



## Accreditation Council for Continuing Medical Education (ACCME®)

### ER/LA Opioid REMS CME Activities in PARS: 2016

This report contains explanations and examples of the data collected by the Accreditation Council for Continuing Medical Education (ACCME®) about the educational activities that are compliant with the [Food and Drug Administration's \(FDA\) Extended-Release and Long-Acting Opioid Analgesics \(ER/LA\) Risk Evaluation and Mitigation Strategy \(REMS\)](#). These activities are offered by continuing medical education (CME) providers accredited in the ACCME System. First published in September 2014, then revised in July 2015, this report has been revised again to reflect cumulative data available as of September 2016.

#### **The ACCME's Program and Activity Reporting System**

The ACCME's [Program and Activity Reporting System \(PARS\)](#) was launched in 2010 to streamline the collection of activity data submitted by ACCME-accredited CME providers in support of ACCME reporting requirements. It contains information about all the CME activities offered by all of the accredited providers in the ACCME System.

In 2013, the ACCME adapted PARS to accommodate data specific to accredited CME activities offered as part of the FDA ER/LA Opioid Analgesics REMS. This adaption of PARS was done as a service to the CME providers, and as an operational support for the REMS process that was, for the first time, integrating accredited CME into this important public health initiative. Activities that meet the FDA's standards for this REMS are referred to as *REMS-compliant*.

All the costs for adapting PARS to the REMS process were borne by the providers funded by the REMS Program Companies (RPC), the consortium of opioid manufacturers that are responsible for fulfilling the FDA ER/LA Opioid Analgesics REMS.

The PARS data collection system for this REMS was created in compliance with the Medbiquitous MEMS 2.0 Standard so as to ensure interchangeability and accuracy.

The ACCME does not require CME providers to report this data. The providers choose to cooperate as part of the terms and conditions of their commercial support agreement with the RPC. Cooperating providers are instructed to complete the section of the PARS Activity Entry form if the activity is ER/LA Opioid REMS-compliant or REMS-related. An illustration of this form section is shown on the next page.

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

Which sections of the FDA REMS did the activity's instruction address? Check all that apply.

- I. Assessing Patients for Treatment with ER/LA Opioid Analgesic Therapy
- II. Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioid Analgesics
- III. Managing Therapy with ER/LA Opioid Analgesics
- IV. Counseling Patients and Caregivers about the Safe Use of ER/LA Opioid Analgesics
- V. General Drug Information for ER/LA Opioid Analgesic Products
- VI. Specific Drug Information for ER/LA Opioid Analgesic Products

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 ?

The following analysis is based on data in PARS as of September 29, 2016.

In ACCME’s PARS database, 100 providers reported 693 REMS-compliant accredited CME activities. Of the 693 activities, 687 were funded by the REMS Program Companies (RPC) (Table 1). In this analysis, the activities that were funded by the RPC and those that were not are reported together. Two providers offered activities in both categories, so those providers are counted in both provider groups.

	Providers	Activities
Non-RPC Funded	6	6
RPC Funded	96	687
<b>Total</b>	<b>100</b>	<b>693</b>

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

The 693 activities were presented in a variety of formats. The most common were lecture or case-based discussions (Table 2).

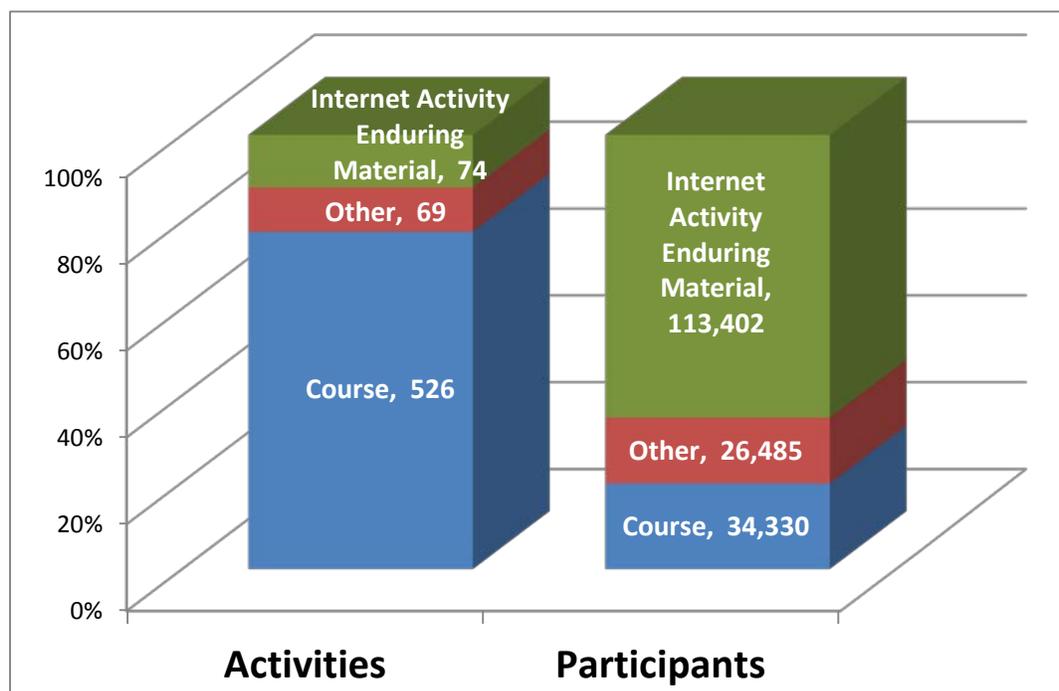
Activity Type	Count	Activity Subtypes*						
		Panel	Lecture	Small Group discussion	Case-based Discussion	Simulation	Skill-based Training	Other
Live - Course	542	34	233	15	109	0	16	13
Live - Internet Course	41	8	19	0	19	2	0	1
Live - Regularly Scheduled Series	1							
<b>Total Live Activities</b>	<b>584</b>	42	252	15	128	2	16	14
Enduring Material - Internet	82							
Enduring Material - Other	25							
<b>Total Enduring Material Activities</b>	<b>107</b>							
Performance Improvement	2							
<b>Grand Total</b>	<b>693</b>	42	252	15	128	2	16	14

\*Providers of live courses and live internet courses may 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.**

Of the 693 ER/LA Opioid REMS-compliant activities that were reported in PARS, 677 have already been held or released: 526 courses, 82 Internet enduring materials, 25 other enduring materials, 41 Internet live, 2 performance improvement and 1 regularly scheduled series.

While the most common activity type was courses, Internet enduring materials drew the most participants (Figure 1).



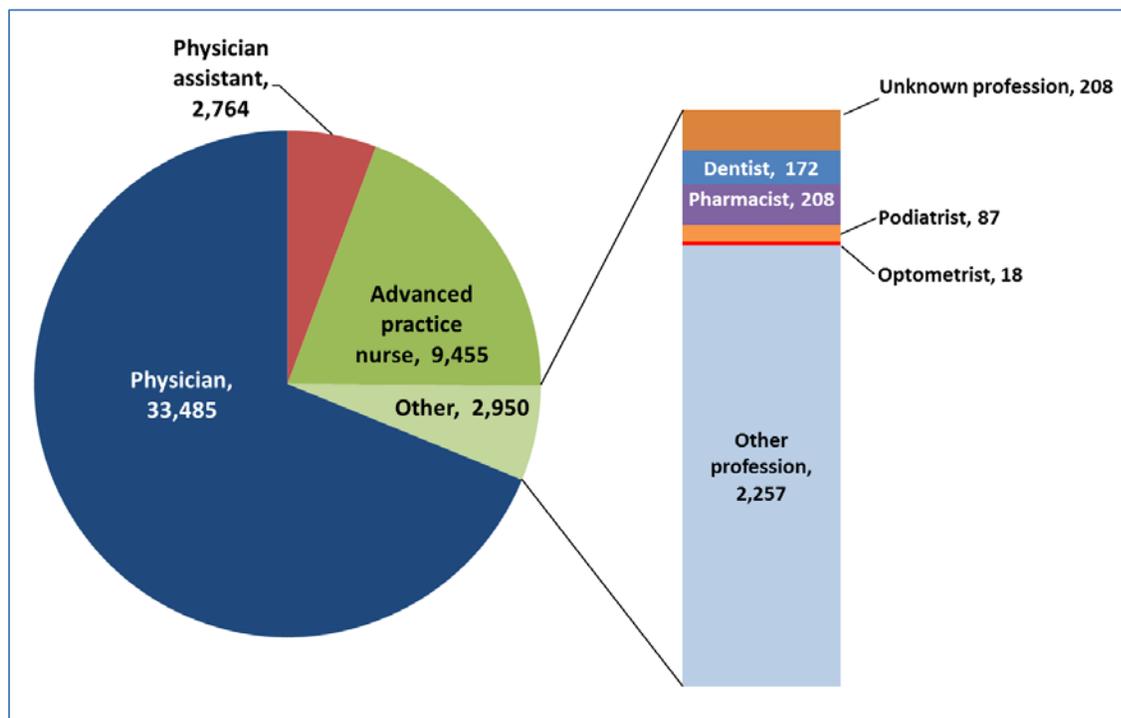
**Figure 1: Numbers and percentages of ER/LA Opioid REMS-compliant CME activities by type. This includes activities that have already been held or are currently available; does not include activities planned for the future.**

Out of 174,217 participants in ER/LA Opioid REMS activities that have been held, 42% were registered to prescribe schedule 2 or 3 drugs (registered prescribers). Approximately 66% of these registered prescribers had written at least one prescription in the last year (FDA-defined prescribers) (Table 3). Of the 48,654 FDA-defined prescribers successfully completing these CME activities that have already

Group	# participants in group	% of preceding group
Participants <i>Successfully completing</i>	174,217	-
Participants successfully completing ... that are registered to prescribe Schedule 2 or 3 drugs	73,251	42%
Prescribers successfully completing ... that are registered to prescribed Schedule 2 or 3 drugs <b>and</b> who wrote at least one prescription in the last year (FDA-defined prescribers)	48,654	66%

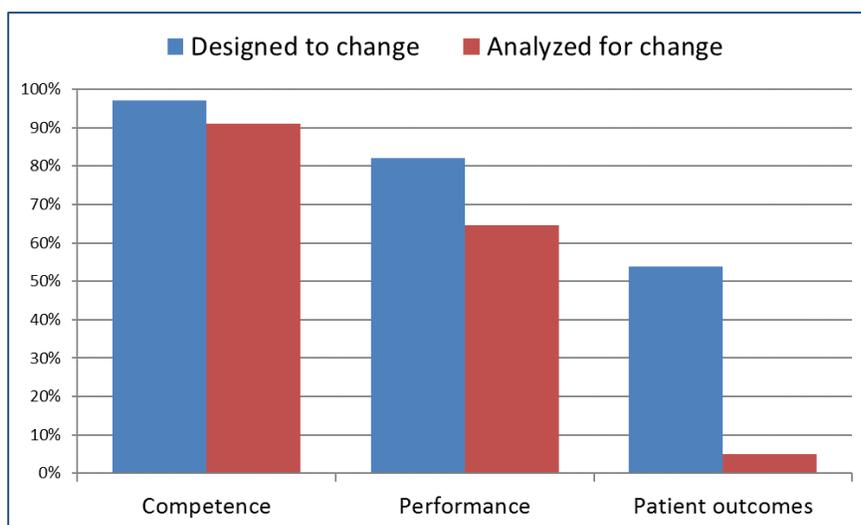
**Table 3. Participants who completed ER/LA Opioid REMS-compliant CE activities, including total numbers, registered prescribers, and FDA-defined prescribers.**

been held, advanced practice nurses, physician assistants, and physicians made up the largest groups of identified participants, totaling 45,704 or 94% (Figure 2).



**Figure 2: FDA-defined prescribers who have successfully completed ER/LA Opioid REMS-compliant CE activities, by profession, n=48,654.**

The ACCME requires providers to design and analyze CME activities for their impact on learner competence, performance, and/or patient outcomes. Figure 3 shows what type of change the CME activity was designed to facilitate and what type of change was analyzed upon completion of the activity. For the 677 ER/LA Opioid REMS-compliant activities that have already been held, 97% were designed to change competence, 82% were designed to change performance, and 5% were designed to change patient outcomes.



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

The ACCME also requires providers to plan activities that address various professional attributes, or competencies, as defined by the Accreditation Council for Graduate Medical Education (ACGME)/ American Board of Medical Specialties (ABMS), the Institute of Medicine, the Interprofessional Education Collaborative, and others. Beginning in late 2013, providers had the opportunity to report in PARS which professional competency(ies) their CME activities addressed. Reporting of competencies became required for all CME activities beginning January 1, 2015. Table 4 presents the data reported as of September 29, 2016.

Competency*	Activities	Total Participants
<b>ACGME/ABMS Group</b>		
Interpersonal and Communication Skills	242	64,198
Medical Knowledge	365	119,067
Patient Care and Procedural Skills	332	118,192
Practice-based Learning and Improvement	121	84,200
Professionalism	170	56,720
Systems-based Practice	101	41,957
<b>Institute of Medicine Group</b>		
Apply quality improvement	50	2,502
Employ evidence-based practice	193	46,700
Provide patient-centered care	195	46,834
Utilize informatics	98	18,354
Work in interdisciplinary teams	123	38,504
<b>Interprofessional Education Collaborative Group</b>		
Interprofessional Communication	112	19,632
Roles/Responsibilities	37	1,796
Teams and Teamwork	37	1,795
Values/Ethics for Interprofessional Practice	89	19,113
<b>Other Competencies</b>	24	2,431

\*Providers may report more than one competency for an activity.

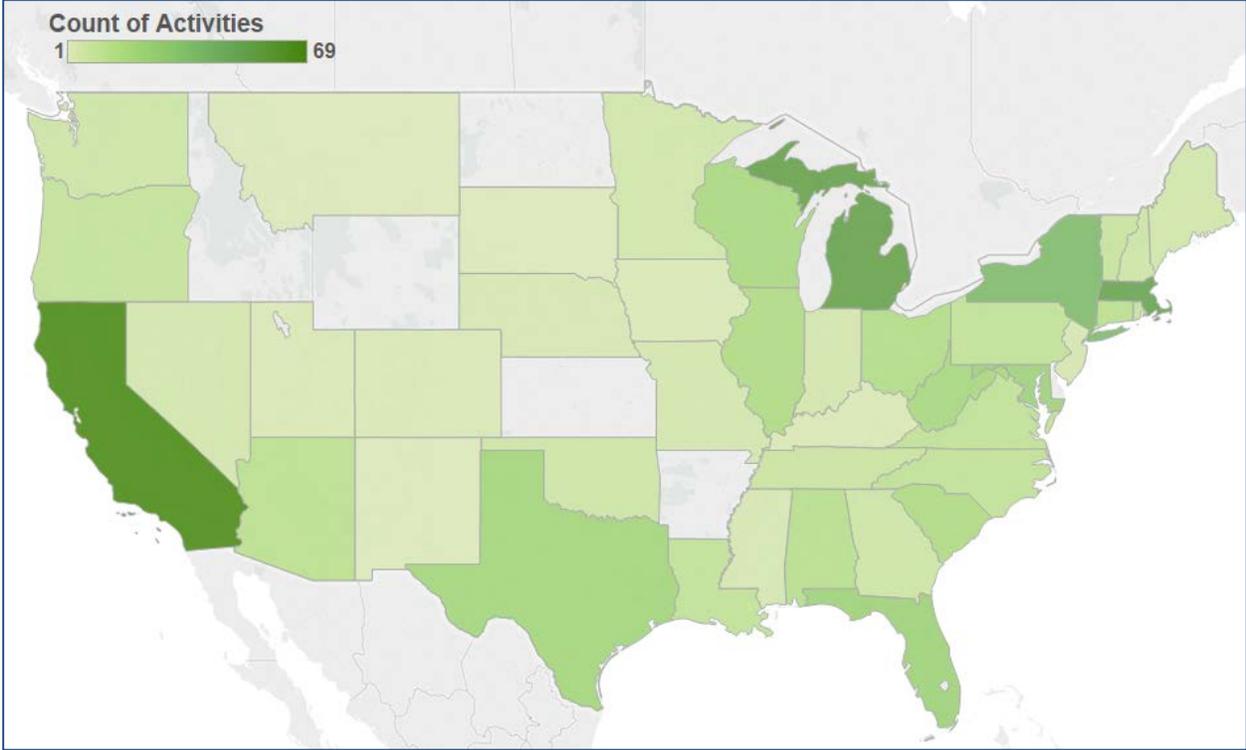
**Table 4: Activities and total participants in ER/LA Opioid REMS CME activities that were designed to address professional competencies.**

Table 5 shows ER/LA Opioid REMS-compliant CME activities that have already been held by type of CME provider. This shows that more hospital/healthcare delivery systems offer this education (47) than other organizational types, while schools of medicine offer the largest number of activities (272) and publishing/education companies reached the most participants (71,589) and FDA-defined prescribers (22,880).

CME Provider Type	Providers	Activities	All Participants	FDA-defined Prescribers
Hospital/Healthcare Delivery System	47	84	3,978	1,577
Insurance Company/Managed Care Company	1	2	-	
Non-profit (Other)	5	20	4,504	1,650
Non-profit (Physician Membership Organization)	27	202	56,041	9,299
Not Classified	1	6	90	52
Publishing/Education Company	7	107	71,589	22,880
School of Medicine	12	272	38,015	13,196
<b>Totals</b>	<b>100</b>	<b>693</b>	<b>174,217</b>	<b>48,654</b>

**Table 5: CME providers, activities, participants, and FDA-defined Prescribers by CME provider type. This includes activities that have already been held or are currently available; does not include activities planned for the future.**

Figure 4 shows the distribution of locations for the presentation of live ER/LA Opioid REMS-compliant activities (planned and already held, n=543). Live activities have been offered in nearly every section of the country. The number of activities offered in each state loosely correlates to the population of the state.



*Note: No live ER/LA Opioid REMS-compliant CME activities were reported outside the contiguous United States.*

**Figure 4: Geographic location of live ER/LA Opioid REMS-compliant CME. This includes activities that have already been held, are currently available, or that are planned for the future.**