



Accreditation Council for Continuing Medical Education

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September 6, 2016

Sylvia Mathews Burwell
Secretary
US Department of Health & Human Services (HHS)
Office for Civil Rights
Hubert H. Humphrey Building
Room 509F, 200 Independence Avenue, SW
Washington, DC 20201

Attention: 1557 RFI (RIN 0945-AA02)

Request for Information: Opioid Analgesic Prescriber Education and Training Opportunities To Prevent Opioid Overdose and Opioid Use Disorder

Dear Secretary Burwell:

The ACCME appreciates the opportunity to respond to your request for information about opioid analgesic prescriber education and training opportunities to prevent opioid overdose and opioid use disorder. We commend HHS for listening to stakeholders and for its commitment to improving education and training on appropriate pain management and opioid prescribing.

The ACCME has long supported the role of accredited continuing medical education (CME) as a strategic partner in public health and safety initiatives. Through collaborations with government, colleague accreditors across the health professions, accredited CME providers, and other stakeholders, we seek to identify and facilitate opportunities for accredited CME to contribute to public health initiatives.

We appreciate the government's recognition of the value of CME in carrying out this critical public health initiative. The collaboration between the government and accredited CME is exemplified by the examples mentioned in your RFI including the Food and Drug Administration (FDA) Extended-Release and Long-Acting (ER/LA) Opioid Analgesics REMS.

CME providers have demonstrated their commitment by partnering with their communities, law enforcement agencies, and local, state, and national governments to support initiatives to reduce prescription drug abuse. We believe that accredited CME has made — and can continue to make — significant contributions to addressing the crisis of opioid misuse, overuse, and overdose. We value our engagement with government agencies and look forward to continuing to work together to make a difference to patients, families, and communities across the country.

We share the deep concerns of the HHS about the growing epidemic of prescription drug abuse — and we are committed to leveraging the power of education to improve prescriber practice and to promote safe and effective care for patients.

ACCME Accreditation System

The ACCME system has the capacity and diversity to address public health and safety initiatives. There are approximately 1,900 accredited CME providers across the country representing a range of institutions including hospitals and healthcare delivery systems; nonprofit physician membership organizations, such as specialty societies; publishing and education companies; schools of medicine; insurance and managed-care companies; and government and military organizations. There are 35 government and military organizations accredited as CME providers, including several agencies within HHS: Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and FDA.

Accredited CME providers offer nearly 150,000 educational activities annually, comprising more than one million hours of instruction offered in a wide range of online and face-to-face formats. This education includes 26 million interactions with physicians and other healthcare professionals each year.

Accreditation Standards

Healthcare professionals are expected to provide safe, effective, ethical, and compassionate care that is based on best practice and evidence. They rely on accredited CME as a key resource to help them fulfill those professional responsibilities. Accreditation standards are designed to ensure that CME is relevant, practice-based, independent of commercial influence or bias, and contributes to healthcare improvement for patients and communities.

The ACCME's core accreditation standards promote evidence-based educational principles. Accredited CME focuses on the real-world needs and gaps of physicians and teams, and is designed to improve the ability of healthcare professionals to deliver safe and effective care. CME providers are required to evaluate and improve their programs' effectiveness in driving healthcare improvement.

In addition to the core standards, the ACCME issues commendation standards, which foster leadership, collaboration, and system-wide change by rewarding CME providers for collaborating in strategic healthcare quality and safety initiatives, among other achievements.

Accredited CME Community Support of FDA ER/LA Opioid Analgesics REMS

The ACCME and the community of CME providers is committed to facilitating the development and delivery of REMS-compliant accredited CME.

ACCME data from March 2013 through April 2016 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.

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 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 section of the country. Online activities reached the most learners. Participants included physicians, advanced practice nurses, physician assistants, dentists, and other healthcare professionals.

The ACCME requires accredited CME providers to design and analyze activities for their impact on learner competence, performance, and/or patient outcomes. Nearly 100% of the REMS-compliant CE activities were designed to change competence, 83% were designed to change performance, and 55% were designed to change patient outcomes.

As a service to the CME community and the FDA, the ACCME modified its data collection system to enable accredited CME providers to submit information specific to their REMS CE activities. The data collection system for the REMS was created in compliance with the MedBiquitous MEMS 2.0 Standard to ensure interchangeability and accuracy.

As a further service to the community, the ACCME created CME Finder at <http://www.cmefinder.org/> — a web-based tool that allows healthcare professionals to search for ER/LA Opioid Analgesics REMS-compliant activities.

Approaches to Education and Training for Healthcare Professionals

In response to your request for information about approaches to education and training for healthcare professionals, we share the lessons learned from our engagement with the FDA ER/LA Opioid Analgesics REMS and other education initiatives focusing on pain management and prescription drug abuse.

Meeting diverse needs: Healthcare professionals do not practice one-size-fits-all healthcare — and their education should not be one-size-fits-all. While it is important that prescribers receive consistent, evidence-based messages about opioid analgesics risks and safe use, a uniform set of educational requirements has the unintended consequence of discouraging participation, reducing motivation, and limiting change in prescribing practices. A uniform curriculum constrains the ability of CME providers to develop education that successfully meets the diverse needs of their healthcare communities.

To take full advantage of the strengths of the accredited CME system, educational guidelines or mandates should be structured to utilize the capacity of the CME community to deliver customized education and participate in rapid response initiatives to emerging health issues.

Accreditation standards provide a roadmap for CME providers to produce relevant, evidence-based, high-quality education. CME providers are experts at delivering education that effectively creates and sustains behavior change. They begin by identifying the needs of the participants. These needs vary by individual, profession, specialty, location, practice setting, and other factors. Palliative care physicians, pharmacists, pediatricians, and primary care nurses, to cite just a few examples, have vastly different practices and learning needs when it comes to opioid prescribing. In addition, prescribers are in various stages of self-assessment — some may have little or no awareness of their need for opioid education, others are confident in their expertise — but may be entirely wrong in their assessment of their competence in this area. Education is a process — not an event. To be successful, educators require the flexibility to design interventions in stages that vary in format and length.

Flexibility in instructional design and content: From small community hospitals to national specialty societies, CME providers have expertise in addressing and assessing the needs of their specific community of learners. To maximize participation and educational effectiveness, CME providers must be empowered to customize opioids-related and pain management CME to their learners' needs. This includes enabling CME providers to create education for individual learners and to designate those individual learners as having completed the education based on the CME provider's determination.

Encouraging efficiency: CME providers should be encouraged to share interventions they develop with other CME providers to avoid unnecessary duplication of effort and to maximize efficiency.

Facilitating rapid, community-based response: Communities across the country are experiencing the opioid abuse epidemic in ways specific to their populations and environments, and to be part of the solution, CME providers need to respond nimbly to local needs. The ACCME System comprises a network of state medical societies that accredit local CME providers, such as community hospitals and regional health systems. These locally based CME providers have expertise in assessing and addressing the needs of their healthcare community. Educational approaches will be most effective if they recognize the value of local CME providers as partners in proactive responses to emerging issues related to the opioid epidemic.

Addressing multiple initiatives: The opioid abuse crisis is receiving increasing attention across the country. Government initiatives, CME mandates, and guidelines are being issued and proposed on the local and national levels. While the rising level of concern about this issue is positive, healthcare professionals are faced with a confusing array of requirements and educational initiatives. In addition, new research is emerging about opioids and pain management. Healthcare professionals need easy access to efficient, up-to-date, evidence-based information that they can apply immediately to their practice. To reduce the burden on healthcare professionals and facilitate their participation, we recommend accredited CME activities are allowed to count toward meeting multiple requirements, such as REMS and state-based opioid education mandates.

CME and MIPS: The ACCME has requested that CMS recognize relevant performance and quality improvement accredited CME as a clinical practice improvement activity within the Merit-Based Incentive Payment System (MIPS). If HHS adds quality measures around safe opioid use to the specialty core measures, as described in the RFI, we believe that accredited CME has the capacity and expertise to support this implementation. In addition, the ACCME has a technical solution to track and report clinicians' engagement with MIPS-compliant performance improvement activities to CMS: Just as we adapted our data collection system to support REMS, we can adapt it to support MIPS.

Encouraging team participation: Prescribers and non-prescribers practice together in teams and all members of the team have an important role in improving prescribing practices, addressing the opioid epidemic, and implementing appropriate pain management strategies. CME on opioid abuse and pain management will be most effective if it reflects that reality.

Key role for patients: The goal of all our efforts is to improve patient safety and care. We believe that patients should play a key role in designing and delivering opioids-related and pain management CME, to help ensure their voices are heard and their best interests are served.

Going Forward: Accredited CME's Role in Addressing Opioid Abuse

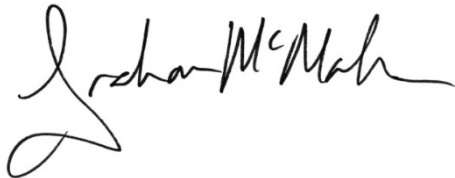
We fully support the ongoing use of accredited CME as a delivery mechanism for prescriber training to support government initiatives on opioid prescribing and pain management. By applying the lessons learned and incorporating a continuous improvement process, we are confident that accredited CME can continue to make an important contribution to reducing opioid misuse and promoting safe prescribing practice.

Responding to the Changing Healthcare Environment

As an accrediting body, our role is to design accreditation standards that serve as a guidepost for the future and respond to the changing healthcare environment. Toward that end, we adopted new standards this July that will encourage and reward CME programs that advance team-based care; involve the patients and the public in CME; address priorities in patient safety, public health, and population health; collaborate with health systems and communities; and contribute to measurable improvements in healthcare professional practice, patient care, and community health. We believe these standards serve to support HHS's goals of educating healthcare professionals about opioid overdose and opioid use disorder.

We look forward to continuing to work together with our community of CME providers and healthcare professionals, HHS, FDA, and other stakeholders to make a positive difference in the health and safety of patients, families, and communities across the nation. We would be happy to provide more feedback to support your deliberations.

Sincerely,

A handwritten signature in black ink, appearing to read "Graham McMahon". The signature is fluid and cursive, with a large loop at the end.

Graham McMahon, MD, MMSc
President and Chief Executive Officer