



ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

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Executive Director

August 28, 2014

The Honorable Marilyn Tavenner
Administrator, Centers 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 Accreditation Council for Pharmacy Education (ACPE) is writing to comment on CMS' proposal to potentially eliminate the existing exclusion for accredited and certified continuing education (CE) under the Open Payments program.

ACPE is the national agency for the accreditation of professional degree programs in pharmacy and providers of continuing education (CE) organizations. We accredit approximately 350 organizations. These organizations are academic institutions, hospitals and health care networks, government agencies (including CMS), national and state associations, educational companies, and publishers. The ACPE-accredited providers generally plan and conduct approximately 33,000 CE activities and distribute over 5 million statements of credit per year to participants who complete the requirements necessary for credit at continuing education activities. In addition, approximately 25% of our providers receive commercial support and a vast majority (> 75%) of continuing pharmacy education providers utilizes physicians as faculty, speakers, and authors. With an emphasis in interprofessional education and where pharmacists are included as part of the healthcare team, we see the number of interprofessional-based CE activities and the percentage to utilize physicians as subject experts increasing. Unfortunately, with the implementation of § 403.904(g)(1), ACPE-accredited CE providers have noted a decline in physician involvement in pharmacy CE activities as well as grant funding despite the existence of appropriate safeguards set in place by ACPE standards and policies.

ACPE formally adopted the Accreditation Council for Continuing Medical Education (ACCME) *Standards for Commercial Support* ("the ACCME SCS") in 2007 (by signed licensed agreement). ACPE's *Standards for Continuing Pharmacy Education*, Standard 5 requires that all CPE programs provide for an in-depth presentation with fair and full disclosure and equitable balance. Appropriate topics and learning activities must be distinguished from topics and learning activities which are promotional or appear to be intended for the purpose of endorsing either a specific commercial drug or other commercial product (as contrasted with the generic product/drug entity and its contents or the general therapeutic area it addresses), or

a specific commercial service (as contrasted with the general service area and/or the aspects or problems of professional practice it addresses).

ACPE believes that CMS should retain the requirement that “the applicable manufacturer does not pay the covered recipient speaker directly” and retain the requirement that “the applicable manufacturer does not select the covered recipient speaker or provide the third party (such as a continuing education vendor) with a distinct, identifiable set of individuals to be considered as speakers for the continuing education program.” These requirements are essential elements of the ACCME SCS.

ACPE believes that learners, planners, teachers and authors in commercially supported accredited continuing professional education should be exempt from reporting within the CMS Open Payments Program if that accreditation system utilizes the ACCME SCS and as previously stated by CMS. Rather than remove the language of § 403.904(g)(1), ACPE’s recommendation is to extend the continuing education exclusion to include any accrediting body that follows the ACCME SCS.

Should CMS wish to consider other accreditors or other equivalent standards, an extant mechanism exists to do so. An inter-professional collaborative of accreditors of continuing education in the health professions called, *Joint Accreditation for Interprofessional Continuing Education*, has been convened since 2009 and is a collaboration of ACCME, ACPE, and the American Nurses Credentialing Center (ANCC). This is the function of professional self-regulation, and does not require additional governmental regulation. Joint Accreditation can provide a verification process to ensure that it evaluates its continuing education providers for compliance with the ACCME SCS. We believe this would establish a valid mechanism to a) retain a list of accreditation systems in which the ACCME SCS are implemented, as is currently the case in the regulations of the Open Payments program, and b) provide verification of this implementation using already existing processes within the system of professional self-regulation in accredited continuing education.

Based on the evidence provided and the likely negative impact of eliminating the existing continuing education exclusion found in 42 CFR § 403.904(g)(1), ACPE respectfully requests that CMS retain § 403.904(g)(1) and consider one of the options to extend the regulation:

1. include ACPE as one of the accrediting bodies in the exemption requirements as well as other organizations that formally adopt the ACCME SCS; and/or
2. include a verification process to ensure that accrediting bodies follow the ACCME SCS.

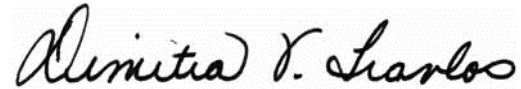
We would be happy to discuss this further with you or if you require clarification in any of the points above please do not hesitate to contact us.

Thank you for consideration of this important request.

Sincerely,



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