

On behalf of the Society for Translational Oncology (STO), we are writing to express our deep concern for a recently proposed CMS policy that we fear would effectively eliminate the Sunshine Act reporting exemption for accredited continuing medical education (CME).

STO, which is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians, is a 501(c)3 nonprofit, professional membership association. STO's mission is to speed the discovery and translation of important new treatments in the field of oncology to the practice of global oncology. STO brings knowledge and strategies for critical new developments in cancer treatment into the practice environment of the community oncologist. To achieve that end, STO provides publications, meetings, and enduring materials that serve to shorten the translational gap between discovery and delivery of care to the patient.

The foundations of STO's educational interventions are the improvement of physician competencies and strategies for the screening, prevention, diagnosis, treatment, and management of patients with cancer; and enhancement of performance-in-practice.

STO is a stakeholder in the health care community and cares deeply about the ability of providers to participate in CME activities. This is especially important in the highly specialized and rapidly changing areas of oncology and hematology, and advancing clinical breakthroughs is imperative to patient outcomes.

Continuing medical education is a vital component of our healthcare system and allows our nation's physicians and healthcare providers to remain up to date with the latest in medical science.

Accredited CME is the gold standard of continuing medical education. By incorporating strong criteria that ensure that the education provided to learners is based firmly in science, accredited CME guarantees that any supporter bias - be it commercial or otherwise - is eliminated from the curriculum.

We strongly urge CMS to appreciate the need to stimulate physician participation in CME rather than adopt policies that could diminish it.

In CMS' February 2013 Final Rule on Sunshine Act implementation, your agency wisely created a bright line "CME exemption" that made it clear to physician participants that they could present at, and attend, accredited continuing education programs without risking the stigma and reputational impact that accompanies a listing in the Open Payments system.

It is our understanding that your stated goal is to expand the definition of "Sunshine exempt" CME to take into account programs that may be accredited for nurses, optometrists, pharmacists, and others. If this is so, we wholeheartedly endorse this goal.

However, we are concerned that your recent proposal of July 3rd would instead eliminate the current CME "safe harbor" from reporting by redefining CME payments as "indirect payments" which may be reportable.

We implore you to ensure that indirect commercial support for CME programs, in which the accredited provider exercises complete discretion on the content, remains exempted from reporting under the Open Payments system. It is essential to patients that their healthcare providers remain well educated and informed on the latest medical science in their field, and therefore we must encourage, rather than discourage, participation in CME.

In addition, abolishing this exemption would have significant negative impact on STO as a small organization. The reporting process would become an overwhelming burden from both time of staff and financial perspectives. Removing the exemption would require significant changes to our already existing CME Learning Management System (LMS), which would become a financial hardship. The STO LMS was completed in early 2014 using the parameters provided by CMS in its original ruling, and a change to this system would require significant financial resources for revision of the software platform funding which STO does not currently have and would only come from securing additional grants, which is a time-consuming and sometimes fruitless process.

Finally, it is important to physicians that they have clear rules that provide a safe harbor from Open Payments reporting when they participate in accredited CME. This is what we understand was intended by Congress and is provided by the Final Rule as it currently stands; we would urge and encourage you to create a similarly clear "safe harbor" for physicians and CME at the conclusion of this process.

Your attention and consideration on this matter is greatly appreciated.