



Accredited Continuing Medical Education and the Food and Drug Administration's Risk Evaluation and Mitigation Strategies

A Fact Sheet for Accredited CME Providers

Updated January 6, 2015

What is an FDA Risk Evaluation and Mitigation Strategy (REMS)?

The Food and Drug Administration Amendments Act of 2007 gave the FDA the authority to require manufacturers of drugs and biological products to put in place special programs if the FDA determines that safety measures are needed beyond the professional labeling to ensure that the benefits of products outweigh their risks. The manufacturers then implement FDA-monitored actions to address those risks. The FDA calls each of these a Risk Evaluation and Mitigation Strategy (REMS).

What is the overall goal of each FDA Risk Evaluation and Mitigation Strategy?

According to the FDA, the [goal of REMS](#) is to ensure that the benefits of a drug or biological product outweigh its risks. The FDA may require a [REMS](#) as part of the approval of a new product, or for an approved product when new safety information arises. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use. Since medicines are very different from each other, each REMS for each medicine is also different. A REMS may include a medication guide or package insert for patients and a communication plan to inform key audiences such as healthcare professionals and medical societies about the risks and safe use measures. For more information, visit www.fda.gov and see the following resources: [Approved Risk Evaluation and Mitigation Strategies \(REMS\)](#) and [FDA Basics Webinar: A Brief Overview of Risk Evaluation and Mitigation Strategies \(REMS\)](#).

What is the FDA REMS for Extended-Release and Long-Acting Opioid Analgesics?

The FDA delivered its Risk Evaluation and Mitigation Strategy (REMS) for extended-release and long-acting (ER/LA) opioid analgesics to the manufacturers in 2012. According to the [FDA news release](#) the REMS "is designed to ensure that healthcare professionals are trained in how to properly prescribe these medicines and how to instruct their patients about using them safely." It has two components: a medication guide and elements to assure safe use.

What is the role of accredited continuing education in the ER/LA Opioid Analgesics REMS? One of the elements to assure safe use is an education program for prescribers about the risks of opioid medications as well as safe prescribing and safe use practices. The REMS requires the manufacturers to provide commercial

support to accredited CME so that it is available free of charge or at nominal cost to prescribers. However, the participation of accredited providers is completely voluntary – as is the participation of prescribers in REMS education.

Which manufacturers are responsible for fulfilling the REMS for Extended-Release and Long- Acting Opioids?

The companies that have come together as a [consortium](#) of opioid manufacturers, the REMS Program Companies (RPC), are the entities responsible to the FDA.

What are REMS-compliant accredited CE activities?

The FDA [writes](#) that: “Training will be considered ‘REMS-compliant training’ under this REMS if:

- 1) it, for training provided by CE providers is offered by an accredited provider to licensed prescribers,
- 2) it includes all elements of the [FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics \(“FDA Blueprint”\)](#),
- 3) it includes a post-course knowledge assessment of all of the sections of the FDA Blueprint, and
- 4) it is subject to independent audit to confirm that conditions of the REMS training have been met.

Is it acceptable for accredited CME providers to develop activities based on the FDA blueprint for the ER/LA Opioid Analgesics REMS?

Yes. Accredited CME providers can base their activities on the [FDA blueprint](#) and be in compliance with the [ACCME Standards for Commercial SupportSM: Standards to Ensure Independence in CME Activities](#). As with any CME activity, accredited providers within the ACCME system must comply with the ACCME accreditation requirements. There is no special use standard or safe harbor for CME that supports the ER/LA Opioid Analgesics REMS. The ACCME Standards for Commercial Support create a framework by ensuring that CME is accountable to participants, to the profession of medicine, and to the public for promoting health care quality improvement. The Standards require CME providers to design activities that are independent, free from commercial bias, and based on valid content. Providers must ensure that all decisions related to the content are made free of the control of commercial interests. As with all accredited CME, the ACCME expects that CME that supports the ER/LA Opioid Analgesics REMS will serve the public interest.

What is the ACCME’s role in the ER/LA Opioid Analgesics REMS?

The ACCME views the FDA ER/LA Opioid Analgesic REMS as an important initiative for addressing a critical public health and patient safety concern. The ACCME believes that accredited CME can be an important factor in the success of this REMS and all REMS that involve continuing professional education. The ACCME is committed to facilitating and supporting accredited education to address the prescription drug abuse epidemic and has worked with the FDA, continuing healthcare education accreditors, and accredited continuing education providers throughout the process of developing and implementing the REMS. The ACCME has made itself available to clarify ACCME policy and to assist all the parties involved in implementing a smooth integration of REMS-compliant CME into accredited CME. As an example, the ACCME has modified the Program and Activity Reporting System (PARS) to accommodate REMS-specific information and the ACCME has agreed to provide the audit function described by the FDA.

How is the continuing education community addressing prescription drug abuse?

For more information, visit [CME in Support of REMS](#).

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The CE community addresses prescription drug abuse in many ways. One way is by developing and presenting education that is explicitly part of the RPC-funded ER/LA Opioid Analgesics REMS that meets all the specific REMS requirements. Another way is through the activities offered by accredited CE providers on a wide range of important topics to educate healthcare professionals about prescription drug safety, and drug abuse prevention, intervention, and treatment. As is always the case, accredited providers design activities to address the professional practice gaps and educational needs of their learners. Activities that are not REMS-compliant may or may not receive commercial support and are not funded by the RPC. These activities may be REMS-related accredited CE as they meet some but not all of the requirements established by the FDA in its definition of a REMS-compliant CE activity. (See the definitions of REMS-compliant and REMS-related activities.)

Are there new ACCME requirements related to ER/LA Opioid Analgesics REMS CME activities?

No. The ACCME does not require accredited providers to offer REMS-compliant or REMS-related CE activities. There are no new or special accreditation requirements for accredited providers within the ACCME system that provide REMS activities. The REMS CE reporting requirements are mandated by the Food and Drug Administration (FDA) and the REMS Program Companies (RPC); they are not ACCME requirements.

For those providers doing REMS activities that are commercially supported by the RPC/Campbell Alliance, Ltd there are some extra operational requirements stipulated by the RPC relating to data collection and reporting that will be outlined in the written agreement between the provider and the RPC. The ACCME has prepared a resource that includes information for providers doing REMS activities that are funded by the REMS Program Companies/Campbell Alliance, Ltd (RPC). This resource describes the ACCME's understanding of the shared responsibilities of the RPC, ACCME, and accredited providers. The resource is appended at the end of this fact sheet.

What are the FDA's expectations regarding data collection and auditing for the ER/LA Opioid Analgesics REMS?

The FDA has mandated that the REMS Program Companies (RPC) report to the FDA on the progress of implementing the ER/LA Opioid Analgesic REMS and that there be an independent audit of REMS-compliant accredited CE activities to confirm that the education has met the FDA requirements. The FDA has agreed that accrediting bodies can serve as the independent auditors. ACCME will report data about REMS-compliant CE activities that are commercially supported by the RPC to a third-party data aggregator, which will then forward the aggregated information to the FDA as evidence of the reach and impact of RPC-funded, REMS-compliant education.

How is the ACCME participating in the data collection and auditing process for the ER/LA Opioid Analgesics REMS?

As a service to the CME community and to the FDA, the ACCME has agreed to contribute to fulfilling the data collection and auditing requirements for the ER/LA Opioid Analgesics REMS. The ACCME has modified its [Program and Activity Reporting System \(PARS\)](#) to enable accredited providers to submit information about REMS CME activities and has a process for generating reports containing data about those activities. The

ACCME believes that these modifications will offer accredited CME providers within the ACCME system a streamlined, efficient, and effective process for submitting data about REMS-compliant activities.

The ACCME has also agreed to conduct independent audits of at least 10 percent of RPC-funded, REMS-compliant activities. Each audit will include a review of whether the content of the activity complied with the requirements outlined in the FDA Blueprint, as well as with the ACCME's Standards for Commercial Support.

Is there a fee for accredited providers to participate in the REMS-compliant CME data collection and auditing process?

In order to provide an equitable process for all accredited CME providers within the ACCME system, the ACCME is assessing a per activity fee from accredited CME providers that receive commercial support from the REMS Program Companies (RPC) to develop ER/LA Opioid Analgesic REMS-compliant CE activities; this fee will enable ACCME to develop, implement, and maintain the systems required to support the data collection, reporting, and auditing process stipulated by the FDA. As of January 1, 2015, the per activity service fee is \$500. To fulfill the FDA's expectation that REMS not be a burden to CE providers and prescribers, the ACCME expects that the fees will be incorporated into the RPC commercial support grants to accredited providers. The fees will be paid to the ACCME by the accredited providers.

ACCME-accredited or state-accredited providers that are doing REMS activities that are not commercially-supported by the RPC are not subject to a fee. They may report REMS-specific activity data in PARS, and this data will be included in aggregate reporting that the ACCME completes as a service to the CME community. However, at this time, these activities will not be included in the REMS auditing process.

What are REMS-related accredited CE activities?

REMS-related accredited CE activities meet some but not all of the requirements established by the FDA in its definition of a REMS-compliant CE activity.

Will the ACCME collect data about REMS-compliant CME that is not commercially supported by the RPC and about REMS-related CME?

Yes. ACCME will report this data, in aggregate, to the stakeholder community.

What is the FDA requirement for long-term evaluations of the prescriber training component of the ER/LA Opioid Analgesics REMS?

The FDA has required long-term evaluations of the ER/LA prescribers who complete REMS-compliant CE activities. Specifically, the FDA is requiring the evaluation of knowledge retention and practice change in ER/LA opioid prescribers 6-12 months after completing the REMS-compliant CE activity. The long-term evaluations will be separate and different from any post-tests that might be conducted by accredited CE providers immediately after all REMS-compliant CE activities.

What organizations are responsible to the FDA for fulfilling the requirements for long-term evaluations?

The [REMS Program Companies \(RPC\)](#) are responsible to the FDA for fulfilling the requirements for long-term evaluations. The RPC will provide funding to organizations that will conduct the long-term evaluations in accordance with FDA specifications. See more information below.

What is the role of accredited CME providers in the long-term evaluations?

The FDA has provided the following description of the REMS Long-Term Evaluations in its ER/LA Opioid

Analgesics REMS Supporting Document:

“A subset of CE providers capable of conducting evaluations of long-term performance outcomes of prescribers who completed their REMS-compliant CE courses, or organizations that specialize in CE outcomes will be engaged to conduct such long-term assessments. CE providers or organizations that specialize in CE outcomes will be selected to conduct assessments of prescribers’ knowledge retention and practice change 6 months to 1 year after the CE courses have been completed. The long-term performance outcomes assessments of prescribers will be in addition to the post-tests conducted by CE providers immediately after all REMS-compliant CE courses. Where possible under the Standards of Commercial Support, the survey questionnaire used for the CE providers’ long-term performance outcomes assessments of prescribers who completed REMS-compliant CE courses will be similar to the survey questionnaire used in the REMS surveys of prescribers.

Survey results will be analyzed to understand what the gaps in understanding are and in which prescribers (e.g., those who have taken the training vs. not; specialists vs. primary care providers; high or low prescribers; by geographic region; by age; etc.).”

Is it acceptable for accredited CME providers to conduct the long-term evaluations?

Accredited CME providers that are interested in conducting the long-term evaluations might provide service in support of the ER/LA Opioid Analgesics REMS in the following ways:

1. Providers can conduct the long-term evaluations within their accredited CME programs. In that case, as with any accredited CME activity, providers must comply with all the accreditation requirements including the [ACCME Standards for Commercial SupportSM: Standards to Ensure Independence in CME Activities \(SCS\)](#). The providers must control the evaluations. The providers cannot accept any directions from the RPC. The providers can base the evaluations on the FDA specifications, in the same way that they can base their activities on the [FDA blueprint](#), but the providers cannot accept any guidance from the RPC.
2. Providers can conduct the long-term evaluations outside of the scope of their accredited CME programs. In that case, the ACCME requirements, including the Standards for Commercial Support, would not be relevant.

Does this information apply to other REMS?

No. This information applies only to the ER/LA Opioid Analgesics REMS. The ACCME appreciates that the FDA recognizes the value of accredited education and believes that accredited CME should be considered as a strategic asset to all those trying to improve drug safety. Since 2009, the ACCME has supported the role of accredited CME as a strategic asset to REMS FDA-approved products, provided the proper controls are in place to ensure independence. The ACCME will be ready to respond if the government calls on accredited CE to support implementation of other REMS.

What resources are available about the ER/LA Opioid Analgesics REMS?

- [CME in Support of REMS](#): This ACCME Web Page provides updates and resources for accredited CME providers that choose to design education to fulfill the REMS goals.
- [FDA Risk Evaluation and Mitigation Strategy \(REMS\) for Extended-Release and Long-Acting Opioids](#): This FDA information page includes links to the ER/LA Opioid Analgesic REMS blueprint, Q&A, news release, and other resources.
- [ER/LA Opioid Analgesics REMS](#): This REMS Program Companies Web site includes information for CE providers.

For more information, visit [CME in Support of REMS](#).

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- [MEMS 2.0 Summary](#): This MedBiquitous Web page features links to resources, including the MEMS Implementation Guidelines for the REMS CE Data Exchange.

The ACCME will continue to provide updates to the accredited CE provider and stakeholder community as the process develops for implementing the ER/LA Opioid Analgesic REMS. If you have questions, please contact info@accme.org.

Reporting of Data about ER/LA Opioid REMS Provided by Organizations Accredited within the ACCME Accreditation Systemⁱ

Responsibilities of Parties Involved

Responsibility		Accredited Provider of Record	RPC/Campbell	ACCME
Awarding Grants and Signing Agreements				
1	Communicate to the accredited Provider of Record their obligations regarding reporting of activities in ACCME's PARS system (i.e., scope of data entry; consent to share information; payment of fee; audit) as part of the Written Agreement with Providers.		✓	
2	Accredited Provider of Record attests to understanding and accepting obligations regarding reporting of activities in ACCME's PARS system through the execution of the Written Agreement	✓	✓	
3	Execute a Letter of Agreement that, <ul style="list-style-type: none"> Meets ACCME accreditation requirements and Specifies the accredited Provider of Record obligations regarding reporting of activities in ACCME's PARS system, including a consent to allow the ACCME to send data to third-party aggregator, submitting to audit, and paying REMS Service Fee(s). 	✓	✓	
4	At execution of the Written Agreement, ensure that the accredited Provider of Record is a signatory to the Agreement. ⁱⁱ	✓	✓	
Initiating the PARS Process				
5	Within ten days of executing the Letter of Agreement, assign an RPC "Program ID" to each funded activity and notify the ACCME and the accredited Provider of Record of this ID.		✓	
6	Give Providers of Record access to MEMS-based ACCME PARS data collection system for activities with RPC-assigned Program ID's.			✓
7	Offer Providers of Record resources about use of PARS.			✓
Payment of Fees				
8	Fund the ACCME service fee		✓	
9	Send accredited Providers of Record an invoice for REMS Service Fees, which will be calculated based on the number of RPC-funded, REMS-compliant activities reported to ACCME by the RPC (see 5. above).			✓
10	Submit payment of REMS Service Fee to ACCME.	✓		
Entering Data in PARS				
11	Refer to www.accme.org for activity-type definitions and PARS reporting instructions. Contact ACCME (info@accme.org) with questions that cannot be answered by information at www.accme.org .	✓	✓	
12	"Open" the activity(ies) in PARS ⁱⁱⁱ by completing, at a minimum, the following fields in the activity record: <ol style="list-style-type: none"> Provider Activity ID (This must match the "Program ID" that the RPC has assigned to the activity) Activity Title Activity Date (enter 12/31/2014 if date is not yet known) Activity Type Activity Location (Courses and Regularly Scheduled Series only – enter "to be confirmed" if location is not yet known) 	Within ten days of executing the Letter of Agreement ✓		

For more information, visit [CME in Support of REMS](http://www.accme.org).

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Responsibility		Accredited Provider of Record	RPC/Campbell	ACCME
13	<p>Add data to the PARS activity record for the following fields,:</p> <ul style="list-style-type: none"> a) Number of Physician Participants b) Number of Non-Physician Participants c) Commercial Support Received? (“yes”) d) Number of Commercial Supporters e) Monetary Amount of Commercial Support (Monetary amount of RPC grant) f) Name(s) of Commercial Supporter(s) (RPC/Campbell Alliance) g) Which REMS does the activity address? h) Is the activity REMS-Compliant or REMS-Related? i) Is the activity an RPC-funded activity, and, if yes, does the provider consent to 1. Having ACCME provide activity data to third-party aggregator, 2. Submitting to REMS audit if the activity is selected, and 3. Paying the REMS Service Fee. j) Which sections of the FDA Blueprint did the instruction address? (REMS-related activities only) k) Number of FDA-defined Schedule 2 or 3 Registered Clinicians Successfully Completing this activity. l) Of those in k) above, how many wrote at least one ER/LA opioid prescription in the past year? <ul style="list-style-type: none"> I. Individuals reported in l) above, by profession II. Individuals reported in l) above, by practice type. 	Once the activity is complete or as the information becomes available 		
14	Verify the validity of each activity as an RPC-funded activity through cross referencing with RPC/Campbell documentation.			
15	Provide support via phone and email for questions about activity-type definitions and PARS reporting.			
Audit				
16	Select a sample of no less than 10% of RPC-funded, REMS-compliant CME activities for audit. The audit will include a review for completeness of content, factual accuracy of content, and that evaluation of change of competence and/or performance and/or patient outcomes occurred in each of the six sections of the FDA Blueprint.			
17	Submit materials to demonstrate compliance with ACCME SCS, completeness of content, accuracy of content, and that the assessment covered all six sections of the FDA Blueprint.			
18	Audit selected activities based on materials received from the Provider of Record.			
19	Prepare an Audit Report that will summarize the audit findings, and provide a copy to the Provider of Record, and, with the provider’s permission, to RPC/Campbell.			
Transmission of Data to Third Party Aggregator				
20	Extract data from PARS database for all activities containing an RPC-issued Provider Activity ID. Send this extracted data to Polaris in a format specified by Polaris at a time agreed upon between ACCME and the RPC.			

ⁱ If grants are awarded to providers accredited inside the ACCME system (directly by the ACCME or by an ACCME Recognized State Medical Society), verify that provider is accredited by consulting the “[Find a CME Provider](#)” page at www.accme.org.

ⁱⁱ It is the responsibility of the accredited provider to follow all ACCME requirements in the planning, implementation, and reporting of the funded activities, including having a signed written agreement for commercial support received from RPC/Campbell Alliance, Ltd. An accredited provider can fulfill the expectations of [SCS 3.4 to 3.6](#) by adopting a previously executed [agreement](#) between an accredited provider and a [commercial supporter](#) and indicating in writing their acceptance of the terms and conditions specified and the amount of commercial support they will receive.

ⁱⁱⁱ Organizations accredited by a state medical society that is not yet using PARS for the collection of its accredited providers' activity data may request access to PARS by emailing info@accme.org. Upon receiving such a request, ACCME will add the organization and user records to PARS for the sole purpose of allowing the provider to enter data about their REMS activities. ACCME will inform the accrediting SMS that the account is being established solely for this purpose.