Accreditation Council for Continuing Medical Education
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April 19, 2016

Robert M. Califf, MD, Commissioner
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA Public Advisory Committee Meeting
Drug Safety and Risk Management Advisory Committee
Anesthetic and Analgesic Drug Products Advisory Committee
Docket No. FDA–2016–N–0820
May 3– 4, 2016

Dear Commissioner Califf**:**

The ACCME is honored by the invitation to participate in the FDA public advisory committee meeting on the Extended-Release and Long-Acting (ER/LA) Opioid Analgesics REMS (Docket No. FDA–2016–N–0820). We commend the FDA for listening to stakeholders and for its commitment to evaluating and improving the REMS program in order to more effectively address the opioid misuse crisis in the US.

The ACCME has long supported the role of accredited CME as a strategic partner in public health and safety initiatives, including FDA REMS. Through collaborations with government, colleague accreditors, accredited CE providers, and other stakeholders, we seek to identify and facilitate opportunities for accredited CME to contribute to public health initiatives.

We appreciate the FDA's recognition of the value of accredited continuing education (CE) in carrying out this critical public health initiative. We believe that accredited CE has made — and can continue to make — significant contributions to addressing the patient safety issues identified in the ER/LA Opioid Analgesics REMS. We value our engagement with the FDA 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 FDA about the growing epidemic of 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.

ACCME Accreditation System

The ACCME system has the capacity and diversity to address public health and safety initiatives. There are more than 1,900 accredited continuing medical education (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.

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 25 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 CE 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.

Independence

The hallmark of accredited CME is independence. Accredited CE offers physicians a protected space to learn and teach without commercial influence. Regulations completely exclude industry from any influence, direct or indirect, over speakers and content. Accredited CME providers must follow strict rules regarding the management of funds and conflicts of interest.

Research has demonstrated that commercial support does not increase the risk for commercial bias when CME providers abide by the ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities℠. A national model, these requirements are a common interprofessional standard shared by CE accreditors across the health professions.

ACCME Support of ER/LA Opioid Analgesics REMS

The ACCME is committed to facilitating the development and delivery of REMS-compliant accredited CE. The ACCME has participated in FDA committee meetings and other events related to REMS; clarified ACCME policy for FDA, CE providers, and manufacturers; developed resources for CE providers; and conducted the audits required by the FDA.

As a service to the CE community and the FDA, the ACCME modified its data collection system to enable accredited CE 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.

Accredited CE Community Support of ER/LA Opioid Analgesics REMS

ACCME data from March 2013 through April 2016 shows that 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 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.

Of the approximately 168,000 learners, close to 63,000 are registered to prescribe Schedule 2 or 3 drugs; and close to 42,000 are FDA-defined prescribers, those registered to prescribe Schedule 2 or 3 drugs and who had written at least one prescription in the last year. Physicians, advanced practice nurses, and physician assistants made up the largest groups of FDA-defined prescribers who participated in the REMS-compliant activities.

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.

(See attachment for a detailed breakdown of this data including figures and tables.)

Lessons Learned and Recommendations

The Blueprint: We appreciate the FDA for developing the blueprint containing the core messages to communicate to prescribers. We agree that it's important that prescribers receive consistent, evidence-based messages about risks and safe use. However, we have found that some of the elements of the blueprint and REMS requirements have constrained the ability of CE providers to develop education that successfully meets the diverse needs of their healthcare communities.

Healthcare professionals do not practice one-size-fits-all healthcare — and their education should not be one-size-fits-all. This approach has the unintended consequence of discouraging participation, reducing motivation, and limiting change in prescribing practices. To take full advantage of the strengths of the accredited CE system, the REMS should be structured to utilize the capacity of the CE community to deliver customized education and participate in rapid response initiatives to emerging health issues.

Accreditation standards provide a roadmap for CE providers to produce relevant, evidence-based, high-quality education. CE 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.

We recommend that the blueprint be revised to focus on high level messages regarding risks and safety, without constraining CE providers' ability to tailor the education. CE providers should be trusted to meet the elements of the blueprint that apply to their healthcare professional community.

Flexibility in instructional design and content: REMS CE requirements should allow CE providers maximum flexibility in determining instructional design and content that meets the needs of their specific learners. Local CE providers have expertise in assessing and addressing the needs of their local healthcare community; national specialty societies and other organizations with regional and national reach have expertise in addressing and assessing the needs of their specific learners. To maximize participation and educational effectiveness, CE providers must be empowered to customize REMS CE to their learners' needs. This includes enabling CE providers to create education for individual learners and to designate those individual learners as having completed the education based on the CE provider's determination.

Encouraging efficiency: CE providers should be encouraged to share the REMS CE interventions they develop with other CE 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, CE providers need to respond nimbly to local needs. By revising the blueprint and the other components of the REMS CE requirements to be less restrictive, CE providers will be able to partner with their institutions, health systems, and communities to respond proactively to emerging issues related to the opioid epidemic.

Addressing multiple initiatives: The opioid abuse crisis is receiving increasing attention across the country. Government initiatives, CE 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. 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 CE activities are allowed to count toward meeting multiple requirements, such as REMS and state-based opioid education mandates.

Recognizing team participation: Prescribers and non-prescribers 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. We believe the FDA should count all learners who complete the education, prescribers and non-prescribers, towards its goals.

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 REMS CE, to help ensure their voices are heard and their best interests are served.

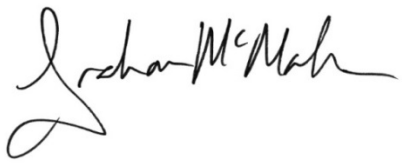
Going Forward: Accredited CE's Role in the ER/LA Opioid Analgesics REMS
We fully support the ongoing use of accredited CE as a delivery mechanism for prescriber training for the ER/LA Opioid Analgesics REMS. By applying the lessons learned and incorporating a continuous improvement process, we are confident that accredited CE can continue to make an important contribution to reducing opioid misuse and promoting safe prescribing practice.

The Role of Accredited CE in Support of Other REMS
We believe that accredited CE can play a significant role in addressing the patient safety issues identified in REMS. We fully support using accredited CE as a delivery mechanism for prescriber education for other REMS, including pre-and post-approval REMS, and single product REMS, provided the proper controls are in place to ensure independence from commercial influence. The collaboration between the FDA and the accredited CE community in support of the ER/LA Opioid Analgesics REMS has laid the groundwork for our continued work together in support of patient safety.

Accredited CE: 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 have proposed new standards that will encourage and reward CE programs that advance team-based care; involve the patients and the public in CE; 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 the FDA's goals of educating healthcare professionals about drug risks and safety issues.

We look forward to continuing to work together with our community of CE providers and healthcare professionals, the 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,



Graham McMahon, MD, MMSc
President and Chief Executive Officer

Attachment: ACCME ER/LA Opioid Analgesics REMS CE Activities

Accreditation Council for Continuing Medical Education (ACCME®)

ER/LA Opioid Analgesics REMS CE Activities

March 2013– April 2016

This report contains data that ACCME has collected about ER/LA Opioid Analgesics REMS continuing education (CE) activities offered by CE providers accredited in the ACCME System.

This report is based on data submitted by CE providers to the ACCME Program and Activity Reporting System (PARS). As a service to the CE community and the FDA, the ACCME modified PARS to enable accredited CE providers to submit information specific to their REMS CE activities. The PARS data collection system for the ER/LA Opioid Analgesics REMS was created in compliance with the MedBiquitous MEMS 2.0 Standard to ensure interchangeability and accuracy.

The ACCME does not require CE providers to report this data. Accredited CE providers choose to cooperate as part of the terms and conditions of their commercial support agreement with the REMS Program Companies (RPC), the consortium of opioid manufacturers that are responsible for fulfilling the FDA ER/LA Opioid Analgesics REMS. Cooperating providers are instructed to complete a specific section of the PARS activity entry form if the activity is ER/LA Opioid Analgesics REMS-compliant or REMS-related. An illustration of this form is shown figure 5 on the last page.

	Providers	Activities
Non-RPC Funded	4	4
RPC Funded	92	643
Total	**96**	**647**

Table 1: Numbers of accredited CE providers offering REMS-compliant CE activities and numbers of activities. This includes all activities that have already been held, are currently available, or planned for the future.

		Activity Subtypes*						
Activity Type	**Count**	**Panel**	**Lecture**	**Small Group discussion**	**Case-based Discussion**	**Simulation**	**Skill-based Training**	**Other**
Live - Course	516	32	226	15	108	0	16	14
Live - Internet Course	30	8	9	0	9	2	0	1
Total Live Activities	**546**	40	235	15	117	2	16	15
Enduring Material - Internet	76							
Enduring Material - Other	23							
Total Enduring Material Activities	**99**							
Performance Improvement	**2**							
Grand Total	**647**	40	235	15	117	2	16	15

**Providers of live courses are not required to report the sub-type(s) of the activity. They may report more than one sub-type for each activity, therefore total sub-types is not expected to equal total activities…*

Table 2. ER/LA Opioid REMS-compliant CME activities, by activity type and sub-type. This includes all activities that have already been held, are currently available, or planned for the future.

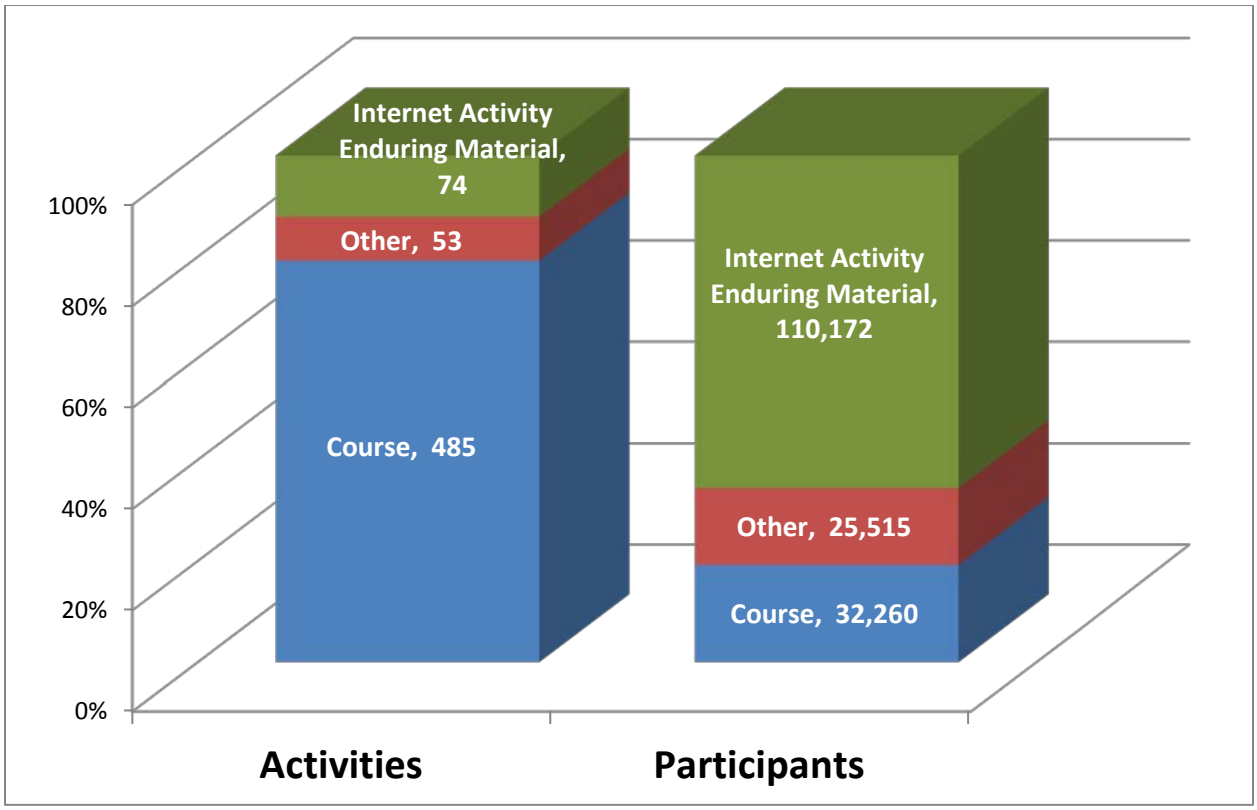


Figure 1: Numbers and percentages of ER/LA Opioid REMS-compliant CME activities by type. This includes activities that have already been held or are currently available; does not include activities planned for the future.

Group	Number of participants in group
Total participants	167,947
Participants successfully completing…who are registered to prescribe Schedule 2 or 3 drugs	62,961
Participants successfully completing…who are registered to prescribe Schedule 2 or 3 drugs **and** who wrote at least one prescription in the last year (FDA-defined "prescribers")	41,608

Table 3. Participants who completed ER/LA Opioid REMS-Compliant CE activities, including total numbers, registered prescribers, and FDA-defined prescribers

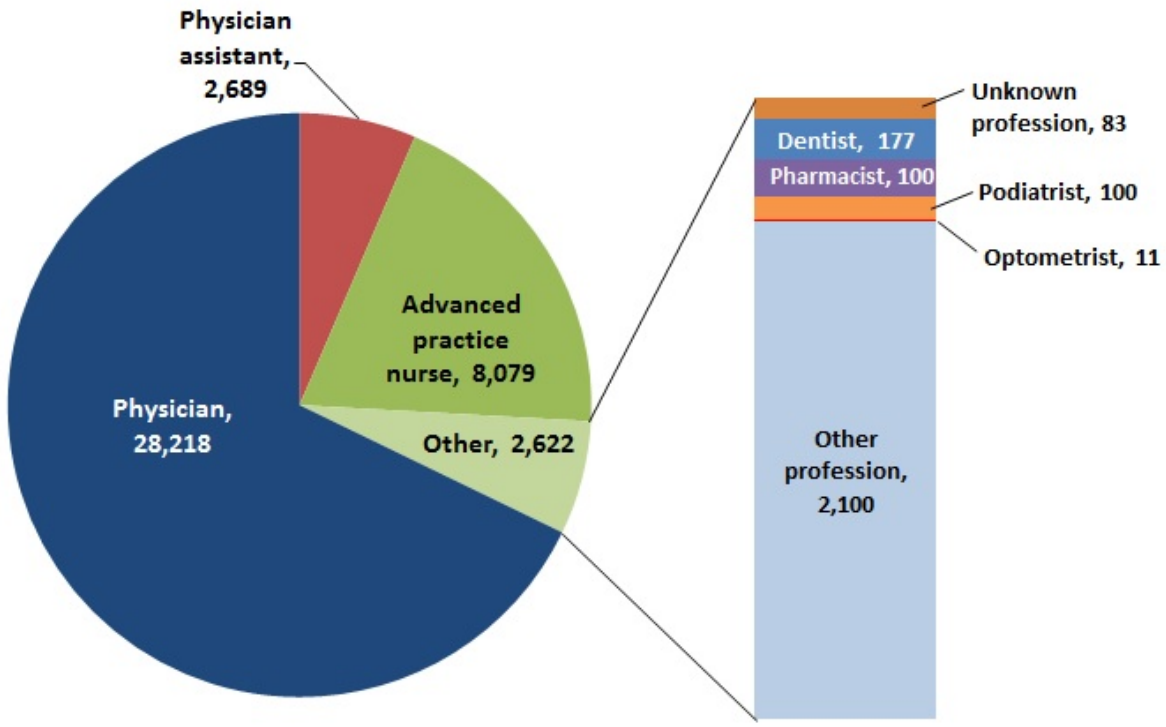


Figure 2: FDA-defined prescribers who have successfully completed ER/LA Opioid REMS-Compliant CE activities, by profession, n=41,608.

Organization Type	CE Providers	Activities	All Participants	FDA-defined Prescribers
Hospital/Healthcare Delivery System	46	81	3,976	1,568
Non-profit (Other)	5	18	4,340	2,774
Non-profit (Physician Membership Organization)	25	180	55,561	9,120
Not Classified	1	6	90	56
Publishing/Education Company	7	80	70,159	15,983
School of Medicine	12	247	33,821	12,107
Totals	**96**	**612**	**167,947**	**41,608**

Table 4: CE providers, activities, participants, and FDA-defined Prescribers by CE provider type. This includes activities that have already been held or are currently available; does not include activities planned for the future.

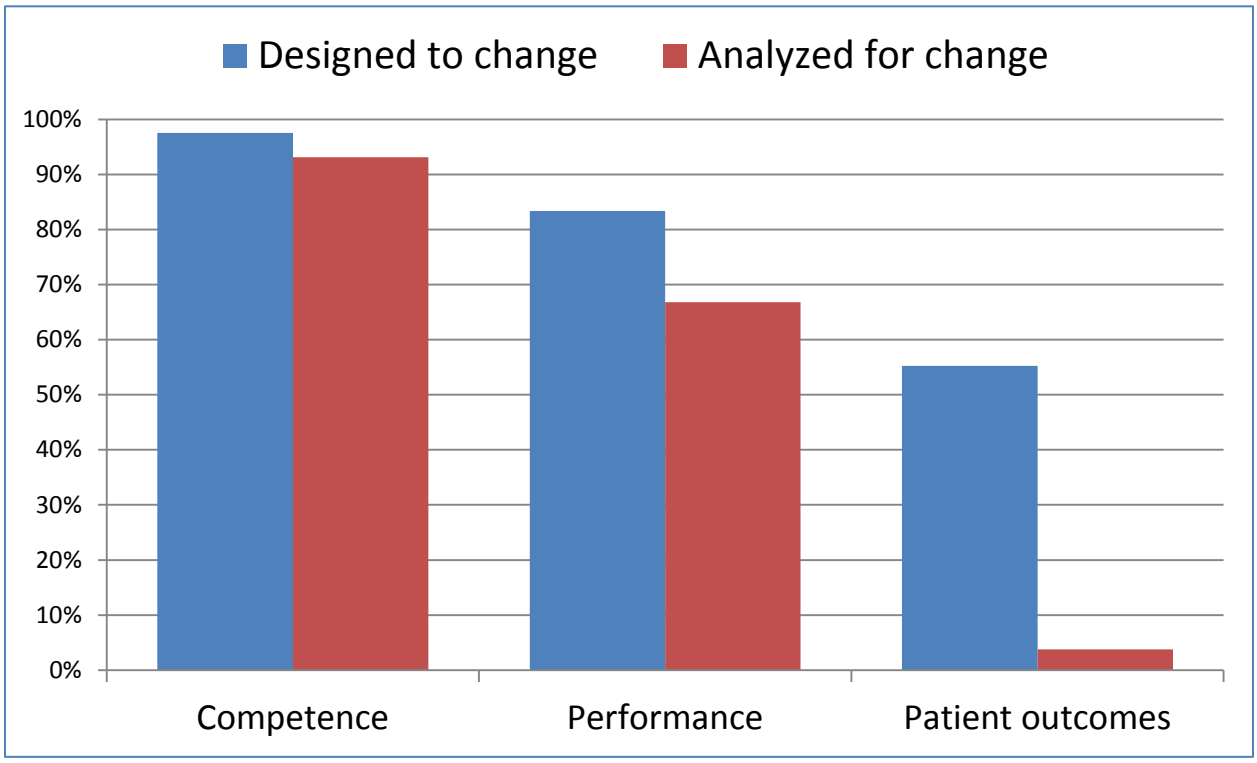


Figure 3: Percentage of activities that were designed and/or analyzed for change in competence, performance, and/or patient outcomes.

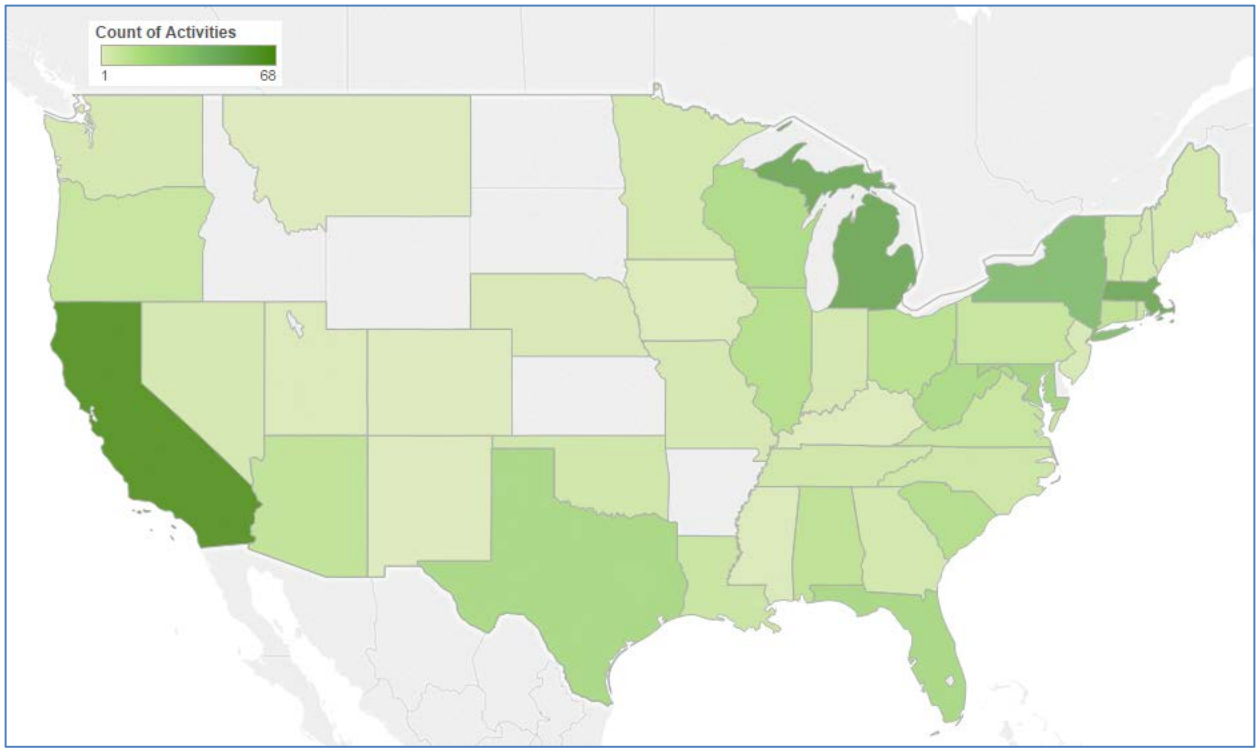
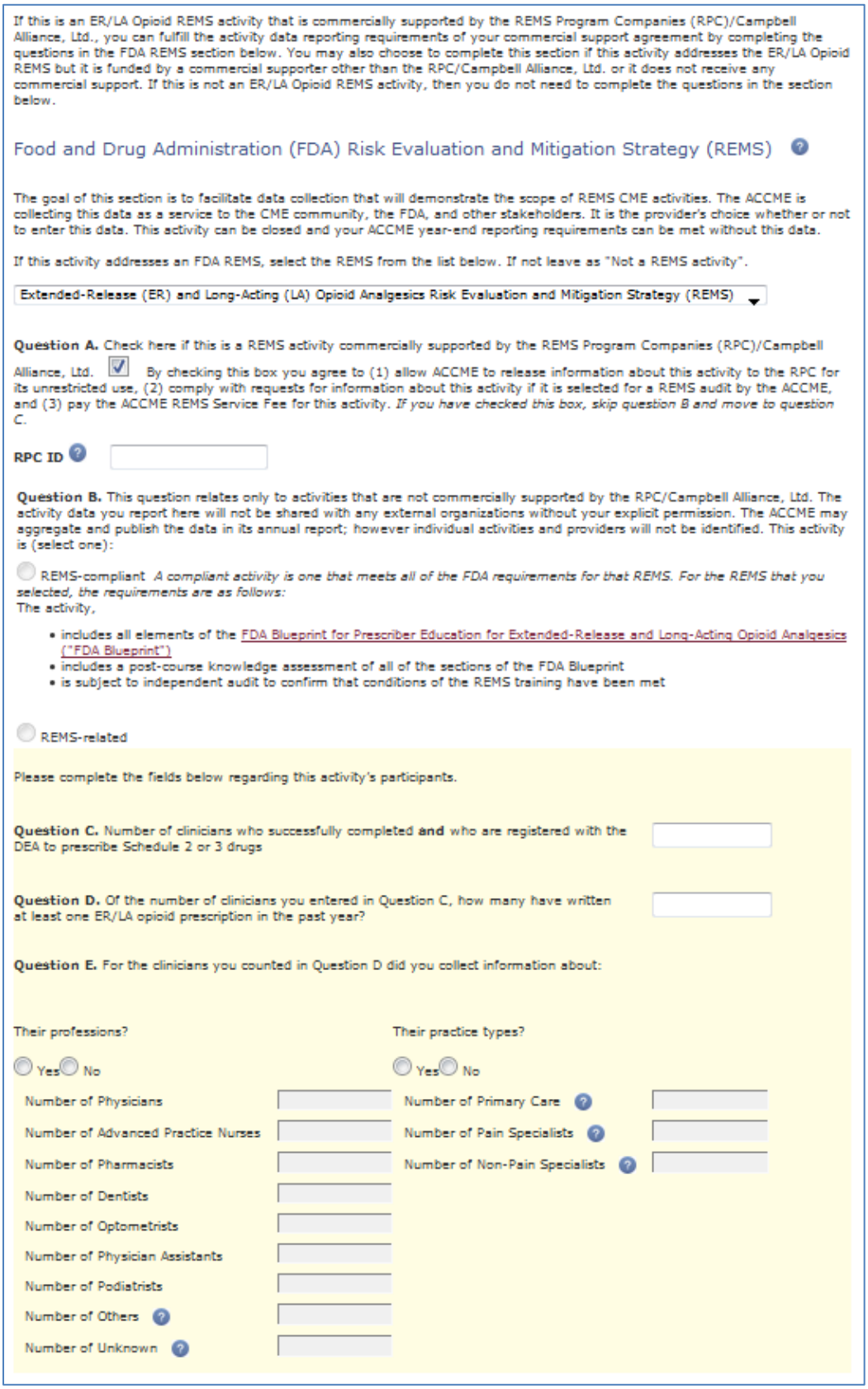


Figure 4: Geographic locations for live ER/LA Opioid Analgesics REMS-compliant CE activities. This includes activities that have already been held or are currently available; does not include activities planned for the future.



If this is an ER/LA Opioid REMS activity that is commercially supported by the REMS Program Companies (RPC)/Campbell Alliance, Ltd., you can fulfill the activity data reporting requirements of your commercial support agreement by completing the questions in the FDA REMS section below. You may also choose to complete this section if this activity addresses the ER/LA Opioid REMS but it is funded by a commercial supporter other than the RPC/Campbell Alliance, Ltd. or it does not receive any commercial support. If this is not an ER/LA Opioid REMS activity, then you do not need to complete the questions in the section below.

Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS)

The goal of this section is to facilitate data collection that will demonstrate the scope of REMS CME activities. The ACCME is collecting this data as a service to the CME community, the FDA, and other stakeholders. It is the provider's choice whether or not to enter this data. This activity can be closed and your ACCME year-end reporting requirements can be met without this data.

If this activity addresses an FDA REMS, select the REMS from the list below. If not leave as "Not a REMS activity".

Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS)

Question A. Check here if this is a REMS activity commercially supported by the REMS Program Companies (RPC)/Campbell Alliance, Ltd. By checking this box you agree to (1) allow ACCME to release information about this activity to the RPC for its unrestricted use, (2) comply with requests for information about this activity if it is selected for a REMS audit by the ACCME, and (3) pay the ACCME REMS Service Fee for this activity. *If you have checked this box, skip question B and move to question C.*

RPC ID

Question B. This question relates only to activities that are not commercially supported by the RPC/Campbell Alliance, Ltd. The activity data you report here will not be shared with any external organizations without your explicit permission. The ACCME may aggregate and publish the data in its annual report; however individual activities and providers will not be identified. This activity is (select one):

REMS-compliant *A compliant activity is one that meets all of the FDA requirements for that REMS. For the REMS that you selected, the requirements are as follows:*
The activity,

- includes all elements of the FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics ("FDA Blueprint")
- includes a post-course knowledge assessment of all of the sections of the FDA Blueprint
- is subject to independent audit to confirm that conditions of the REMS training have been met

REMS-related

Please complete the fields below regarding this activity's participants.

Question C. Number of clinicians who successfully completed **and** who are registered with the DEA to prescribe Schedule 2 or 3 drugs

Question D. Of the number of clinicians you entered in Question C, how many have written at least one ER/LA opioid prescription in the past year?

Question E. For the clinicians you counted in Question D did you collect information about:

Their professions? Yes No

Number of Physicians
Number of Advanced Practice Nurses
Number of Pharmacists
Number of Dentists
Number of Optometrists
Number of Physician Assistants
Number of Podiatrists
Number of Others
Number of Unknown

Their practice types? Yes No

Number of Primary Care
Number of Pain Specialists
Number of Non-Pain Specialists

Figure 5: An illustration of the form that CE providers use to submit data about REMS CE Activities in the ACCME Program and Activity Reporting System (PARS).