

April 20, 2017

The Honorable Claire McCaskill United States Senate Washington, DC 20510

Dear Senator McCaskill:

## Re: Opioid Investigation

The Accreditation Council for Continuing Medical Education (ACCME) sets the standards and requirements for organizations that deliver continuing medical education (CME) on behalf of the profession and the public. I and we share your deep concerns about the epidemic of prescription opioid abuse, addiction, and overdose, and we are committed to leveraging the power of education to improve prescriber practice and to promote safe and effective care for patients.

# The ACCME accreditation system is the firewall between promotion and education.

The ACCME was founded 35 years ago by seven organizations<sup>i</sup> representing the medical profession to set and monitor the standards that, amongst other goals, ensure that educational programs offered by organizations that we accredit are independent and free of commercial bias. We are a 501c3 organization.

The ACCME accreditation system provides safe spaces for clinicians to learn – where they can have the confidence that accredited CME is balanced, evidence-based, commercially independent, designed to meet real needs, and evaluated appropriately. Credits generated from learning with accredited CME are used by licensing and credentialing authorities (such as state medical boards) to determine compliance with regulatory requirements. Several states require clinicians to complete accredited opioid educational programs as part of these regulatory expectations.

Our organization accredits more than 1,900 accredited CME organizations across the country representing a range of institutions including hospitals and healthcare delivery systems, nonprofit physician membership organizations, publishing and education companies, schools of medicine, insurance and managed-care companies, and 35 government and military organizations, including the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services, and the Food and Drug Administration (FDA). Together these providers offer more than 148,000 educational activities each year to support physicians' lifelong learning, including many designed to promoting best practices in opioid prescribing.

### **Accreditation Standards and Independence**

ACCME <u>accreditation standards</u> are designed to ensure that accredited CME is relevant, practice-based, independent of commercial influence or bias, and contributes to healthcare improvement for patients and communities. We inspect for and review compliance with the standards, and also perform our own investigations of accredited providers in response to inquiries or complaints.

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The hallmark of accredited CME is independence—promotion or marketing is prohibited in CME accredited within the ACCME System. Thus, accredited CME offers clinicians a protected space to learn and teach without commercial influence. These standards are a national model and have become a common interprofessional standard shared by continuing education accreditors across the health professions, including nursing and pharmacy.

Pharmaceutical and device manufacturers are ineligible for accreditation. These manufacturers conduct marketing and promotion activities, and may even refer to these promotional programs as "CME" despite the lack of accreditation. It is critical that your inquiries distinguish between the promotion activities of industry and activities in accredited CME.

## **Grants for Accredited CME are Permitted, but Influence Is Not**

Pharmaceutical and device manufacturers are permitted to provide grants to ACCME-accredited organizations through a carefully regulated process; 11% of accredited activities receive grant support from these manufacturers. Our ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities™ are designed to completely exclude industry from any influence, direct or indirect, over speakers and content in accredited CME and dictate strict rules regarding the management of funds and conflicts of interest.

### **ACCME Collaborations**

The ACCME routinely collaborates with organizations to address national health priorities, including the opioid epidemic. Federal agencies, including the FDA, CDC, National Coordinator for Health Information Technology, and Agency for Healthcare Research and Quality, have included ACCME and accredited CME as a strategic partner in their public health initiatives. Our collaborative efforts have included work with the National Academy of Medicine and the White House Office of National Drug Control Policy, among others.

The ACCME plays a leadership role in the Conjoint Committee on Continuing Education (CCCE), a national coalition of 26 organizations<sup>ii</sup> representing medicine, nursing, dentistry, pharmacy, physician assistants and nurse practitioners. CCCE's goal is to employ continuing education in the health professions to improve the performance of the US health system, and its strategic focus is to support continuing education that is compliant with the FDA Extended-Release and Long-Acting (ER/LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS).

### Collaboration with FDA on Appropriate Opiate Education

Since 2009, the ACCME has supported the role of accredited CME as a strategic asset to the FDA's REMS, provided the proper controls are in place to ensure independence. The first REMS to incorporate accredited CME is the <a href="ER/LA Opioid Analgesics REMS">ERMS</a>, approved by the FDA in July 2012. The centerpiece of the ER/LA Opioid Analgesics REMS is a prescriber education program about the risks of opioid medications as well as safe prescribing and safe use practices. The education is controlled, designed, and delivered by accredited CME organizations, and managed through accreditors' data systems.

ACCME <u>data</u> from March 2013 through April 2016 (additional data for 2016 will be available soon) shows that 96 CME providers, accredited within the ACCME System, reported 647 ER/LA Opioid Analgesics REMS-compliant activities, educating close to 168,000 healthcare professionals. We continue to encourage additional accredited CME organizations to participate in the REMS program.

The activities were offered by a diverse set of accredited CME providers including hospitals and healthcare delivery systems, specialty societies, publishing and education companies, and

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schools of medicine. The education was delivered in a variety of online and face-to-face formats; the most common format was live activities, which were offered in nearly every community across the country. Online activities reached the most learners. Participants included physicians, advanced practice nurses, physician assistants, dentists, and other healthcare professionals.

## **Responding to the Changing Healthcare Environment**

The ACCME is committed to advancing the role of accredited CME as a strategic partner in public health and safety initiatives through collaborations with government, colleague accreditors across the health professions, accredited CME organizations, and other stakeholders. We are passionate about educational quality, and continue to work to ensure that accredited physician education serves the public health of communities, and is protected from industry influence. We plan to continue our efforts to ensure clinicians have access to high-quality educational programs including those in the FDA REMS program that help clinicians prescribe pain medicines responsibly and appropriately.

The ACCME and its accredited educator community welcome the opportunity to work with you to make a positive difference in the health and safety of patients, families, and communities across the nation. We are happy to answer any questions you may have, to meet with you, and to provide additional feedback to support your deliberations and those of the Committee on Homeland Security and Governmental Affairs.

Sincerely,

Graham McMahon, MD, MMSc

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President and Chief Executive Officer

<sup>&</sup>lt;sup>1</sup> American Board of Medical Specialties, American Hospital Association, American Medical Association, Association for Hospital Medical Education, Association of American Medical Colleges, Council of Medical Specialty Societies, Federation of State Medical Boards

ii Accreditation Council for Continuing Medical Education, Accreditation Council for Graduate Medical Education, Accreditation Council for Pharmacy Education, Alliance for Continuing Education in the Health Professions, Alliance of Independent Academic Medical Centers, American Academy of Family Physicians, American Association of Colleges of Nursing, American Association of Nurse Practitioners, American Association of Colleges of Osteopathic Medicine, American Academy of Physician Assistants, American Board of Medical Specialties, American College of Physicians, American Dental Education Association, American Hospital Association, American Medical Association, American Nurses Credentialing Center, American Osteopathic Association, Association for Hospital Medical Education, Association of American Medical Colleges, Council of Medical Specialty Societies, Federation of State Medical Boards, Joint Commission, Journal of Continuing Education in the Health Professions, MedBiquitous, National Board of Medical Examiners, Society for Academic Continuing Medical Education