A Collaboration Between Government and the Continuing Education Community Tackles the Opioid Crisis: Lessons Learned and Future Opportunities

Norman Kahn, MD; Kathy Chappell, PhD, RN, FNAP, FAAN; Kate Regnier, MA, MBA; Dimitra V. Travlos, PharmD; Doris Auth, PharmD

Abstract: In 2016, 116 people died each day from opioid-related drug overdoses and in 2017, the Department of Health and Human Services declared the opioid crisis a public health emergency. During the preceding years, the continuing education (CE) accreditors in the health professions identified a need for a strategic, coordinated effort that would involve an interprofessional coalition of multiple stakeholders to respond to this emerging public health challenge. The Conjoint Committee on Continuing Education, a national coalition of organizations in the professions of medicine, nursing, dentistry, pharmacy, and physician assistants, stepped up to assume a leadership position. To address the scope of safety issues involved in opioids, the US Food and Drug Administration required that extended-release and long-acting opioid analgesic product manufacturers make training available to prescribers of their products and recommended that the training should be conducted by accredited, independent CE providers. CE accreditors in the health professions initiated an unprecedented collaboration that leveraged the accredited CE community to deliver prescriber education as part of the Food and Drug Administration Opioid Analgesics Risk Evaluation and Mitigation Strategy. This article describes the history of this interprofessional collaboration including lessons learned and opportunities for future collaboration to address public health issues.

Keywords: opioid crisis, IPCE, collaboration, public health, REMS

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PROBLEM

The opioid crisis created an urgent challenge for providers of continuing education (CE) in the health professions. CE providers aimed to meet the needs of clinicians by delivering accurate, up-to-date, and evidence-based information about appropriate pain management and safer opioid prescribing. The field was fast evolving; yet, individual CE providers did not have a means of coordinating efforts to maximize the reach and efficiency of education, to share curricula, exemplary practices, and lessons learned. In addition, all members of the health care team—prescribers and nonprescribers—have an important role in improving prescribing practices. The CE community needed to break through silos between professions and facilitate the delivery of interprofessional CE (IPCE) to address the opioid crisis.

PURPOSE

The accreditors for CE in the health professions, in collaboration with the Food and Drug Administration (FDA) and accredited CE providers, formed a coalition of interprofessional stakeholders, for the purpose of creating and implementing a nationwide, strategic, and coordinated effort to educate the clinician community about the risks of opioid medications as well as safer opioid-prescribing practices.

INTRODUCTION

In 2011, the nation was stunned by reports from the US Centers for Disease Control and Prevention that the number of deaths from opioids had exceeded those from motor vehicle accidents. By 2016, 116 people were dying each day from opioid-related drug overdoses and in 2017, the Department of Health and Human Services declared the opioid crisis a public health emergency.[1] In the past 6 years, the CE community in the health professions has responded to the emerging public health issue by identifying clinician gaps related to appropriate pain management and safer opioid prescribing, and has offered education intended to improve clinicians' ability to deliver effective and safe patient care. The accreditors for CE in the health professions have long believed that CE has an important role in contributing to public health and safety initiatives. Although individual CE programs were addressing the opioid crisis, the accreditors identified a need for a strategic, coordinated effort

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N.K. served as Executive Vice-President and CEO, Council of Medical Specialty Societies; currently is Convener, Conjoint Committee on Continuing Education.

***Dr. Kahn:** Convener, Conjoint Committee on Continuing Education, Chicago, IL;*

***Dr. Chappell:** Senior Vice President, Accreditation, Certification, Measurement, Quality, and Institute for Credentialing Research, American Nurses Credentialing Center, Silver Spring, MD;*

***Ms. Regnier:** Executive Vice President, Accreditation Council for Continuing Medical Education, Chicago, IL;*

***Dr. Travlos:** Assistant Executive Director and Director, Continuing Pharmacy Education Provider Accreditation, Accreditation Council for Pharmacy Education, Chicago, IL; and*

***Dr. Auth:** Associate Director, Division of Risk Management, Office of Surveillance and Epidemiology, CDER/FDA, Silver Spring, MD*

***Correspondence:** Norman Kahn MD, Convener, Conjoint Committee on Continuing Education, 35 East Wacker Dr., Suite 850, Chicago, IL 60601-2106; e-mail: nkahn@cmss.org*

that would involve an interprofessional coalition of multiple stakeholders. The Conjoint Committee on Continuing Education (CCCE), a national coalition of organizations in the professions of medicine, nursing, dentistry, pharmacy, and physician assistants, stepped up to assume a leadership position. Reorganized in 2012, CCCE is dedicated to leveraging accredited CE to improve the US health care system. In response to the growing opioid crisis, CCCE decided to focus on supporting the role of education in improving clinician and team practice related to opioid prescribing.

COLLABORATING TO CREATE A NEW APPROACH

In 2011 and 2012, the CE accreditors in the health professions (who are members of CCCE) and the US FDA engaged in a dialogue to identify opportunities to tackle the problem together. The role of accreditors is to set standards to assure and advance quality CE; part of their responsibility is to identify opportunities for CE to contribute to emerging health issues. The FDA has the authority to require special programs called Risk Evaluation and Mitigation Strategies (REMS) when it determines that safety measures are needed beyond the professional labeling to ensure that the benefits of products outweigh their risks. REMS programs are reviewed and approved by the FDA, are implemented by the product manufacturers, and typically include education for clinicians.

The FDA determined that a REMS was needed for extended-release and long-acting (ER/LA) opioid analgesic medications. The CE accreditors reached out to the FDA and recommended that the clinician education component of the REMS be delivered by accredited CE providers, instead of manufacturers, because education by the latter is perceived as promotional of the manufacturers' products. The FDA required that ER/LA opioid analgesic product manufacturers make training available to prescribers of ER/LA opioid analgesics and recommended that the training should be conducted by accredited, independent CE providers. To date, the ER/LA Opioid Analgesic REMS is the only REMS that has used CE. The product manufacturers are also responsible for providing the FDA with evaluations, or REMS assessment reports, according to a specified timetable. REMS assessment reports are reviewed by the FDA to determine whether the REMS is meeting its intended goals and whether any modifications to the REMS, are necessary.

The FDA, which is accredited through Joint Accreditation for Interprofessional Continuing Education, was aware of the potential for health care provider education to contribute to addressing public health issues.[2] Joint Accreditation, established by the accreditors in medicine, nursing, and pharmacy, offers organizations multiple accreditations through one process, facilitating the delivery of IPCE. The FDA and accreditors of CE in the health professions convened a series of meetings to discuss the potential for working together to address the scope of safety issues involved in prescribing opioids. They collaborated to initiate a new approach that would leverage the expertise and capacity of the accredited CE community to deliver prescriber education. The CE community includes CE accreditors, accredited organizations, organizations across the continuum of the education of health professionals, leaders in health professional education, faculty, and many volunteers. This new approach involved a willingness on the part of both the accreditors and the FDA to adapt their usual processes in the interest of public safety. The FDA's goal was to maximize prescriber participation in safety education and believed this could best be achieved if the education was accredited. Clinicians trust accredited CE and they are routinely involved in learning to meet licensing and other requirements, as well as to fulfill their professional responsibility for lifelong learning; therefore, clinicians would potentially be more likely to complete the REMS education because it would help them meet multiple responsibilities without additional burden.

The accreditors' concern was in maintaining the independence of accredited CE from commercial influence. This independence is the cornerstone of accredited CE, and the accreditors and accredited providers are accountable to the public for ensuring this independence. Therefore, if accredited CE providers were to be involved in delivering REMS prescriber education, opioid product manufacturers could not have any role in, or influence over, the planning, delivery, design, or evaluation for the prescriber education, including the selection of content, faculty, or participants.

The FDA and accreditors decided the best approach would be for the FDA, with the CE community's input, to develop the content outline, referred to as the FDA Blueprint, which accredited CE providers would use as the basis for developing its educational interventions. The manufacturers of opioid analgesics would be required to provide pooled funding in the form of commercial support for the accredited CE so that it would be available free of charge or at nominal cost to prescribers. The process for allocating commercial support would be governed by existing accreditation standards. With that framework, the accreditors were confident that the accredited CE community could participate in the REMS without compromising independence.

BLUEPRINT FOR ACTION

The FDA approved the ER/LA Opioid Analgesics REMS in July 2012.[3] It was the first REMS to incorporate accredited CE and one of the first class-wide REMS that included multiple products. The centerpiece of the ER/LA Opioid Analgesics REMS is a prescriber education program.

To be REMS-compliant, accredited CE activities need to address the core content of the "blueprint" developed by FDA for that purpose. The FDA explained that the content was directed to prescribers, but might be relevant for other health care professionals such as pharmacists and nurses. The content of the original FDA blueprint included content on general and product-specific information about the ER/LA opioid analgesics; information on proper patient selection for use of these drugs; guidance for safely initiating therapy, modifying dosing, and discontinuing use of ER/LA opioid analgesics; guidance for monitoring patients; and information for counseling patients and caregivers about the safe use of these drugs and was not intended to be exhaustive, nor a substitute for a more comprehensive pain management course.

The introduction to the FDA Blueprint stated that accreditors and CE providers "will ensure that the CE activities developed comply with the standards for CE of the Accreditation Council for Continuing Medical Education (ACCME), or another CE accrediting body, depending on the target audience's medical specialty or health care profession." [4] In effect, this meant that

TABLE 1.

ER/LA Opioid REMS-Compliant CME Activities, by Activity Type and Subtype

		Activity Subtype(s)*						
Activity Type	Count	Panel	Lecture	Sm.–Group Discussion	Case-Based Discussion	Simulation	Skill-Based Training	Other
Live–course	679	35	277	15	127	0	16	16
Live–Internet course	55	8	20	0	20	2	0	1
Live–regularly scheduled series	2							
Total live activities	**736**	43	297	15	147	2	16	17
Enduring material–Internet	120							
Enduring material–other	34							
Total enduring material activities	**154**							
Performance improvement	**2**							
Grand total	**892**	43	297	15	147	2	16	17

*Continuing education providers may report the subtypes for live courses and live Internet courses. They may report more than one subtype for each activity; therefore, total subtypes is not expected to equal total activities.
CME, continuing medical education; ER/LA, extended-release and long-acting; REMS, Risk Evaluation and Mitigation Strategy.

the accredited CE would adhere to the ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities,[5] which have become an interprofessional and international model for assuring independence from industry in the CE of health professionals. The Standards have been adopted by CE accreditors in multiple health professions, including accreditors in the fields of family medicine, nursing, optometry, physician assistants, and pharmacy. The principles of independence embodied in the Standards have also been recognized as a core principle by international CE accreditors.[6]

The ER/LA opioid analgesic manufacturers formed a consortium, called the REMS Program Companies (RPC). The RPC pooled funds through a third-party contractor to administer grants to the accredited CE providers to deliver REMS-compliant CE. Accredited CE providers also have the option to offer REMS-compliant CE with or without RPC funding.

Because the educational messages were developed by the FDA and the FDA blueprint included specific instructions about independence, the accreditors informed accredited CE providers that they could deliver REMS-compliant education and remain compliant with the accreditation requirements. There were no new requirements and there was no need to develop a special use standard or safe harbor for REMS-compliant CE. Delivering REMS-compliant CE is an option, not a requirement for accredited CE providers.

The CE accreditors encouraged CE providers to take advantage of the opportunity to contribute to combating this public health crisis and offered education and resources to help providers understand and fulfill the expectations for REMS-compliant education.

COORDINATING NATIONWIDE EDUCATION EFFORTS

For this ambitious initiative to succeed, the accreditors and providers needed a platform for sharing challenges and lessons learned. The CCCE took the lead in coordinating ongoing communications with the FDA and formed workgroups to respond to issues and concerns that arose as the REMS was implemented. Workgroups address issues such as data collection; outcomes assessment and evaluation; promotion and awareness; educational methods; and coordination among state and federal agencies.

The accreditors assumed responsibilities for helping meet FDA requirements and worked together to develop systems that streamlined the data-reporting process for CE providers. They collaborated with the MedBiquitous Consortium to support data collection that met the FDA requirements. Founded by Johns Hopkins Medicine and professional medical societies, MedBiquitous had created a standard that helps organizations bring data together for better research on the reach and impact of CE. MedBiquitous revised the standard to facilitate the collection of data about REMS-compliant CE across the health professions.[7] Accreditors integrated the new MedBiquitous technology standard, MEMS 2.0, into their already existing data collection processes, enabling accredited CE providers to use their own accreditor's data collection system to input information about REMS-compliant CE activities. With the data they collect, the accreditors generate reports submitted to the RPC for the FDA.

The accreditors also agreed to conduct the independent audits of at least 10% of RPC-funded, REMS-compliant activities, as outlined in the REMS. The audits verify that the REMS-compliant CE activity was reviewed by an independent content expert to ascertain that it reflects the most current evidence-based information, accurately and completely represents the content of the FDA Blueprint, complied with key aspects of the ACCME standards for independence, and has been evaluated for changes in knowledge and/or competence and/or performance and/or patient outcomes in each of the six sections of the FDA Blueprint.

SCOPE AND IMPACT OF REMS-COMPLIANT CE

The accredited CE community responded to the FDA's call to action. CE providers participated in interprofessional collaborations, working with law enforcement, addiction organizations, public health agencies, local government, and community groups to contribute to local and national initiatives to address the opioid epidemic. 2014 to 2018 data from the ACCME shows that 109 accredited providers CE reported 892 REMS-compliant activities educating nearly 400,000 learners across the country. Activities have been delivered nationwide in a variety of online and face-to-face formats, with live activities offered in every region of the country. As shown in Table 1, the majority of activities (83%) were live courses; the next most popular format was Internet-enduring materials (13%). As shown in Figure 1, although the majority of activities

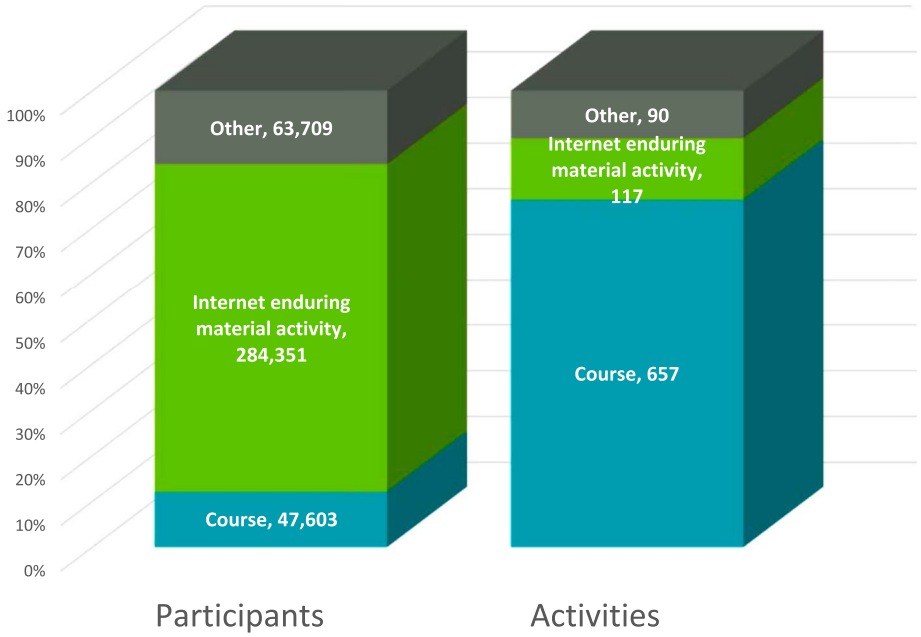

FIGURE 1. Numbers and percentages of ER/LA opioid REMS-compliant CE activities by type and participants. CE, continuing education; ER/LA, extended-release and long-acting; REMS, Risk Evaluation and Mitigation Strategy.

were live courses, Internet-enduring material activities drew the majority of learners (72%).[8]

Participating CE providers represent a range of organizational types including hospital/health care delivery systems, medical schools, nonprofit physician membership organizations, publishing/education companies, and an insurance/managed-care company. As shown in Figure 2, learners have included physicians, advanced practice nurses, registered nurses, physician assistants, dentists, pharmacists, and other health care professionals. Providers report that 100% of their activities were designed to change learners' competence (skills/strategies); 95% were evaluated for those changes. Eighty-three percent were designed to change performance; 64% were evaluated for those changes. Sixty percent were designed to

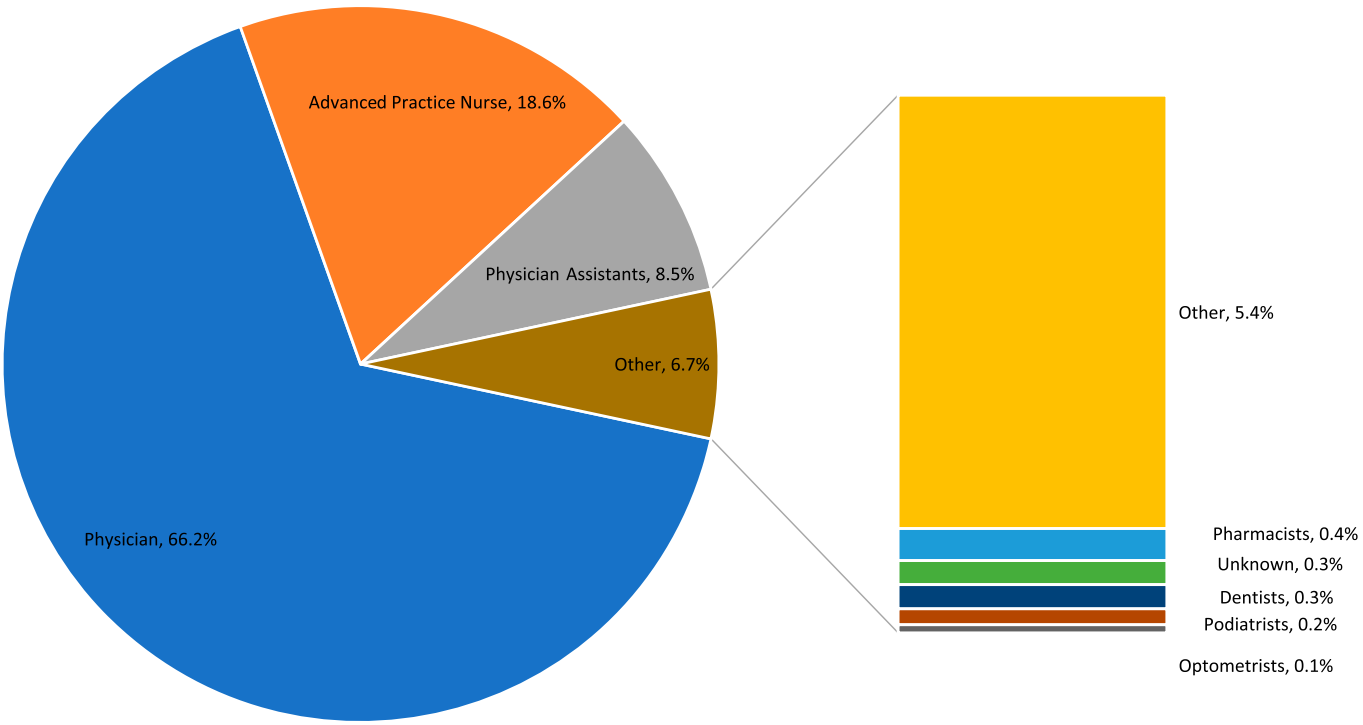

FIGURE 2. Prescribers (as defined by the FDA) who have successfully completed ER/LA opioid REMS-compliant CE activities, by profession (n = 93,192). CE, continuing education; ER/LA, extended-release and long-acting; FDA, Food and Drug Administration; REMS, Risk Evaluation and Mitigation Strategy.

change patient outcomes; evaluating these changes is more challenging—with eight percent of activities evaluated for changes in patient outcomes.[8] CE providers' efforts received national recognition.[9] Data show that REMS-compliant CE improved knowledge, attitudes, confidence, and self-reported clinical practice in safer opioid prescribing.[10]

CHALLENGES AND LESSONS LEARNED

The CE community and the FDA have continued to identify and discuss the challenges and the opportunities of the collaboration. Here are the key lessons learned from the ER/LA Opioid Analgesics REMS that we present to help inform the ongoing evolution of this initiative.

Creating a More Flexible Blueprint

The FDA required that REMS-compliant CE activities include all elements of the blueprint and that providers assess participants on all aspects of the blueprint. CE providers felt this structure restricted their ability to customize the length and content of education. Also, the focus on a knowledge assessment falls short of what the accreditors require (ie, evaluation of change in competence or performance or patient outcomes) and was a barrier to implementing other, more effective forms of assessment. Although it is important that prescribers receive consistent, evidence-based messages about risks and safer use, accreditors and CE providers found that some of the elements of the FDA Blueprint and REMS requirements constrained the ability of CE providers to develop education that meets the diverse needs of their health care communities. Educators require the flexibility to design interventions in stages that vary in format and length to address the different practices and learning needs of their learners' professions. 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, CE providers need to respond nimbly to local needs.

Recognizing Team Participation

The FDA set goals for implementation; these measures focused on counting prescribers as participants. Prescribers and nonprescribers practice together in teams and all members of the team have an important role in improving prescribing practices and addressing the opioid epidemic. REMS CE will be most effective if it reflects that reality. Accreditors recommended that the FDA counts all learners who complete the education, prescribers and nonprescribers, toward its goals.

Assessing Outcomes

The number of learners completing the education, although important, is not an adequate measure of achievement. In its assessment of success, the RPC needs to also include outcome measures that demonstrate changes in learners' practice and impact on patient care.[11]

Key Role for Patients

The goal of all our efforts is to improve patient safety and care. The accreditors believe that patients should play a key role in designing REMS CE, to help ensure their voices are heard and their best interests are served.

Better Coordination

The opioid epidemic is receiving increasing attention across the country. Government initiatives, state CE mandates, and practice guidelines are being issued and proposed on local and national levels. Although the rising level of concern about opioid prescribing is positive, health care professionals are faced with a confusing array of requirements. Education efforts are often perceived as duplicative, or even competitive. In addition, multiple state agencies are mandating health profession education on pain management and opioid prescribing, which is often perceived as inconsistent, confusing, and noncompliant 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.

Building Awareness

The accredited CE community needs a coordinated campaign for building awareness among clinicians and other stakeholders about the availability and effectiveness of REMS-compliant CE. In addition to the confusion about different educational initiatives and requirements described above, there persists some perception among the medical community and the public that the independence of REMS-compliant CE is compromised by RPC funding. More communication is needed about the safeguards for independence in accredited CE.

Evolving Science

New research is emerging about opioids and pain management. Clinicians need easy access to efficient, up-to-date, evidence-based information that they can apply immediately to their practice. To reduce the burden on clinicians and facilitate their participation, accredited CE activities should be allowed to count toward meeting multiple requirements, such as REMS and state-based opioid education mandates.

Identifying Best Practices

CCCE plans to explore best practices to integrate education into ongoing practice behaviors such as academic detailing by pharmacists, online dashboards to provide real-time feedback to clinicians, and just-in-time access to experts. CE providers need opportunities to communicate and share their challenges and successes; a community of practice is needed to help providers adopt innovative education methods, such as adaptive learning, described in more detail below.

Promote Innovative Approaches

The CE community needs to adapt innovative approaches to education and use educational technology to support and sustain clinician change. The CCCE is working on promoting personalized CE, which would be presented through the educational model of adaptive learning. Adaptive learning activities start with an assessment, resulting in individual needs assessment data, followed by personalized focused education aimed at areas of educational or practice need. Such adaptive learning activities have been developed to support quality and performance improvement activities and are used in some programs for maintaining specialty certification.

Promoting Research

More research is needed to determine what interventions are most effective in improving clinician practice and patient care so that exemplary practices can be more broadly shared and adopted in the CE community.

Reduce Burdens

Accreditors and regulatory bodies need to continue to collaborate to align their expectations, to reduce burdens for clinicians, and to promote their engagement in REMS. For example, clinicians should be able to use their participation in educational activities about the opioid REMS to meet the requirements for licensing and certifying boards, the Joint Commission, and government programs such as the Merit-Based Incentive Payment System of the Centers for Medicare and Medicaid Services. In this way, clinicians, be they current or future prescribers or members of practice teams, would have multiple aligned incentives to complete such REMS-compliant CE activities.

2018 AND BEYOND: A NEW BLUEPRINT AND MORE

In 2018, the FDA issued a new, draft blueprint based on the advice of its advisory committee, responses gathered from the CE community, other federal agencies, and numerous other stakeholders including consideration of public comments that it received. The Blueprint requires that the education covers broader information about appropriate pain management, including alternatives to opioids for the treatment of pain and includes immediate-release opioid analgesics that are intended to treat pain in the outpatient setting. The blueprint also states that clinicians need to consider "all options for pain management including nonpharmacologic and nonopioid pharmacologic options, and to reserve opioid analgesics for when nonopioid options are inadequate and when the benefits of the opioids are expected to outweigh the risks." The blueprint says that education must be offered not only for prescribers, but also for other health care professionals who participate in the treatment and monitoring of pain.[4] In addition, the core messages of the blueprint are directed to prescribers, pharmacists, and nurses, but are also relevant for other health care providers who participate in the care and management of patients with pain. The blueprint was finalized on September 18, 2018, on approval of the Opioid Analgesic REMS.

The CCCE plans to continue its work in collaboration with CE providers, health care professionals, the FDA, and other stakeholders to improve and increase the reach and impact of REMS-compliant CE. CCCE aims to incorporate more of an emphasis on IPCE with the firm belief that engagement of all members of the health care team, including patients, is required to achieve a demonstrative impact on the opioid epidemic. We plan to further expand the stakeholder group and initiate a wider collaboration that will create a more unified and coordinated education approach to the opioid epidemic.

The collaboration between the FDA and the CE community is a model that has the potential to be replicated to address other challenges in health care, such as health care disparities and chronic illness. By understanding how this collaboration was built and by considering the challenges we face and the lessons learned, our hope is that health care leaders, educators, and clinicians will invest time, energy, and resources in other collaborations that leverage the power of education to make a positive difference in the health and safety of patients, families, and communities across the nation.

LESSONS FOR PRACTICE

- Collaborations initiated by accreditors, the CE community, and the government can make substantial contributions to addressing public health crises.
- All members of health care teams—including patients—have important contributions to make and should be included in public health initiatives.
- Educators, government agencies, and other stakeholders need to coordinate efforts to reduce clinician burden and facilitate meaningful change.
- The CE community needs the freedom and flexibility to adopt innovative approaches and use educational technology to sustain clinician change.
- More research is needed to determine and disseminate information about what CE interventions are most effective in improving clinician practice and patient care.

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