

Accreditation Council for Continuing Medical Education (ACCME®) ER/LA Opioid REMS CME Activities in PARS: 2017

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, this report has been revised again to reflect cumulative data available as of April 2017.

The ACCME's Program and Activity Reporting System

The ACCME's <u>Program and Activity Reporting System (PARS)</u> 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. 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? Their practice types? Yes No Yes No Number of Physicians Number of Primary Care (2) Number of Advanced Practice Nurses Number of Pain Specialists 🕝 Number of Pharmacists Number of Non-Pain Specialists 🕝 Number of Dentists Number of Optometrists Number of Physician Assistants Number of Podiatrists Number of Others @ Number of Unknown 🕝

The following analysis is based on data in PARS as of April 18, 2017.

In ACCME's PARS database, 105 providers have reported 767 REMS-compliant accredited CME activities. Of the 767 activities, 749 were funded by the REMS Program Companies (RPC) (Table 1). The analysis that follows includes data from both activities that were funded by the RPC and those that were not funded by the RPC. Two providers offered activities in both categories, so those providers are counted in both provider groups.

	Providers	Activities
Non-RPC Funded	10	18
RPC Funded	95	749
Total	105	767

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

These 767 activities were presented in a variety of formats. The most common were live lecture or case-based discussions (Table 2).

		Activity Subtype(s)*						
		le!	Lecture	Sm Group Discussion	Case-based Discussion	Simulation	Skill-based Training	er
Activity Type	Count	Panel	Lec	Sm. Dis	Cas Disc	Sim	Skil	Other
Live - Course	602	35	253	15	112	0	16	15
Live - Internet Course	44	8	19	0	19	2	0	1
Live - Regularly Scheduled Series	1							
Total Live Activities	647	43	272	15	131	2	16	16
Enduring Material - Internet	90							
Enduring Material - Other	28							
Total Enduring Material Activities	118							
Performance Improvement	2							
Grand Total	767	43	272	15	131	2	16	16

^{*}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 767 ER/LA Opioid REMS-compliant activities that were reported in PARS, 744 have already been held or released: 581 courses, 88 Internet enduring materials, 28 other enduring materials, 44 Internet live, 2 performance improvement and 1 regularly scheduled series.

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

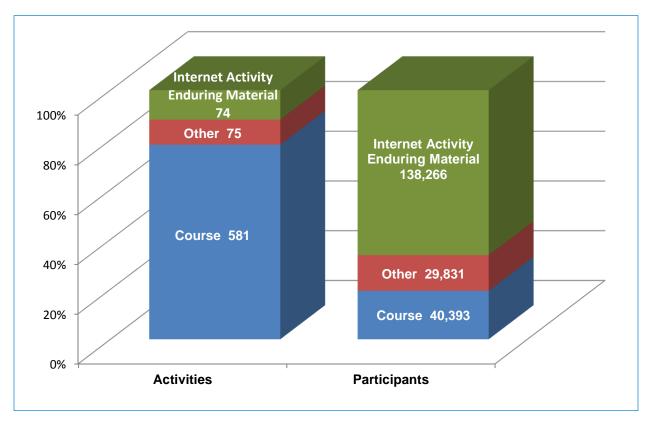


Figure 1: Numbers and percentages of ER/LA Opioid REMS-compliant CME activities by type. This includes activities that have already been held or are currently available; it does not include activities planned for the future.

Out of 208,490 participants in ER/LA Opioid REMS activities that have been held, 48% were registered to prescribe schedule 2 or 3 drugs (registered prescribers). Of these, approximately 62% were FDA defined prescribers who had written at least one prescription in the last year (Table 3).

Group	# participants in group	% of preceding group	
Participants Successfully completing	208,490	-	
Participants successfully completing who are registered to prescribe Schedule 2 or 3 drugs	100,521	48%	
Prescribers successfully completing who are registered to prescribe Schedule 2 or 3 drugs <u>and</u> who wrote at least one prescription in the last year (FDA-defined prescribers)	61,958	62%	

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

Of the 61,958 FDA-defined prescribers successfully completing these CME activities that have already been held, advanced practice nurses, physician assistants, and physicians made up the largest groups of identified participants, totaling 60,697 or 95% (Figure 2).

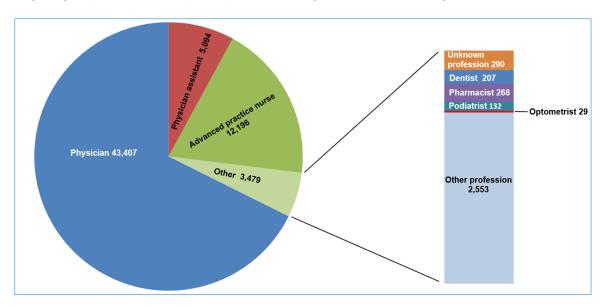


Figure 2: FDA-defined prescribers who have successfully completed ER/LA Opioid REMS-compliant CE activities, by profession (n=61,958).

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 744 ER/LA Opioid REMS-compliant activities that have already been held, 100% were designed to change competence, 82% were designed to change performance, and 59% were designed to change patient outcomes.

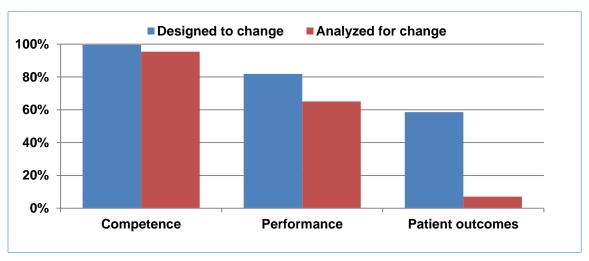


Figure 3: Percentage of activities that were designed and/or analyzed for change in competence, performance, and/or patient outcomes.

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 April 18, 2017.

Competency*	Activities	Total Participants
ACGME/ABMS Group		
Interpersonal and Communication Skills	301	102,689
Medical Knowledge	450	152,657
Patient Care and Procedural Skills	422	148,580
Practice-based Learning and Improvement	144	92,874
Professionalism	223	92,084
Systems-based Practice	147	63,633
Institute of Medicine Group		
Apply Quality Improvement	75	12,601
Employ Evidence-based Practice	258	79,012
Provide Patient-centered Care	253	77,659
Utilize Informatics	144	39,465
Work in Interdisciplinary Teams	167	63,700
Interprofessional Education Collaborative Group		
Interprofessional Communication	157	44,919
Roles/Responsibilities	49	2,214
Teams and Teamwork	52	12,850
Values/Ethics for Interprofessional Practice	114	31,619
Other Competencies	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 (48) offer this education than other organizational types, while schools of medicine offer the largest number of activities (282) and publishing/education companies reached the most participants (88,739) and FDA-defined prescribers (30,424).

CME Provider Type	Providers	Activities	All Participants	FDA-defined Prescribers
Insurance Company/Managed Care	1	2	47	11
Company				
Not Classified	1	6	90	52
Hospital/Healthcare Delivery System	48	84	3,945	1,488
Non-profit (Other)	6	23	4,847	1,825
School of Medicine	12	282	50,346	16,523
Non-profit (Physician Membership	28	230	60,476	11,635
Organization)				
Publishing/Education Company	7	117	88,739	30,424
Totals	103	744	208,490	61,958

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=603). 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.

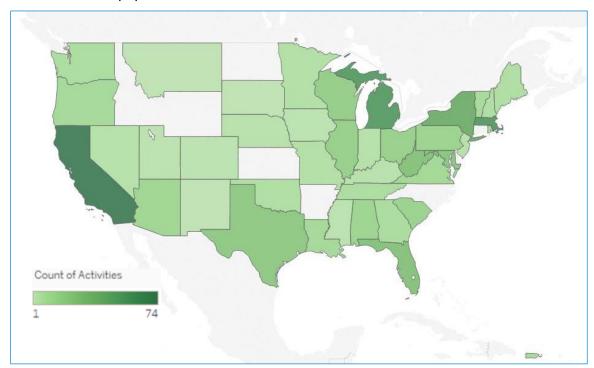


Figure 4: Geographic location of live ER/LA Opioid REMS-compliant CME. This includes activities that have already been held, are currently available, or that are planned for the future.