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Centers for Medicare & Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development  
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To Whom It May Concern:

It is my pleasure to submit these comments on behalf of the CME Coalition ([www.cmecoalition.org](http://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 the need to ensure that CMS minimize any barriers to healthcare provider access to continuing medical education.

### **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.

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.

### **Comment**

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.

Further, we applaud CMS' decision in the Sunshine Act Final Rule to implement reporting exemptions for payments underwriting certain accredited CME activities where there is no influence from commercial supporters on the educational curriculum or materials. Although we are seeking greater clarification around several of these reporting "exemptions," the CME Coalition recognizes that the scope of this public comment opportunity is limited to dispute resolution and comment related matters.

In the context of CME, there unfortunately remains considerable stakeholder confusion and a range of interpretations around which payments are to be reported and which are exempt. Accordingly, we anticipate considerable variation in the nature of applicable manufacturers' submissions to Open

Payments. For example, we believe that some applicable manufacturers will unnecessarily over-report payments for reporting-exempt accredited CME activities due to misinterpretations of the Final Rule. Furthermore, for reportable payments that physicians receive for participating in non-exempt CME activities, such as serving as faculty at nursing or pharmacy programs, there will be a strong interest on the part of these doctors in ensuring that the reported data provides this important context.

Given these issues, not to mention the lack of certainty around the treatment of certain meals and refreshments served in a group setting at accredited events, we believe there is a high likelihood that some disputes could take significant time to resolve, especially if third-party CME providers are asked to provide documentation about particular events or programs. As such, we anticipate significant physician interest in the reported payments that are attributed to them, with a high likelihood that a considerable number will be contested.

Given this situation, not to mention the uncertainty among physicians and other stakeholders concerning the dispute resolution process as it is now contemplated more broadly, we believe that CMS should allow physicians more time to register into the system before their data goes public. Especially given that the window start date has been uncertain, we believe that as a practical matter, many physicians and teaching hospital staff may be unable to register and check their data within the 45 days currently proposed. Additionally, given that physician must go through a two-phase process, namely, they must register, get approved, and then figure out how to look for their data, **we recommend that CMS provide them with a 120-day review period.**

Finally, given the fact that a doctor's reputation is easy to impugn, but incredibly difficult to resuscitate, we encourage CMS to err on the side of allowing physicians ample opportunity to correct the record on their reported payments before they are made public, rather than run the risk of unwarranted reputational damage that has the potential to harm careers. For a variety of reasons, including the fact that there simply is not enough physician awareness as to the workings or new timing of the Open Payments program, **we strongly urge CMS and OMB to delay for six months, until March 31, 2015, the publication of information collected under the Open Payments program.**

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

Andrew Rosenberg, J.D.

*On behalf of the CME Coalition*