February 23, 2015

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Re: Comments Regarding the Senate HELP Initiative to Examine Drug, Device Development and Review Process

Dear Chairman Alexander and Ranking Member Murray:

The CME Coalition applauds the Senate HELP Committee for their bipartisan initiative to expedite safe treatments, devices and cures to patients. The future of medical innovation in this country is bright, and the Committee's commitment to this cause will ensure that America continues to lead the way in discovering the latest breakthroughs in medical technology. But on behalf of the CME Coalition, we wish to emphasize that unless doctors are given the tools and education they need to implement the newest innovations in medicine, the promise of such innovation won't make it to the bedside. Accordingly, we are writing to encourage the Committee to ensure that physician access to continuing medical education (CME) remain a high public policy priority.

Of specific concern to the Coalition is a provision in the Physician Payment Sunshine Act that has been interpreted by the Centers for Medicare and Medicaid Services (CMS) to include "transfers of value" related to the provision of CME within the law's defined reporting requirements. While the Sunshine Act intended to make payments to physicians more transparent, rulemaking from CMS has reached beyond the intent of Congress, calling into question whether accredited educational programs could be subject to the law's reporting requirements, making them less attractive to physicians and more challenging for CME supporters. Specifically, although the agency has emphasized throughout five years of rulemaking that "industry support for accredited or certified

continuing education is a unique relationship," its inconsistent sub-regulatory guidance has confounded industry stakeholders, and is threatening to undermine physician participation in CME.

As physician access to CME is undermined by an uncertain regulatory atmosphere, we urge the Committee to take action as part of its commitment to delivering the latest treatments to patients. Indeed, the Committee should work to develop policies that will *encourage*—rather than *obstruct*—the professional development of our nation's physicians and healthcare workers. To that end, we encourage the Committee to consider legislation that would clarify the original intent of Congress to exempt CME from the Sunshine Act's reporting requirements, and we would welcome the opportunity to provide input on developing such a solution.

About the 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.

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

Background on the Sunshine Act

The Physician Payment Sunshine Act is a healthcare policy first introduced in 2007 by Senators Charles Grassley (R-IA) and Herb Kohl (D-WI), which was later incorporated into law as a part of

the Affordable Care Act, passed in March 2010. A measure intended to bring transparency to financial relationships between providers and industry, the Sunshine Act requires pharmaceutical and device manufacturers to report their direct and indirect payments or other transfers of value made to healthcare providers and teaching hospitals (covered recipients). This financial data is collected by the Centers for Medicare and Medicaid Services (CMS), who report the information publicly on a website launched in September 30, 2014.

While the Sunshine Act was designed to shed "light" on potential conflicts of interest, 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. Specifically, the Sunshine Act protected CME by excluding coverage of indirect payments to "covered recipients" by "applicable manufacturers," such as industry contributions to CME programs.

Unexpectedly, in a December 2011 proposed rule, CMS indicated that they would rely on a "catch-all" provision in the Sunshine Act to require reporting for most CME providers, professional medical associations, patient advocacy groups, and other non-profit organizations. While CMS never finalized this proposal, the agency has advanced a variety of different rules around reporting for CME that has confounded stakeholders left CME providers with many questions about what information they are required to collect. Indeed, the Wall Street Journal recently reported that the most recent guidance from the agency "marks the fifth time that CMS has offered yet another interpretation of its final rule on disclosing CME payments."

As CMS struggles with their implementation of the Sunshine Act, CME stakeholders face an environment clouded with uncertainty as they seek to secure commercial support for future curricula. And with the current rule on CME payment disclosures scheduled to take effect in 2016, there is a limited window of time to act before speakers and attendees will be directly impacted by CMS' indecision in the rulemaking process.

How CME Improves 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."[1] Another study found that physicians who attended an industry-supported educational activity for chronic obstructive pulmonary disease were 50 percent more likely to provide evidence-based care than nonparticipants were.[2] In addition, patients suffering from hypertension were 52 percent 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.[3] Yet another 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."

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 percent of total CME funding in 2013, down from 46 percent of total funding in 2007.[4]

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.[5] The study found that 90 percent 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 oncologists indicated that commercial support is a significant reason high-quality oncology CME is available. Furthermore, approximately 88 percent said it is "somewhat" to "very likely" that implementation of new or emerging therapies would be slower if commercial support is reduced, and 89 percent 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.

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

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

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

[4] ACCME 2013 Annual Report

[5] 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.

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.

Why the Sunshine Act Exemption Matters 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 a requirement for CME-related 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. Indeed, in a recent poll of 527 CME participants, almost 70 percent stated that the elimination of the CME exemption would discourage them from participating in industry-supported CME activities.[6]

Conclusion

We are passionate about continuing medical education because we see the direct beneficial impact it has on physician excellence and patient outcomes. Forcing payments to providers who participate in and speak at these events to be reported in the Sunshine Act database 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.

The Senate HELP Committee's new bipartisan initiative has the potential to transform the way that advancements in medicine are discovered and developed. But unless doctors are able to access these latest updates in medical innovation, we risk falling short on our promise to deliver the latest science to our patients' bedsides. We look forward to working with the Committee to ensure the preservation of CME as a valuable pillar of our healthcare system, and would welcome the opportunity to work with the Committee to ensure that legislative language adequately protects CME.

Sincerely,

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

[6] *2014 Opinions about Elimination of the CME Exemption on the Sunshine Act*, Primary Care Network, Aug. 14, 2014