commercial supporter, participation in CME. Any benefit that might be gained from requiring the publication of these payments is simply not matched by the predictable, negative impact on this vital component of our healthcare system, and we urge you to protect or expand the CME reporting exemption in your final rule.

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

Sincerely,

Andrew M. Rosenberg, J.D.
Senior Advisor, CME Coalition

Appendix A

Complying Would be Overly Burdensome and Contrary to Executive Order 13563

CMS has not calculated the regulatory burden on CME providers if it were to include indirect payments from CME providers and other groups. Moreover, the proposed CMS regulations are contrary to Executive Order 13563. The Order, *Improving Regulation and Regulatory Review*, states that the regulatory system “must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative.” The proposed regulations have not taken into account the effect on providers.

The impacts of tracking, recording, and reporting on CME providers were not accounted for in the CMS financial impact assessment of the initial proposed rules and were not proposed in CMS’s July 3, 2014 notice. CMS has not evaluated 1) allowing CME providers 45 days to review the accuracy of such payments if they are to be posted by applicable manufacturers; 2) the time, staff, costs, and resources needed by CME providers and other groups to communicate with applicable manufacturers about the nature and magnitude of such payments; 3) the adverse impact publishing faculty payments will have on the integrity, accountability, and independence of CME programs; and 4) 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 speakers and faculty including, but not limited to, honoraria, food, travel, incidentals, and NPI numbers. CME providers will also have to track attendees in almost every scenario given the broad awareness and knowledge standards. This will decrease attendance (and ultimately harm patient care) while increasing administrative burdens.

Moreover, CMS’s 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’s proposed interpretation of awareness did not determine how the benefits of imposing such regulations on CME providers justify the costs. Moreover, CMS’s inclusion of CME providers does not suggest any careful tailoring because it imposes a significant burden on CME providers. While CMS suggests it considered adding entities to the list of accrediting bodies and

considered adopting standards, the agency dispenses with such alternatives in two or three conclusory sentences. The CME Coalition took part in active discussions with the agency about expanding the list of accrediting bodies and provided numerous resources and other materials to assist the agency in establishing a formal process.

In addition, it appears as though CMS, when making its proposed rule, did not consider that no other federal agency – including FDA and HHS-OIG – directly regulates accredited or certified CME. Thus, in promulgating the proposed regulation, CMS did not consider “regulatory approaches that reduce burdens and maintain flexibility” for CME providers and stakeholders by proposing to be the first agency that would place such an unnecessary burden – particularly now at the thirteenth hour; that is, more than two years after the regulations were finalized.

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, “[g]reater 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’s proposed regulations to include CME providers does 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 divert them to tracking payments.

Estimate of Economic Burden on Compliance for CME providers

We estimate that this regulation will cost hospitals, associations, and other CME providers a total of \$197,586,521 for three years: \$69,735,507 for the first year and \$63,525,507 per year for years two and three.

In 2013, according to the ACCME Annual Report, a total of \$659,935,583 in grants were given by companies in support of CME programs.³³ The economic impact of reporting the educational “transfers of value” to participants would constitute 10.6% of the total commercial support being refocused towards complying with the reporting requirements outlined out in the proposed regulation. Because commercial support for CME has dropped each year by roughly 6%, this burden would be greater than our estimate. This would cause a huge economic burden on CME activities designed to educate physicians in general.

There are 23,493 courses held each year with support of industry, and a total of 2,619,130 physician participants attend these courses throughout the year.³⁴ According to the ACCME, approximately 830 organizations report receiving commercial support for their CME activities.

As a result, the rule as written would require an additional 830 organizations to report payments or transfers of value to physicians back to the applicable manufacturer.

³³ ACCME Annual Report Data 2013, <http://www.accme.org/news-publications/publications/annual-report-data/accme-annual-report-2013>

³⁴ ACCME Annual Report Data 2013

Based on the estimate of 830 organizations, with 4,157 physician attendees per organization, this would amount to CME providers keeping track of 2,619,130 physician participants. If there were three commercial supporters per activity (accounting for the fact that some have one and some have 50 sponsors including booth rental), we estimate this would come to six transactions/per participant/activity, which would be the equivalent of 15,714,780 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 back to the applicable manufacturer.

An FTE can accurately track 20 transactions/hour. This means it would require 785,739 hours of recording time and data-entry time to enter the 15,714,780 transactions. 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 quick or 18% of the time to review transactions from hospitals and other CME providers. This would amount to 170,080 hours by physicians reviewing their data prior to reporting to the covered manufacturer, supplier, or GPO.

For review of the CME data, we estimate that it will require 170,082 hours or 80 transactions for a physician or teaching hospital to review per/hour. This is based on the 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 one half of the employment in this category.

In addition to the costs listed, there will also be costs for aggregate-spend computer tracking systems at more than 830 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 \$7,000 each, this would add another \$5,810,000 to the costs.

We also believe there will be significant additional time required to track down the physicians NPI numbers, state license numbers, and other relevant information for widely attended events, such as grand rounds, annual meetings, internet courses, and other activities. Because the source of this information is still uncertain, we can't know which state license numbers will pass the review by CMS. One Coalition member noted that compiling this information would require significantly more time than the time needed to enter the data.

Estimated Compliance Costs for CME Providers (Year 1)

	Estimated Entities Reporting to AM's (CME providers and joint sponsors)	Estimated Entries	Estimated hours	Hourly Rate	Average Total Cost Per Entity	Total Burden
CME Providers Entry	830	15,714,780	785,739	\$65.01	\$61,543	\$51,080,892
CME Review (physicians)	334,500		170,080	\$75.52		\$12,844,615
Computer Software and Training	830				\$7,000	\$5,810,000
CME Total			955,819			\$69,735,507

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.

Estimated 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	872	15,714,780	785,739	\$65.01	\$61,543	\$51,080,892
CME Review (physicians)	334,500	15,714,780	170,080	\$75.52		\$12,844,615
CME Total			955,819			\$63,925,507

Estimated Total 3 Year Cost for CME Providers Implementation

Year	Cost
Year 1	\$69,735,507
Year 2	\$63,925,507
Year 3	\$63,925,507
3-year cost for CME providers	\$197,586,521

State Level Providers

Since 2006, the number of state level CME providers has dropped 24.4%. We believe this additional accounting requirement 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 not contribute to keeping our physician workforce as up to date as possible.

