



COUNCIL OF MEDICAL SPECIALTY SOCIETIES

COMMITTED TO EXCELLENCE IN PROFESSIONALISM, EDUCATION AND QUALITY OF CARE

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August 19, 2014

The Honorable Marilyn Tavenner
Administrator, Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Tavenner,

The Council of Medical Specialty Societies (CMSS), with 41 member societies representing 750,000 physicians in the US, is writing to comment on CMS' proposal to potentially eliminate the existing exclusion for accredited and certified continuing education (CME) under the Open Payments program.

In full disclosure, CMSS participated in negotiating the language of the Physician Payments Sunshine Act (PPSA) and the final rule promulgated by CMS on February 1, 2013. In both instances, CMSS made three key points (below), which remain critical and must be retained in the Open Payments program. Failure to clearly retain these three principles will undermine professional and public trust in the continuing education of physicians, and the participation in CME by both faculty and attendees, thus effectively gutting the system of CME in the US. This is not hyperbole – this is simply the clear recognition of reality. This is why CMS included these three points in the final rule, and CMS must retain them now:

1. The distinction must be made and maintained between **accredited and certified CME**, offered by accredited CME providers offering credit certified by the CME credit systems in medicine, contrasted with the promotional education of physicians, offered by companies. All providers of accredited and certified CME strictly adhere to firewalls established through the *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, promulgated by the Accreditation Council for Continuing Medical Education (ACCME), as revised in 2004, and universally implemented in accredited and certified CME.
2. **Faculty** at accredited and certified CME programs are not subject to reporting under the now Open Payments program as faculty relationships are with the accredited CME provider, not with any company which might grant commercial support to the CME provider. Grants to CME providers establish a relationship between the company and the CME provider, but not with the independent faculty.
3. **Attendees** at accredited and certified CME programs are not subject to reporting under the now Open Payments program as attendees have no relationship with any company which might grant commercial support to the CME provider.

CMS must retain in the Open Payments program the safeguards to distinguish independent accredited and certified continuing medical education from promotional education.

CMSS and its member societies value independent medical education as a proven mechanism to continually improve the quality of care provided in the US. The medical education community in the US has put in place an effective firewall to keep continuing medical education independent, through strict universal adherence to the *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, promulgated by the ACCME, as revised in 2004. These Standards for Commercial Support (SCS) have been adopted by all three CME credit systems in the US: the American Academy of Family Physicians (AAFP), the American Medical Association (AMA) and the American Osteopathic Association (AOA). These are the groups which accredit



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(ACCME, AAFP, AOA) and certify (AAFP, AMA, AOA) CME for physicians in the US.

Because these are the accreditors and certifiers, and because of the universal adherence of the medical profession to the ACCME SCS, it is critical to continue to reference these groups and the Standards (SCS) in the rule-making for the Open Payments program. To eliminate the section specifically mentioning these groups and standards opens the door for unapproved standards that are not universally accepted, and for groups outside of these to set standards which are not part of the CME accreditation system in the US. Such action would undermine independent CME in the US. It is unnecessary to risk this unintended outcome – CMS should simply retain the section of the Open Payments program which includes this limited number of accreditors and credit systems, and the standards (SCS) they all follow. That is why these groups and the Standards were included in the February 1, 2013 final rule.

Should CMS wish to consider other accreditors or other equivalent standards, an extant mechanism exists to do so. An inter-professional coalition of accreditors of continuing education in the health professions called, *Joint Accreditation*, has been convened since 2009 and is a collaboration of ACCME, the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC). This is the function of professional self-regulation, and does not require additional governmental regulation.

To continue to be clear, CMS must retain the exception for payments for accredited and certified continuing medical education (CME) under the Open Payments program. Accredited and certified CME differs from other types of promotional educational programming offered directly by pharmaceutical and device manufacturers because accredited and certified CME contains safeguards specifically designed to protect against commercial influence (the ACCME SCS). The importance of maintaining the distinction between independent, accredited and certified CME and other types of promotional education to physicians cannot be overstated. To avoid the introduction of commercial influence into education which is not accredited and certified and therefore not adherent to the firewall created by the ACCME SCS, CMS must maintain the distinction between accredited and certified CME versus promotional education to physicians.

Therefore, in the strongest terms, CMSS recommends that CMS maintain the exclusion detailed at §403.904(g)(1), the reporting of payments associated with certain continuing education events.

Physician faculty and attendees at accredited and certified continuing medical education are not reportable under the Open Payments program due to the profession's strict adherence to the firewall created by the ACCME Standards for Commercial Support, not by the timing of when a company discovers their names.

It has been suggested that elimination of the section retaining the accreditors and standards, as described above, may be justified by referring to the timing of a transfer of value, be it indirect or direct. There are two reasons why this proposal is ill advised.

First, CME programs are planned months, and sometimes years, and promoted in advance. Many CME programs are planned and promoted to their intended audiences far enough in advance that attainment of commercial support grants by the CME provider is incomplete. Moreover, as faculty are selected and identified during the activity planning process by the accredited CME provider, their names are promoted in the activity programming to the intended audience. It is not realistic, nor would it be perceived as transparent, if faculty names were hidden until the day of the program, nor would physicians attend such programs. As a result, over time during the planning process, even if the company does not request faculty names, companies providing commercial support to CME providers will potentially learn the names of the faculty, usually before the program, and certainly within two quarters after the program, through promotion of the program itself. Therefore, establishing a policy whereby an arbitrary determination of the presence of a relationship is made based on the timing of learning of the faculty names is unworkable – the names of faculty at CME programing cannot and should not be hidden.



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Second, CMS has agreed that a grant from a company to an accredited and certified CME provider does not establish a relationship with the faculty, due to the firewall established by strict universal adherence in accredited and certified CME to the ACCME SCS. Therefore, it is not necessary to undermine the recognition of the protection of the faculty by eliminating from the rule mention of the Standards which create the firewall, and replacing them with an arbitrary and unworkable timing proxy.

Lastly, the same can be said for attendees. While attendees might not be identified in advance of a CME program, they are certainly identifiable during and after the program. However, CMS has always recognized that attendees have no relationship with companies which might choose to provide grants of commercial support to CME providers for accredited and certified CME. Therefore, it is not necessary to establish an arbitrary timing proxy for attendees. Attending accredited and certified CME does not establish a reportable relationship with any supporting companies.

Summary

We understand that CMS' intent may be to simplify the Open Payments rule and to protect the government from pressure to add to a list of continuing education accreditors and standards, when it is not the government's role to adjudicate such requests. We respect these desires of CMS, and respond that the proposed solutions will have unintended consequences worse than the problem they are promulgated to potentially solve.

We hope we have described why the proposed changes are unworkable, yet also how retaining the critical section of the Open Payments program does not need to put CMS in a position to supplant inter-professional self-regulation which has a successful track record of protecting the independence of accredited and certified continuing medical education for more than a decade. Leave the rule the way it was intended to reflect the law. Allow the professions to self-regulate their continuing education, which is their responsibility to society, and which they do successfully.

Sincerely,

Norman Kahn MD
Executive Vice President and CEO

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