

CONJOINT COMMITTEE ON CONTINUING EDUCATION

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Submission to Docket ID: FDA-2017-N-1094

Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics – Exploring the Path Forward; Public Workshop; Request for Comments

The Conjoint Committee on Continuing Education (CCCE), a national coalition of 26 organizations in the professions of medicine, nursing, dentistry, pharmacy, physician assistants and nurse practitioners, is pleased to respond to the FDA's call for comments on training health care providers on pain management and safe use of opioid analgesics.

The CCCE's **goal** is to use accredited continuing education for health professionals to improve the performance of the U.S. health care system. The CCCE's **strategic focus** is to improve health professionals' knowledge, performance and patient outcomes through educating prescribers of opioid analgesics, and their collaborative health care teams, in FDA's Risk Evaluation and Mitigation Strategies (REMS) for opioid analgesics. The various health professions are **working** to use our educational tools to stem the public health crisis of unintended deaths from prescription opioid analgesics.

"The role that health care provider training plays, within the broader context of ongoing activities, to improve pain management and the safe use of opioids"

The 26 national organizations comprising the Conjoint Committee on Continuing Education (CCCE) prioritize the concept of professional self-regulation, in which professions have a responsibility to educate their own members in areas in which each profession may best serve society. Currently, American society is experiencing a crisis of unintended deaths from prescription opioid analgesics, which are prescribed and managed by members of our professions. While we accept the challenge to educate the members of our professions, we also recognize the important role of enforcement, as well as public and community health activities, in addressing the current crisis.

At the request of the FDA, and of the REMS Program Companies (RPC), in 2012 the CCCE contributed to the development of the FDA "Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics." Since then and currently, accredited providers of continuing education in the health professions have been offering "FDA Blueprint-compliant" (often referred to as "REMS-compliant") Continuing Education (CE) through live and on-line CE activities. Such CE providers include hospitals, non-profit professional associations, health professions schools, and other accredited providers of CE.

More than 200,000 health professionals have completed such training, including more than 60,000 health professionals who have prescribed an extended-release or long-acting (ER/LA) opioid in the past year. More than 140,000 health professionals who have completed the REMS-compliant training are either eligible to prescribe but have not prescribed in the past year, or are members of practice teams managing patients who have been prescribed ER/LA opioids.

All REMS-compliant CE activities are designed to increase the knowledge of learners in how to prescribe opioids safely. Most of the CE activities are also designed to improve clinician practice performance in safe opioid prescribing, while many are designed to improve patient outcomes.

In addition to meeting the requirements of the FDA Blueprint, these REMS-compliant CE activities incorporate a variety of nationally recognized competencies for health professionals, including:

Competencies:

Accreditation Council for Graduate Medical Education (ACGME), American Board of Medical Specialties (ABMS), and American Academy of Physician Assistants (AAPA):

- Interpersonal and communication skills
- Medical knowledge
- Patient care and procedural skills

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- Practice-based learning and improvement
- Professionalism
- Systems-based practice

Institute of Medicine (IOM, now NAM):

- Apply quality improvement
- Employ evidence-based practice
- Provide patient-centered care
- Utilize informatics
- Work in interdisciplinary teams

Inter-professional Education Collaborative

- Inter-professional communication
- Roles/responsibilities
- Teams and teamwork
- Values/ethics for inter-professional practice

“How best to provide health care providers, who prescribe or are directly involved in the management or support of patients with pain, appropriate training in pain management and the safe use of opioids”

Each of the health professions accredits CE for its members, ensuring that CE is based on sound adult education methodologies, contains valid content, and assures independence from commercial interests. CE providers currently offer both on-line and live activities. On-line activities attract more learners than do live activities, while the percentage of learners who complete the full REMS-compliant training is higher through live activities.

Each of the professions has found that it is critical to train both prescribers and members of practice teams, as modern management of chronic pain, like other chronic illnesses, is conducted by teams of health professionals.

The CCCE is strongly in favor of “counting” all clinician members of practice teams who successfully complete REMS-compliant CE.

Each of the professions recognizes that there is significant overlap of the knowledge needed to safely prescribe immediate-release opioids as well as extended-release and long-acting opioids. Indeed, many CE providers are already incorporating such education focused on immediate-release opioids in the current REMS-compliant CE.

The CCCE is in favor of incorporating education on immediate-release, as well as extended-release and long-acting opioid analgesics into a revised Blueprint for REMS-compliant CE.

CCCE also recognizes that REMS-compliant education needs to focus on pain management, including alternatives to opioid analgesics, not just on safe opioid prescribing. Many REMS-compliant CE programs are already focused on appropriate pain management, as well as safe opioid prescribing.

The CCCE is in favor of changes to the Blueprint incorporating an educational focus on appropriate pain management, in addition to safe opioid prescribing.

There is debate in the professions regarding the effectiveness of mandating REMS-compliant CE for prescribers, as compared with offering such CE voluntarily for prescribers and for members of practice teams. Without delving deeply into this debate, both points of view have merit. Mandatory CE is attractive because it will result in increased numbers and percentages of prescribers completing the CE. On the other hand, the experience of the professions with mandatory CE, such as that legislated by many states in many different areas of practice (not just opioids), demonstrates that many health professionals fulfill their mandatory CE requirement through what has been described as “box-checking behavior,” with a paucity of evidence to indicate that mandatory education results in

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increased knowledge, changes in practice behaviors or improved patient outcomes. If the key measure of success is number of prescribers completing training, then mandatory CE would be an effective strategy.

Voluntary CE, on the other hand, attracts learners who have self-assessed a need for such education in their practice settings, resulting in motivation not only to complete training, but to increase knowledge and change practice behaviors in order to improve patient outcomes. That said, many clinicians who might be perceived to “need” such REMS-compliant CE may not choose to avail themselves of the education, for a variety of reasons.

The CCCE is currently (as of July 2017) working on a third option, which might be termed “personalized CE,” which would be presented through a relatively new educational model referred to as “adaptive learning,” and which would be aligned with incentives in the practices of clinicians. Current adaptive learning activities have been developed to support quality and performance improvement activities and are used in some programs for maintaining certification, offered by certifying boards, which are members of the American Board of Medical Specialties (ABMS).

Based on the existing models, the CCCE is exploring a plan to design and promulgate an adaptive learning tool*, accredited by multiple professions, which would include an initial self-assessment based on the FDA Blueprint, and including elements required by various states for re-licensure. Upon completion of the self-assessment tool, the clinician would get immediate feedback, creating an individualized needs assessment for continuing education, or gap analysis for performance improvement. This has the advantage of individualizing the REMS-compliant CE activity, which has been a challenge for CE providers to date.

Educational interventions would be tailored to the individualized needs assessment, and would include the rationale for each option in answering the question, including links to references. The learner would then have the opportunity to re-answer those questions previously answered incorrectly until a threshold percentage (to be determined) of questions are answered correctly.

These individualized adaptive learning modules should meet the criteria for:

- CE credit in each health profession
- Maintaining board certification in the profession (if applicable)
- Maintaining On-going and Focused Professional Practice Evaluation, as required by The Joint Commission (TJC)
- Periodic re-licensure by states in which the health professional is licensed
- CE or other Improvement Activities of the Merit-based Incentive Payment System (MIPS) of the Center for Medicare and Medicaid Services (CMS)

In this way, health professionals, be they current or future prescribers, or members of practice teams, would have multiple aligned incentives to complete such REMS-compliant CE activities.

On July 7, 2017, in a CCCE-convened meeting in which representatives of the FDA and the RPC were also present, the CCCE made a commitment to pursue such adaptive learning as well as other personalized learning REMS-compliant CE activities.

“Issues and challenges associated with possible changes to Federal efforts to educate health care providers on pain management and the safe use of opioids”

Multiple federal agencies are currently involved in addressing the opioid epidemic through clinician education, and these efforts are often perceived as duplicative, or even competitive. In addition, multiple state agencies are mandating provider education in pain management and opioid prescribing, which are often perceived as inconsistent, confusing, and not compliant with the FDA Blueprint.

To better address the interface between federal and state agencies involved in addressing the opioid epidemic through clinician education, better coordination will be required.

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The CCCE has identified a number of strategies to expand and enhance the effectiveness of REMS-compliant education to assure that clinicians are educated on pain management and the safe use of opioids.

1. CCCE will engage in a pilot to collect additional learner data to better understand which health professionals and members of practice teams are engaged in REMS-compliant education. In addition, CCCE will explore additional strategies aimed at understanding who is participating in the current education, and how to better reach intended audiences, including receiving frequent data reports from the RPC and expanding the use of existing data reporting systems.
2. CE providers associated with the CCCE, if not already doing so, will begin to incorporate education on immediate-release opioids, as well as ER/LA opioids, in REMS-compliant CE.
3. CE providers associated with CCCE will incorporate into REMS-compliant CE a focus on the assessment and management of pain, including alternatives to opioids, as well as appropriate and safe use of IR and ER/LA opioid analgesics.
4. CE providers and accreditors in the CCCE health professions will “count” learners in REMS-compliant CE who have prescribed an opioid in the past year, *or* who are eligible to prescribe opioids, *or* who are members of practice teams managing patients with pain.
5. CE accreditors and providers associated with CCCE will design REMS-compliant CE to measure more than just numbers of prescribers who complete REMS-compliant CE, but also increases in knowledge, changes in strategies, “intent to change” and changes in practice behaviors, and, where appropriate, changes in patient outcomes that result from engagement in education.
6. CCCE will work collaboratively with RPC and FDA to address perceived barriers to completion of REMS-compliant CE, and to safe opioid prescribing, including fear of prescribing opioids, lack of knowledge of alternatives to opioids for pain, inadequate reimbursement for the time required to manage chronic pain and to implement safe opioid prescribing, inconsistent state mandates for opioid education, and more.
7. CCCE will explore best practices in supportive practices to integrate education into on-going practice behaviors, such as “academic detailing” by pharmacists, on-line “dashboards” to provide real time feedback to clinicians, real-time access to consultants, and more.
8. CCCE and its educational partners will work to research, design and implement personalized learning tools (as described above*) for health professionals who manage patients with pain.
9. CCCE recommends that RPC add to its grant cycle at the end of 2017 support for research and development of personalized learning REMS-compliant CE activities by accredited CE providers.
10. CCCE believes that a national awareness campaign would support our educational efforts.

The Conjoint Committee on Continuing Education (CCCE) is committed to addressing the current epidemic of unintended deaths from prescription opioids through the education of health professionals in the management of pain and safe opioid prescribing. We look forward to continuing a collaboration among the continuing education community in the health professions, the companies which make opioid analgesics, and the Food and Drug

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Administration to address this crisis through accredited health professional education. We appreciate that public health, enforcement agencies and others are also committed to fulfilling their unique roles as partners in this effort. We look forward to enhanced coordination of all involved, to maximize the efficient and effective use of resources in a coordinated effort to succeed.

CCCE Member Organizations:

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 Academy of Physician Assistants
American Association of Colleges of Nursing
American Association of Colleges of Osteopathic Medicine
*American Association of Nurse Practitioners
American Board of Medical Specialties

American College of Physicians
American Dental Educators 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
The Joint Commission
Journal of Continuing Education in the Health Professions
National Board of Medical Examiners
Society for Academic Continuing Medical Education

**These three organizations are also members of the CO*RE Collaboration (core-rems.org). Their activities, specific metrics and outcomes are reported via CO*RE.*

Partner:

MedBiquitous Consortium

Interested parties:

REMS Program Companies (RPC)
Food and Drug Administration (FDA)
National Governors Association (NGA)

CCCE Convener:

Norman Kahn MD nkahn@cmss.org

CCCE MEMBERS

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 Nurse Practitioners

American Association of Colleges of Osteopathic Medicine | American Academy of Physician Assistants | American Association of Colleges of Nursing

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