

EXTENSION RFA

- REQUEST FOR (GRANT) APPLICATIONS (RFA)

Overview Information

Organization Issuing RFA	Risk Evaluation and Mitigation Strategy Program Companies (RPC)
RFA Title	Extension Grant: Extended-Release and Long-Acting Opioid Analgesics: Risk Evaluation and Mitigation Strategy (REMS)
RFA Code	ER/LA 070316 Extension
RFA Goal	<p>The goal of this RFA is to extend support for current RPC-funded Providers who can demonstrate prior and anticipated success in providing high-quality REMS-compliant Continuing Education (CE) designed to assist in ensuring that the benefits of extended-release/long-acting (ER/LA) opioid analgesics outweigh the risks (in patients whose clinicians have determined ER/LA opioid analgesics to be an appropriate treatment option).</p> <p>The mechanism by which this is intended to occur is by educating healthcare Providers (HCPs), particularly, as specified by the Food & Drug Administration (FDA) REMS goals, those HCPs who prescribe ER/LA opioid analgesics. The education will be based on the <i>FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics</i> (FDA Blueprint or Blueprint – click here), with the aim to optimize both knowledge acquisition and the translation of that knowledge into practice.</p> <p>Grant applicants should be particularly mindful of the FDA-mandated REMS goal that 192,000 ER/LA opioid analgesic prescribers will have successfully completed REMS-compliant CE by February 28, 2017.</p> <p>Successful proposals will detail plans to :</p> <ul style="list-style-type: none">▪ Utilize, adapt, and where appropriate to address FDA Blueprint revisions, update current educational content with the goals to:<ul style="list-style-type: none">➢ Enable continued delivery of initiatives designed to deliver content to learners using technologies that facilitate ease of access and completion➢ Reach/attract <i>new and/or expanded</i> audiences of ER/LA opioid analgesic prescribers▪ Assist in positively impacting safe and appropriate patient care while meeting all REMS requirements detailed in the next section.

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	<p>Applicants Should:</p> <ul style="list-style-type: none">• Specifically describe prior and anticipated successes of the program for which an extension is being sought in terms of its ability to:<ul style="list-style-type: none">○ Optimize knowledge acquisition and the translation of knowledge into practice○ Deliver content using technologies and/or approaches that facilitate learners’ completion of activity covering full Blueprint and the FDA-requisite assessment covering all six sections of the Blueprint○ Reach/attract new and/or expanded audiences of ER/LA opioid analgesic prescribers○ Positively impact safe and appropriate patient care while meeting all REMS requirements○ Fill a gap considering currently available live and online activities (for example, electronic activities for mobile utilization, engaging print formats, accelerated or rapid delivery of CE).○ Address challenges or obstacles identified in previous ER/LA opioid REMS-compliant activities
<p>RFA Elements Essential to Meet REMS-Compliant CE Requirements</p>	<p>Educational design of proposed CE activities must incorporate all of the requirements for REMS-compliant CE training:</p> <ul style="list-style-type: none">• All activities within each educational program must provide instruction/materials covering all FDA Blueprint elements contained within the six sections of the document.• All activities must include an assessment that covers all six sections of the FDA Blueprint. Preferred consideration will be given to grant applications that integrate the assessment throughout the activity in order to increase the likelihood of learners completing the assessment, an FDA requirement for the learner to be counted toward the REMS goals. <p>(Please note: The related MedBiquitous specification states that “successfully completing” the REMS education means “Completing all components of an educational activity and meeting the education provider’s criteria for passing. Components of an educational activity include instruction, assessment of learning, and potentially evaluation.” For a full list of REMS-related definitions developed by the MedBiquitous Working Group, please see Appendix A.)</p> <ul style="list-style-type: none">• The educational activities are subject to independent audit by the CE Accrediting Bodies.<ul style="list-style-type: none">➤ This audit is intended to occur prior to learners encountering the

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	<p>activity, and as such, Providers conducting CE under RPC-supported grants agree to submit all materials to their Accrediting Body at least 45 days before the activity start date.</p> <ul style="list-style-type: none"> ➤ RPC-supported Providers agree to provide documentation to RPC in which a medical expert, independent of, but chosen by the Provider, attests that the activity meets the REMS-compliant CE requirements. This requirement, intended to assure that all RPC-supported activities are fully REMS-compliant, applies to all activities, regardless of whether or not the activity is selected for audit by an Accrediting Body. • The activities must be conducted in accordance with the standards for accredited CE set by the appropriate Accrediting Body or Bodies (ACCME, AAFP, AANP, AAPA, ACPE, ADA, ANCC and AOA). <p>FDA has set explicit definitions and goals regarding the primary target audience for REMS education and how many learners from this target audience will complete REMS-compliant CE by certain time frames (see Section 1). Since RPC is held responsible by FDA for meeting these goals, the Provider’s proposed approach to engaging the primary target audience to “complete” REMS-compliant CE is a key criterion on which all proposals will be evaluated.</p>
<p>Potential Revisions to the MedBiquitous Definitions</p>	<p>The MedBiquitous Working Group is in the process of considering updates to the Medical Education Metrics (MEMS 2.0) that may impact how CE Providers estimate the number of ER/LA opioid prescriber completers. Any updates will be communicated promptly via the Grant Management System (GMS).</p>
<p>FDA- Requested Demographic Information</p>	<p>As part of the requirements for this REMS, the RPC conducts annual Prescriber Surveys to measure retention of information conveyed as during REMS-compliant CE activities. FDA has recently requested that RPC-supported CE Providers collect demographic information for those individuals who complete REMS-compliant CE activities and meet the definition of an ER/LA opioid prescriber completer. FDA is requesting that CE Providers collect the following demographic information:</p> <ul style="list-style-type: none"> • Medical Degree • Specialty • Years in Practice • Gender

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	<ul style="list-style-type: none"> • Geographic Region • Average Prescribing Volume in the past month • Types of extended-release and long-acting opioid analgesics prescribed within the last six months
Key Dates	<p>RFA Posted: March 7, 2016 Application Due Date: 5:00pm ET May 9, 2016 Award Notification Date: Q3 2016</p>
RFA Document Parameters	<p>Grant applicants should submit applications in MS Word.</p>
Submission Link	<p>Grant applications must be submitted via the Grant Management System (GMS), which will be accepting new grant applications in response to this RFA beginning on March 7, 2016. The GMS may be accessed by way of the RPC website at www.ER-LA-OpioidREMS.com via the right-hand-side link, “Continuing Education Provider Information.” For this specific RFA, the appropriate RFA code is RFA 070316 Extension.</p>
Questions on RFA?	<p>Please contact Polaris Grant Coordinator Marcus Bender: Phone: 1-800-376-9756; Email: grants@er-la-opioidrems.com</p>

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Section 1: Scope of Problem and Background on ER/LA Opioid Analgesics REMS

Scope of the Problem: The Intersection of Dual Public Health Issues

As detailed in the Institute of Medicine (IOM) Report “*Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*,” chronic pain remains a serious public health problem with significant implications for both individuals and society.

As many as 100 million adults in the US report having a common chronic pain condition, exceeding the number affected by heart disease, cancer, and diabetes. Chronic pain contributes substantially to morbidity, mortality, disability and quality of life. In addition to the adverse physical and psychosocial impact of pain on individuals and their families, the economic burden of pain on society and the healthcare system is high. The IOM Report suggests that in the US, the chronic pain-related incremental costs of health care and the cost of lost productivity attributable to chronic pain total up to \$635 billion (in 2010 dollars) annually.¹ These findings were reiterated in The Draft National Pain Strategy released in 2015 by the Department of Health and Human Services (DHHS)-created Interagency Pain Research Coordinating Committee (IPRCC)².

This widespread recognition of the deleterious individual and societal effects of chronic pain has driven increased attention to the need for appropriate diagnosis and management of chronic pain disorders. Therein resides a second important public health/patient safety problem, the misuse and abuse of opioid analgesics. While prescription pain medications such as opioid analgesics offer important treatment options for people with severe pain, these drugs can be misused, abused or diverted to others for illicit use. Each year approximately 4.5 million Americans use prescription pain medications for nonmedical purposes³ contributing to over 16,000 deaths annually.⁴

ER/LA Opioid Analgesics REMS and the REMS Program Companies

The ER/LA Opioid Analgesics REMS is designed to ensure that the benefits of ER/LA opioid analgesics outweigh the risks (in patients whose clinicians have determined ER/LA opioid analgesics to be an appropriate treatment option). The goal of this REMS is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid

¹ <http://www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx>

² <http://iprcc.nih.gov/docs/DraftHHSNationalPainStrategy.pdf>

³ Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality. September 4, 2014. The NSDUH Report: Substance Use and Mental Health Estimates from the 2013 National Survey on Drug Use and Health: Overview of Findings. Rockville, MD. Available at: <https://store.samhsa.gov/shin/content/NSDUH14-0904/NSDUH14-0904.pdf>. Accessed January 8, 2016.

⁴ Centers for Disease Control and Prevention. Injury Prevention & Control: Prescription Drug Overdose Data Overview. Available at: <http://www.cdc.gov/drugoverdose/data/overdose.html>. Accessed January 08, 2016.

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analgesics while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.⁵

The FDA determined that a single shared system was to be implemented for all products within this drug class. As a result, an Industry Working Group (IWG) was formed, which subsequently evolved into the RPC, now comprising those companies⁶ with an approved new drug application and/or approved abbreviated new drug application for an ER/LA opioid analgesic product, and which have marketed those products. For a complete listing of the RPC member companies, see http://ce.er-la-opioidrems.com/lwgCEUI/rems/pdf/List_of_RPC_Companies.pdf. A component of this REMS is the provision of “REMS-compliant training” to educate prescribers of ER/LA opioid analgesics. RPC-supported REMS-compliant training” (education) will be provided through accredited continuing education (CE) activities supported by independent educational grants from the RPC.

The FDA has developed a Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics, which is posted on the FDA website for use by accredited CE Providers to develop the actual CE activities and requisite REMS assessment. In order to be considered REMS-compliant, CE must include all elements of the Blueprint, available at: (http://www.accessdata.fda.gov/drugsatfda_docs/rems/ERLA_opioids_2015-10-23_FDA_Blueprint.pdf)

Desired Outcomes and FDA Expectations of RPC-Supported REMS Education

The desired outcome of ER/LA Opioid Analgesics REMS-compliant CE is to increase understanding of appropriate patient assessment and prescribing practices, as well as other information that can help reduce misuse, abuse, and overdose deaths associated with ER/LA opioids analgesics. Education that is focused on the expected results outlined below should result in healthcare professionals incorporating practices that can assist in maintaining that the benefits of opioid analgesic medications outweigh the risks.

The expected results of the REMS education as described by the FDA in the FDA Blueprint introductory section are that prescribers of ER/LA opioid analgesics will:

- Understand how to assess patients for treatment with ER/LA opioid analgesics
- Be familiar with how to initiate therapy, modify dose, and discontinue use of ER/LA opioid analgesics
- Be knowledgeable about how to manage ongoing therapy with ER/LA opioid analgesics

⁵ Adapted from the FDA Approved ER/LA Opioid Analgesics REMS document (June 2015 version). ER/LA Opioid Analgesics REMS (<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf>)

⁶ As of January 2016

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- Know how to counsel patients and caregivers about the safe use of ER/LA opioid analgesics, including proper storage and disposal
- Be familiar with general and product-specific drug information concerning ER/LA opioid analgesics

While these are the overall FDA REMS expectations, successful proposals should translate these into CE-compliant objectives and outcomes

In order to be REMS-compliant, and therefore eligible for educational grant support from the RPC, the educational activity(ies)/material(s) must address all elements of the FDA Blueprint. (http://www.accessdata.fda.gov/drugsatfda_docs/rems/ERLA_opioids_2015-10-23_FDA_Blueprint.pdf)

The FDA has set goals/time frames for the number of ER/LA opioid analgesic prescribers completing REMS-compliant CE.

The first FDA-mandated CE goal⁷ stipulates that 80,000 ER/LA opioid analgesic prescribers will have successfully completed REMS-compliant CE, as defined in the RFA Overview Information (page 1), by February 28, 2015.

Subsequent goals established by the FDA in the REMS are:

- ***160,000 ER/LA opioid analgesic prescribers will have successfully completed REMS-compliant CE by February 28, 2016.***
- ***192,000 ER/LA opioid analgesic prescribers will have successfully completed REMS-compliant CE by February 28, 2017.***

Key Learnings and Challenges:

Since the inception of REMS-compliant CE activities in early 2013, CE Providers have been accruing information on both REMS CE challenges, as well as key learnings. In the interests of optimizing REMS education for learners and achieving the REMS education goals, CE Providers have worked collaboratively to share this information within the CE Community and with all REMS stakeholders. Highlights of key learnings and challenges are provided below. Additional information can be found in [Appendix B](#).

- ***Providers must understand the MedBiquitous definition*** of “ER/LA Opioid Prescriber Successfully Completing” REMS CE since these are the only learners who may be counted toward FDA goals

⁷ FDA. “Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics,” 2015.

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- **Low REMS awareness, coupled with the time investment required, demands a strategic, innovative approach to attracting ER/LA opioid analgesic prescribers to complete REMS-compliant CE.**
- On average, **40-50% of all “participants” who begin REMS CE will go on to “successfully complete” REMS CE**; about the same percentage of these successful completers have actually written at least one ER/LA opioid prescription in the past year and can therefore “be counted” toward the FDA goals
- **A key participation metric for all REMS-compliant CE is the number of learners who have prescribed an ER/LA opioid in the past year.** This information enables Providers to report how many learners may be counted toward the FDA REMS goals. To increase the likelihood of accurate self-report and allay concerns some learners may have about disclosing information on their prescribing practices, it is helpful for the Provider to explain the rationale for the question and that information will only be reported in a de-identified, aggregate manner.
- **Innovative partnerships** with professional organizations, malpractice insurance companies, health systems, institutional credentialing bodies, etc. may increase awareness of REMS CE, engage learners to participate, and may increase the likelihood that participants will “successfully complete” the full activity
- **Providers have reported that integrating the learning assessment throughout the activity** (vs. administering it at the end of the activity) has been key to optimizing the number of learners “successfully completing” REMS CE.
- **Receiving a “REMS Certificate of Participation”** appears to be valued by learners and may increase the likelihood of learners “successfully completing” the full activity
- **Numerous “opioid-related” (but non-REMS-compliant) CE activities exist which dilute the number of learners completing REMS-compliant CE. This is particularly challenging when the non-REMS-compliant CE fulfills state-mandated licensure requirements or is offered/endorsed by prominent, non-industry related organizations (such as NIDA, ONDCP or SAMHSA).**

Definitions and Clarifications:

As part of the REMS, the FDA characterized prescribers that were the intended audience for the REMS CE. CE-compliant definitions were then developed and finalized by the MedBiquitous Working Group, which included representation from Accreditors, national CE Provider organizations, CE Providers, FDA, RPC, and other REMS CE-related stakeholders. For a full list of definitions developed by the MedBiquitous Working Group, please see [Appendix A](#).

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Key definitions relevant to this RFA include:

- ER/LA opioid prescriber: “An individual clinician who is registered with the DEA (Drug Enforcement Agency) to prescribe Schedule 2 and/or 3 controlled substances and has written at least one ER/LA opioid script in the past year.” (Please see MedBiquitous website for reference: <http://www.medbiq.org/mems/definitions>)
Note: To be counted toward these FDA mandated CE-goals, a learner must meet the MedBiquitous definition of “prescribers successfully completing”⁸ all components of an educational activity.
- “Prescribers successfully completing” a REMS educational activity: “FDA REMS defined ER/LA opioid analgesic prescribers that have completed all components of an educational activity and met the education provider’s criteria for passing. Components of an educational activity include instruction, assessment of learning, and potentially evaluation.” (Please see definition of “prescribers_successfully _completing” at the MedBiquitous website: <http://medbiq.org/mems/definitions>)

The FDA Blueprint and additional information on REMS-compliant CE can be found on the RPC website at www.ER-LA-OpioidREMS.com.

⁸MedBiquitous Medical Education Metrics Definitions <http://medbiq.org/mems/definitions>. Accessed January 2016.

Section 2: Funding Opportunity and Award Information

<p>Anticipated Number of Awards</p>	<p>The number of extension grants awarded in 2016 will be dependent on the number of grant applications received that clearly show success in executing prior activities and identify how new partnerships and/or activities will recruit/engage additional ER/LA opioid prescriber completers. Requests must fully address the REMS requirements, FDA Blueprint and the ability of the CE Provider(s) to engage the target audience to complete a REMS-complaint CE activity.</p>
<p>Award Budget</p>	<p><i>Budgets should be consistent with the <u>realistic</u> total number of ER/LA opioid analgesic prescribers that the Provider estimates will successfully complete a REMS-compliant CE activity. The realistic estimate should be explained in the proposal and should reflect the Provider’s experience to date. Also include the rationale for any changes to the anticipated percentage of learners who will “successfully complete” the full activity/assessment.</i></p> <p>Preference will be given to cost-effective, collaborative, and innovative educational activities that minimize redundancies in development costs and leverage potential synergies.</p> <p>Providers may propose budget models with multiple levels of support, which would enable RPC to award funds for a subset of activities.</p> <p>Note: The RPC will ONLY support budget proposals in full compliance with Transparency Reports and Reporting of Physician Ownership Interests provisions of the Social Security Act 1128G (42 U.S.C. 1320a-7h) (Physician Payment “Sunshine Act” or “Open Payments”).</p> <ul style="list-style-type: none"> • Providers will ensure that no grant funds from the RPC will be used for payments associated with the provision of food, beverages, travel, or lodging for meeting attendees. • Providers should be aware and abide by applicable state-specific reporting requirements.
<p>Award Project Period</p>	<p>Because of the need to report ongoing progress to the FDA, the expectations are that:</p> <ul style="list-style-type: none"> • The initial activity within the proposed extension program must

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	<p>begin within three months of signing the Letter of Agreement (LOA).</p> <ul style="list-style-type: none">• Based on the number of applications received, it is the intent of the RPC to complete the review process and notify selected grantees approximately in the third quarter 2016.
Other Award Information	<p>To optimize the learning opportunities, the RPC intends to fund multiple Accredited Providers and educational partners with different, yet complementary, initiatives. Preference will be given to those Providers that propose high-quality, diverse programs that will enable achievement of the education participation goals and outcomes as described in the FDA-approved ER/LA Opioid REMS.</p> <p>Grant applicants must demonstrate how the proposed education will fully meet or exceed the requirements for REMS compliance. The proposed education must be cost-effective for the scope of the proposal, and satisfy the RFA Criteria outlined in Section 4 (e.g., innovation, number of ER/LA opioid analgesic prescribers expected to complete all components of the REMS-compliant CE, etc.).</p>

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Section 3: Applicant Eligibility Criteria

- ❑ The Requestor must be an Accredited Provider who has received or is currently receiving RPC funding and will serve as the [Provider of Record](#) for the proposed activities.

- ❑ The Requestor must be accredited to provide CE by a national accrediting body (e.g., ACCME, AAFP, AANP, AAPA, ACPE, ADA, ANCC, AOA, or equivalent accrediting body) or by an official state accrediting agency, and must demonstrate that their organization is in good standing at the time of submission.

- ❑ The Requestor must have demonstrated successful execution of RPC-funded REMS-compliant education/activities and articulate why new and innovative efforts to reach and motivate ER/LA opioid prescriber completers will be successful. The adaptation of current programs for mobile utilization or use of a flipped classroom technique would be considered examples of innovation. Effective communication skills, as evidenced by solid partnerships and collaborations, are highly valued.

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Section 4: RFA Submission Information

Grant proposals must include *all of the following components*; Providers should use the below numbered sections in their submission, following the outline below.

	Application Component	Description
1	Provider of Record	Name of Accredited Provider and person(s) responsible for this project, including contact information
2	Partner Organizations	<p>Name of any partner organizations involved with the proposed education, along with respective roles/responsibilities, contact information, and how the partner will assist in recruiting new learners to REMS-compliant CE.</p> <p>Highlight any changes in partnerships (new or eliminated) and provide rationale for why you think these changes will be successful.</p>
3	Overview of Proposed Educational Program	<p>One (1) to two (2) page summary/abstract outlining <i>new</i> strategies or efforts which reflect applicants' experience in implementing REMS-compliant CE related to:</p> <ul style="list-style-type: none"> ▪ overall project goals ▪ target audience: specifically the new target audience(s) or partial completers of prior activities ▪ proposed adaptations to existing educational activities/modalities that fill gaps identified in the needs assessment ▪ method for measuring outcomes ▪ the estimated number of ER/LA Opioid Prescriber Completers and rationale for arriving at this number ▪ cost per ER/LA Opioid Prescriber Completer ▪ amount of grant funds being sought

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	Application Component	Description
4	Faculty Selection Criteria/Team Member Qualifications	<ul style="list-style-type: none"> • Description of methods and criteria used to select proposed faculty and/or individuals involved in the development and implementation of proposed educational initiatives • Do not provide the names of proposed faculty members. Proposals will be rejected if names of faculty are listed. • Description and qualifications of the members of the team responsible for implementing the project
5	Audience(s)	<p>The primary audience for REMS CE, as outlined by the FDA, are clinicians who are registered with the DEA, eligible to prescribe Schedule 2 and/or 3 controlled substances, and have written at least one ER/LA opioid prescription in the past year.</p> <p>Other healthcare professionals involved in the care of patients who require these medications to manage their pain may be encouraged to participate in the educational activities.</p> <p>Within this broadly defined target audience, clearly identify your specific <i>target audience(s)</i>.</p> <ul style="list-style-type: none"> ▪ Why this particular audience? <ul style="list-style-type: none"> ○ If new audience: Include how prior activities have not reached this audience or how you will be more successful in reaching this audience. Explain what methods will be used to motivate audience to “successfully complete” all components of your educational activity (including assessment). ○ If partial completers of prior activities: Include rationale and methods that will be used to motivate to complete full activity, including assessment

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	Application Component	Description
6	Scope/Populations	<p>Specify the scope of your educational program and how this differs from prior program(s) :</p> <ul style="list-style-type: none"> • National • Regional (Multi-City, Multi-State) • State • Health System or Integrated Delivery Networks • Hospital or Medical Center • Other Community Practice Collaborations
7	Needs Assessment	<p>Needs assessment should be concise (1- 2 pages - 12 point font; 1 inch margins, and double spaced), properly referenced and include one or more of the following*:</p> <ol style="list-style-type: none"> (a) Evidence and rationale for choosing new target audiences. (b) Evidence of knowledge, practice, and/or educational modality gaps specific to your target audience in the geographic area(s) where the proposed program will occur. (c) Results from any surveys or assessments you have executed with your specific target audience, where the survey tool was <i>specifically based on the FDA Blueprint</i>. <p><i>*Note: A lengthy overview of general needs related to opioid risk and safety is not necessary as this has been previously established and described in the literature. This needs assessment should be specific to knowledge, audience and educational modality gaps that are addressed by your unique proposal.</i></p>

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	Application Component	Description
8	<p>Description of Educational Program & Design</p> <p>Note: See Section 5 for details on how proposals will be reviewed and evaluated</p>	<p>Detailed description of proposed educational program and its activities, and how it will:</p> <ul style="list-style-type: none"> • Align with <u>all elements of the FDA Blueprint (e.g. “map” the Blueprint sections to the proposed activity)</u> • Meet all REMS-compliant CE requirements (See Overview Information). • Describe adaptations to current or previous RPC- funded program/activities and how the adaptations will meet the goals and close the gaps in knowledge, competence, performance, and/or educational modality gaps for your target audience based on your needs assessment. • Be based on adult learning principles, utilize innovative instructional design principles, and employ best educational practices/methods to engage the intended audience to “successfully complete,” and to optimize both knowledge acquisition and the transfer of that knowledge into clinical practice. • Reinforce the value of including a multidisciplinary team in patient care. <p>Also include</p> <ul style="list-style-type: none"> • An attestation regarding full compliance with all applicable standards of your accrediting body, as well as other relevant standards, guidelines, and requirements as they apply to the conduct of independent medical education. (Include documentation that the Provider of Record is in good standing at the time of application.) • A statement that your organization will cooperate with the independent third parties (independent of RPC) conducting the FDA-required Long-Term REMS Evaluations of RPC-supported CE activities six to twelve months following activity completion.

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9	Validation of Clinical Content	<p>Detailed description of process by which the following will be validated by independent medical expert(s) prior to learners encountering the activity:</p> <ul style="list-style-type: none"> • All elements of the FDA Blueprint are covered in the educational activity/materials to ensure completeness of content • Content of the activity reflects the most current evidence-based information and that the content of the FDA Blueprint is represented accurately <p>Note: Due to internal FDA review timelines, it is possible that new ER/LA opioid analgesic information may be posted to the FDA website before being integrated into the Blueprint. Prior to finalizing activity content and periodically thereafter, it is the Provider’s responsibility to check the FDA REMS website for any new information that may affect the content of the REMS CE.</p> <ul style="list-style-type: none"> • Assessment covers all six sections of the FDA Blueprint (See Component 10 below for additional information.) • Provider has ensured fair balance and controlled for bias <p>Note: Validation of clinical content and confirmation of other independent audit-related requirements apply to all REMS-compliant activities, regardless of whether the activity is actually selected for independent audit by the Accreditor. RPC-supported Providers agree to provide documentation to RPC in which a medical expert, independent of, but chosen by the Provider, attests that the activity meets the REMS-compliant CE requirements described in Overview Information, whether or not the activity is selected for audit by an Accrediting Body.</p>

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	Application Component	Description
10	Outcome Evaluation/Knowledge Assessment	<p>Provide detailed description of how you intend to measure outcomes associated with your educational program, including the <i>valid and reliable measures</i> you intend to employ in your evaluation activities/assessment of learning. Educational impact on healthcare professional’s knowledge, competence, and performance may include attitudes, perceptions, and skills.</p> <p>In addition to educational programs covering all elements of the FDA Blueprint, as per the FDA REMS requirements, the program must:</p> <ul style="list-style-type: none"> • Include an assessment that covers all <i>six sections of the FDA Blueprint</i>. Preferred consideration will be given to grant applications which integrate the assessment throughout the activity in order to increase the likelihood of learners completing the assessment, an FDA requirement for the learner to be counted toward the REMS goals. (<i>To be counted toward the FDA goals, ER/LA opioid prescriber-completers must have “successfully completed” all components of an education activity and met the education Provider’s criteria for passing. See MedBiquitous “FDA ER/LA Opioid REMS defined: successfully_completing”</i>). • Be subject to independent audit by the Accreditors to confirm that conditions of the REMS education have been met.
11	Marketing Plan for the Proposed CE Program	<p>Detail your <i>marketing strategy</i> for how the target audience will be reached, motivated to participate in your program, and be engaged to complete all components of the education activity, including assessment of learning. Include steps you will take if it appears you may fall short of meeting the commitments to educate the estimated number of ER/LA opioid analgesic prescribers that you proposed in your grant application.</p> <p>Note: Refer to Key Learnings and Challenges (Appendix B) when developing your marketing strategy.</p>
12	Budget	<p>Detail budget using the template residing in the REMS Grant Management System portal.</p>

	Application Component	Description
		<p>FDA has required RPC-supported CE to be provided at no cost, or at a nominal cost to the participant (e.g., a small amount to cover costs such as parking). In keeping with the FDA’s requirements, the RPC thus discourages charging a fee for RPC-supported CE. In the event the Provider chooses to include a nominal registration fee, this fee should not exceed \$25 per participant completing CE covering the full FDA Blueprint.</p> <p>RPC will cover the cost of REMS service fees for Accreditors who require reimbursement of costs the Accreditor incurs in conjunction with FDA-mandated independent audits and data aggregation/reporting. There is a specific line on the budget template which indicates how to estimate REMS Service Fees for the activities you propose.</p> <p>Explanation of rationale, efficiencies, and cost-effective approaches to live and/or enduring activities, including an estimated cost per ER/LA opioid prescriber “completer”. <i>Note: rationale should include an explanation of how the proposal’s estimated number of ER/LA opioid prescriber/completers was calculated.</i></p> <p>Statement that:</p> <ol style="list-style-type: none"> 1. The program activities meet the accreditation/certification requirements and standards of the ACCME, AAFP, AANP, AAPA, ACPE, ADA, ANCC, AOA (or equivalent accrediting body) or by an official state accrediting agency. 2. No RPC member company or their agents have selected or provided suggestions for any speaker involved in the program activities. 3. The grant monies provided are for the program activity as a whole and are not meant to be a direct payment to any speaker since ultimate disbursement of the grant monies is within the sole control of the Provider. <p>Proposed cost per ER/LA opioid prescriber completer as defined in Section 1 for entire project should be calculated</p>

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	Application Component	Description
		and provided as part of the budget.
13	Timeline of Project	<p>Detailed project timeline for each phase and milestone. This will serve as the basis for the milestone payments in the grant as described below:</p> <ul style="list-style-type: none"> • Execution of LOA, submission and acceptance of initial activity listing, and notification of RPC-supported activities to Accrediting Organizations : 35% • Start of first activity and upon acceptance of update report, content validation documents and/or audit report(s): 25% • Mid-term of grant timeline and upon acceptance of update report (including progress against the grant metrics that the Provider submitted in the approved proposal): 30% • Completion of last activity and receipt/acceptance of required grant-related documentation (including final metrics for the education activity and budget reconciliation): 10%

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Section 5: Grant Application Review Criteria

Grant applications will be thoroughly and critically reviewed by members of the RPC Grant Review Committee and the RPC Oversight Committee.

Grant applications should include, but are not limited to, activities and audiences that have not been successfully approached in the past. There is interest, by the RPC, in advancing opportunities for REMS education within Integrated Delivery Systems, Accountable Care Organizations, various Health Plans or Third Party Payers, Workers Compensation Organizations, Insurers (if other than listed above), Professional Organizations, organizations which administer state licensure requirements, and Institutional Accrediting bodies. Applicants proposing partnerships with these organizations must provide a copy of communication from the partner, acknowledging their engagement with the applicant and interest in implementing the activities described in the grant request.

The RPC is most interested in activities that may not have been planned and executed in previous rounds of grant approval. Submitters should examine the activities that have already been completed and strive to include new or creative ideas for expanding audiences and various activities. The RPC is very specific and cautionary about the inclusion of all elements of the FDA REMS for ER/LA opioid analgesics.

Grants will be awarded based on Providers' ability to include elements in their proposals that clearly and sufficiently address the following criteria:

Criteria	Description
Compliance	Requestor (Provider of Record) continues to meet eligibility criteria outlined in Section 3 .
Alignment	Includes all elements of the FDA Blueprint (click here for Blueprint) <ul style="list-style-type: none">• presents a detailed mapping of how all elements will be covered in educational activities/programs/materials• explicitly states that each of the six sections of the FDA Blueprint will be covered in the assessment
Number of ER/LA opioid analgesic prescribers fully completing the REMS-compliant CE	Relative to the FDA goals and MedBiquitous definitions described in Section 1 of this document, provision of a realistic estimate of the number of ER/LA opioid analgesic prescribers expected to fully complete CE ("Completers") is required. Your grant application should include a detailed explanation of how the proposal's estimated number of ER/LA opioid prescriber/completers was calculated.

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	<p><i>Consideration should be given to whether or not your audience has been previously engaged by you and/or other RPC-supported CE Providers.</i></p> <p>Fully completing the REMS-compliant CE means that ER/LA opioid analgesic prescribers have minimally:</p> <ul style="list-style-type: none"> • Received information/instruction that covers all elements of the FDA Blueprint • Completed an assessment of learning that covers all six sections of the FDA Blueprint and meets the education Provider’s criteria for passing <p>Note: Refer to <i>Key Learnings and Challenges</i> (Appendix B) when estimating the number of ER/LA opioid analgesic prescribers completing the REMS-compliant CE.</p>
<p>Qualifications of Provider and partners</p>	<p>Employs effective partnerships/coalitions across professional, governmental, and/or community organizations that can achieve broad reach, engagement, and impact. Consider the inclusion of such groups as, Accountable Care Organizations, Integrated Delivery Networks, State Licensing Boards, and Group Health organizations.</p>
<p>Needs assessment ^{9,10,11}</p>	<p>Your needs assessment should be specific to the audience and should determine the goals of the extension activities, ensuring the content of the educational material is relevant and adapted to the needs and clinical practice circumstances of the learners.</p>
<p>Educational design/methods ^{8,10,12,13,14,15,16,17}</p>	<p>You should ensure that the proposed educational design/method fills a gap, considering currently available REMS-compliant live and online activities (for example, electronic activities for mobile</p>

⁹ Bordage, G., B. Carlin, and P. E. Mazmanian. “Continuing Medical Education Effect on Physician Knowledge Effectiveness of Continuing Medical Education: American College of Chest Physicians Evidence-Based Educational Guidelines.” CHEST Journal 135, no. 3_suppl (2009): 29S–36S.

¹⁰ Moore, D. E., J. S. Green, and H. A. Gallis. “Achieving Desired Results and Improved Outcomes: Integrating Planning and Assessment Throughout Learning Activities.” Journal of Continuing Education in the Health Professions 29, no. 1 (2009): 1–15.

¹¹ Jamison R.N., Sheehan K.A., Scanlan E., Matthews M., Ross E.L. “Beliefs and attitudes about opioid prescribing and chronic pain management: Survey of primary care providers” .Journal of Opioid Management. 2014 Nov-Dec;10(6):375-82. .2014.

¹² Bloom, B. S. “Effects of Continuing Medical Education on Improving Physician Clinical Care and Patient Health: a Review of Systematic Reviews.” International Journal of Technology Assessment in Health Care 21, no. 3 (2005): 380–385.

¹³ Chiauuzi, E., K. J. Trudeau, K. Zacharoff, and K. Bond. “Identifying Primary Care Skills and Competencies in Opioid Risk Management.” Journal of Continuing Education in the Health Professions 31, no. 4 (2011): 231–240.

¹⁴ Van Hoof, T. J., and T. P. Meehan. “Integrating Essential Components of Quality Improvement into a New Paradigm for Continuing Education.” Journal of Continuing Education in the Health Professions 31, no. 3 (2011): 207–214.

¹⁵ Institute of Medicine. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. National Academy Press, 2011.

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	<p>utilization, engaging print format).</p> <ul style="list-style-type: none"> • <i>Multi-method, multi-media</i>: Content is delivered using evidence-based methods and multiple <i>formats</i>—including, but not limited to, audio, visual, case discussions, role plays and other features of active learning and problem-based learning approaches—to guide learners in reflection and application of new knowledge to their practice settings. • Activities are innovative and creative in nature, motivating learners to participate and complete all activities. Explain new opportunities and activities planned. <p><i>Multi-exposure (education sessions)</i>: For multi-exposure formats, content is delivered in digestible chunks or modules, over time, in ways that optimize learning.</p>
<p>Knowledge transfer¹⁸</p>	<ul style="list-style-type: none"> • Principles from the field of implementation science are incorporated into overall learning program to address barriers to the application of the knowledge conveyed in the program. • <i>Application of CE-compliant outcomes measures of knowledge, competence, performance, etc.</i>
<p>Interprofessional education^{14,19}</p>	<p>Facilitates interprofessional education and educational activities, particularly for Healthcare Providers practicing in settings in which care is delivered by multidisciplinary teams.</p>
<p>Valid and reliable outcome measures^{14,20,21}</p>	<p>Educators should provide evidence for the validity and reliability of CE evaluation and outcome assessment methods. Preference will be given to proposals that integrate assessments throughout the educational activity (versus waiting until the end of the entire activity),</p>

¹⁶ Légaré F., Freitas A., Thompson-Leduc P., Borduas F., Luconi F., Boucher A., Witteman H.O., Jacques A. “The majority of accredited continuing professional development activities do not target clinical behavior change.” *Academic Med.* 2015 Feb;90(2):197-202[1]

¹⁷ Squires J.E., Sullivan K., Eccles M.P., Worswick J., Grimshaw J.M. “Are multifaceted interventions more effective than single-component interventions in changing health-care professionals' behaviours? An overview of systematic reviews” *Implement Sci.* 2014 Oct 6;9:152.

¹⁸ Ratanawongsa, N., P. A. Thomas, S. S. Marinopoulos, T. Dorman, L. M. Wilson, B. H. Ashar, J. L. Magaziner, R. G. Miller, G. P. Prokopowicz, and R. Qayyum. “The Reported Validity and Reliability of Methods for Evaluating Continuing Medical Education: a Systematic Review.” *Academic Medicine* 83, no. 3 (2008): 274–283.

¹⁹ Sargeant, J., F. Borduas, A. Sales, D. Klein, B. Lynn, and H. Stenerson. “CPD and KT: Models Used and Opportunities for Synergy.” *Journal of Continuing Education in the Health Professions* 31, no. 3 (2011): 167–173.

²⁰ Marinopoulos SS, Dorman T, Ratanawongsa N, Wilson LM, Ashar BH, Magaziner JL, MillerRG, Thomas PA, Prokopowicz GP, Qayyum R, Bass EB. Effectiveness of Continuing Medical Education. Evidence Report/Technology Assessment No. 149 (Prepared by the Johns Hopkins Evidence-based Practice Center, under Contract No. 290-02-0018.) AHRQ Publication No.07-E006. Rockville, MD: Agency for Healthcare Research and Quality. January 2007.

²¹ Price, D. W., E. K. Miller, A. K. Rahm, N. E. Brace, and R. S. Larson. “Assessment of Barriers to Changing Practice as CME Outcomes.” *Journal of Continuing Education in the Health Professions* 30, no. 4 (2010): 237–245.

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	to optimize ER/LA opioid prescriber-completion, since completing the assessment is part of “prescribers successfully completing” the activity, as per the MedBiquitous definitions (see Appendix A).
Budget	Reasonable cost per learner given the proposed educational program (see Section 2)
Marketing plan for CE program	Detailed marketing strategy outlined for how target audience will be reached; including new audiences, activities and methods; how audiences will be motivated to participate in the educational activity, engaged to complete all components of the educational activity, and to meet the education Provider’s criteria for passing. Components of an educational activity include instruction, assessment of learning that covers all six sections of the FDA Blueprint, and potentially evaluation.

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Appendix A: Medical Education Metrics Definitions

Medical Education Metrics (MEMS 2.0) provides a standard XML format for CE outcomes data, including data related to FDA ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy (ER/LA Opioid REMS) education. One key component of evaluating the reach of the ER/LA Opioid REMS is evaluating the number of learners by category. One particularly important category is the number of ER/LA opioid analgesic prescribers successfully completing REMS-compliant education.

MEMS 2.0 uses the following definitions:

FDA ER/LA Opioid REMS defined: ER/LA_opioid_prescriber: An individual clinician who is registered with the DEA to prescribe Schedule 2 and/or 3 controlled substances and has written at least one ER/LA opioid script in the past year.

FDA ER/LA Opioid REMS defined: successfully_completing: Completing all components of an educational activity and meeting the education provider's criteria for passing. Components of an educational activity include instruction, assessment of learning, and potentially evaluation.

FDA ER/LA Opioid REMS defined: prescribers_successfully_completing: FDA REMS defined ER/LA opioid analgesic prescribers that have completed all components of an educational activity and met the education provider's criteria for passing. Components of an educational activity include instruction, assessment of learning, and potentially evaluation.

practice_type: A description of the clinician's practice by broad category (For example, primary care). For a vocabulary of practice types related to the evaluation of pain management, see the Medical Education Metrics Vocabularies (http://medbiq.org/mems/vocabularies#practice_type).

schedule_2_or_3_registered_clinician: An individual clinician who is registered with the DEA to prescribe Schedule 2 and/or 3 controlled substances.

schedule_2_or_3_registered_clinicians_successfully_completing: Schedule 2 or 3 registered clinicians that have completed all components of an educational activity and met the education provider's criteria for passing. Components of an educational activity include instruction, assessment of learning, and potentially evaluation.

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Appendix B: Key Learnings and Challenges as Reported by CE Providers:

While there are currently >75 different REMS approved by the FDA, the ER/LA Opioid Analgesics REMS represents the first use of accredited CE to fulfill a REMS “training” requirement.

Since the inception of REMS-compliant CE activities in early 2013, CE Providers have been accruing information on both REMS CE challenges, as well as key learnings. In the interests of optimizing REMS education for learners and achieving the REMS education goals, CE Providers have worked collaboratively to share this information within the CE Community and with all REMS stakeholders.

A synopsis of key challenges and learnings reported to date by CE Providers follows:

REMS CE Challenges:

- Relatively low “REMS awareness,” as well as ambiguity about “what REMS is” contributes to lack of motivation for HCPs to complete REMS CE
 - While clinicians are well-aware of the patient safety/public health issues related to opioids, the term “REMS” itself is not particularly meaningful to HCPs
 - Since there are many REMS, HCPs do not necessarily equate “REMS” with the ER/LA Opioid Analgesics REMS
- REMS-compliant CE requirements are daunting to busy clinicians:
 - Substantial investment of time. CE Providers have reported that up to 2-3 hours are required in order to cover all information in the Blueprint utilizing current educational design strategies
 - Learners must complete a REMS-compliant assessment in order to count toward the FDA goals (assessment is not a requirement for all CE)
- The prescriptive nature of REMS-compliant CE, as well as the fact that there is presently no way for knowledgeable clinicians to demonstrate evidence of prior learning/competence, reduces learners’ incentive to complete REMS-compliant CE
- Concurrent non-REMS-compliant opioid-related CE targets the same audience as the REMS-compliant programs
- Learners can be reluctant to self-report that they have prescribed ER/LA opioid(s) within past year
- Reduced numbers of clinicians writing ER/LA opioid prescriptions may limit number of HCPs interested in completing REMS CE

Key Learnings from REMS CE Providers:

- Critical that Providers understand the MedBiquitous definition of “ER/LA Opioid Prescriber Successfully Completing” REMS CE since these are the only learners who may be counted toward FDA goals (See [Appendix A](#) for additional information)
- Based on Providers’ experience to date:
 - On average, 40-50% of all “participants” who begin REMS CE will go on to “successfully complete” REMS CE
 - On average, 40-50% of “successful completers” of REMS CE have written at least 1 ER/LA opioid Rx in the past year and can therefore “be counted” toward the FDA goals
- Providers have reported that integrating the learning assessment throughout the activity (vs. administering it at the end of the activity) has been key to optimizing the number of learners “successfully completing” REMS CE. (In one instance, a Provider reported that this approach increased the number of “successful completers” nearly four-fold.)
- Modular approaches require prompt and repeated reminders to encourage/engage learners to “successfully complete” the full activity (i.e. modules and assessment covering all 6 sections of the FDA Blueprint)
- To help allay concerns and increase likelihood of accurate self-reporting, it is important for Providers to explain the rationale for asking learners whether they have prescribed an ER/LA opioid in the past year
- Offering REMS Certificates of Participation appears to be valued by learners and may increase the likelihood of learners “successfully completing” the full activity, including learning assessment
- Innovative partnerships with professional organizations, malpractice insurance companies, health systems, institutional credentialing bodies, etc. increase awareness of REMS CE, engage learners to participate, and may increase the likelihood that participants will “successfully complete” the full activity
- Innovative methods to cover the full Blueprint content in a reasonable amount of time may increase completion of the entire activity (e.g. providing verbal instruction on key

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Blueprint elements in conjunction with providing print/electronic information/reference materials related to specific drugs for review)