



May 16, 2018

The Honorable Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Administrator Verma:

On behalf of our membership of nearly forty nonprofits and companies, all of whom are committed supporters of encouraging the participation by health care providers in continuing medical education (CME) activities, we are writing to encourage CMS to revise the current rules implementing Section 6002 of the Affordable Care Act (the Physician Payments Sunshine Act). Specifically, we request that CMS provide a clearly defined reporting exemption for payments in support of independent continuing medical education to healthcare professionals and encourage you to promulgate a reporting exemption for the provision of medical texts and journal reprints.

We strongly believe that commercial support payments for CME that do not meet the Sunshine Act's definition of payments should be definitively exempted from reporting. Indeed, independent, accredited CME is the Gold Standard of continuing education and is consistently relied upon by health professionals, as well as the federal government, in the pursuit of public health objectives. As a nation, we should be encouraging and facilitating accredited physician continuing education, not stigmatizing it by requiring the collection and reporting of payments that underwrite it.

Additionally, as a means of encouraging improved physician knowledge and performance, we respectfully suggest that CMS revisit its current reporting requirement for the value of medical texts and journal reprints provided during the course of continuing medical education activities.

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.

Numerous 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.

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. 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 approximately 700 nationally accredited CME providers.

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.”

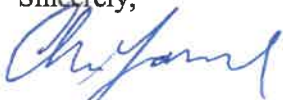
The CME Coalition has actively participated in the regulatory process underlying the current Final Rule governing Open Payments, as well as subsequent meetings and communications with CMS to encourage clear guidance exempting support for accredited CME from Open Payments reporting. Our interactions with CMS over the last several years on this matter have been exceedingly constructive, and as a result, current CMS sub-regulatory guidance, in particular FAQ #8165, clearly suggests that independent commercial support for most CME activities is not to be reported.

But while the current FAQ provides the CME stakeholder community with solid guidance, the history of this issue, in which there have been numerous revisions to the policy via FAQ updates, leaves us with a need for the kind of certainty that only a definitive Final Rule can deliver. As a practical matter, we believe that the current Final Rule governing Open Payments is written in such a way as to leave open the door for a range of interpretations concerning the treatment of commercial support for independent continuing medical education. This has created inconsistency in interpretation by some manufacturers, as well as trepidation among others that the current FAQ could be easily replaced without the benefit of a comment and rulemaking process.

As a result, we urge you to bring clarity to this issue for everyone in the CME community — doctors, educators, and commercial supporters — by promulgating language in a future rulemaking to specifically exempt these payments, as was originally contemplated when the law was passed, as well as to allow for the provision of medical texts and journal reprints during the course of CME.

We would welcome the chance to share ideas or suggested language with you if that would be helpful, and are very appreciative for this opportunity to share our views.

Sincerely,



Chris Lamond, Executive Director  
CME Coalition