

RPC CONTINUING EDUCATION REQUEST FOR APPLICATION

Overview

Sponsoring Organization	Opioid Analgesic Risk Evaluation and Mitigation Strategy Program Companies (RPC)
CE RFA Title	Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS, or the REMS)
CE RFA Code	OA 110121
CE RFA Goal	<p>The goal of the RPC’s Continuing Education (CE) Request for Application (RFA) is to support high-quality REMS-compliant accredited continuing medical education (CME) or CE, as defined by the applicable accrediting organization(s), designed to educate prescribers and other healthcare providers (HCPs), including pharmacists and nurses, on the treatment and monitoring of patients with pain. For a full list of relevant HCP professions, please reference the FDA-Requested Learner Level Data Information section. Through education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with non-pharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies, which is intended to assist HCPs in reducing adverse outcomes of addiction/substance use disorder, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse of opioid analgesics.</p> <p>The mechanism for achieving this goal is by educating HCPs, based on the U.S. Food and Drug Administration (FDA) requirements for the Opioid Analgesic REMS. <i>Such education is to be based solely on the Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain that was approved by the FDA in September 2018 (FDA Blueprint). The education should seek to optimize knowledge acquisition and translate that knowledge into practice.</i></p> <p>Successful grant applications submitted in response to the 2021 CE RFA should detail educational initiatives as outlined in Section 4 of this CE RFA.</p> <p>As part of the 2021 CE Grant Cycle, the Joint Accreditors (Accreditation Council for Continuing Medical Education [ACCME], Accreditation Council for Pharmacy Education [ACPE], and American Nurses Credentialing Center [ANCC]) will convene an Independent Grant Review Committee (GRC). The purpose of the Independent GRC is to provide feedback to the RPC on the quality of grant applications submitted in response to the 2021 CE RFA and to recommend grant applications for funding by the RPC. The Independent GRC will be comprised of individuals who:</p> <ul style="list-style-type: none"> ▪ Have relevant subject matter expertise ▪ Are not affiliated with the grant applicants under consideration ▪ Are not currently on the board or staff of any accreditors
CE RFA Elements Essential to Be REMS-	<p>Educational design of proposed CE activities must incorporate all of the requirements for REMS-compliant accredited CE training:</p> <ul style="list-style-type: none"> ▪ All CE activities must cover all elements of the FDA Blueprint. ▪ Each CE activity must include an assessment that covers all sections of the FDA Blueprint.

<p>Compliant Accredited CE</p>	<ul style="list-style-type: none"> ➤ Grant applications should include plans for increasing the likelihood of individuals completing the entire assessment. ➤ CE providers should collect educational outcomes data as requested by the FDA and developed independently of the RPC. Note that this data is reported annually to the FDA by the RPC. ➤ The RPC encourages grant applicants to outline plans for measuring HCP retention of the FDA Blueprint, as well as translating knowledge into practice. ➤ Grant applicants are encouraged to outline the development of interprofessional education and CE activities, particularly for HCPs practicing in settings with multidisciplinary healthcare teams. <p>Please reference the MedBiquitous specifications for a full list of REMS-related definitions currently under revision by the MedBiquitous Metrics Working Group (Appendix A).</p> <ul style="list-style-type: none"> ▪ For accredited CE providers requesting grant support under this CE RFA, provide a detailed description of the planned educational outcomes for the CE activity, as well as the following information: <ul style="list-style-type: none"> ➤ Moore’s levels of outcomes the CE activity is designed to impact <ul style="list-style-type: none"> — For more information on Moore’s levels of outcomes, please reference Appendix E. ➤ CE format (live, enduring, web) ➤ Date(s) of CE activity ➤ Duration of activity (i.e., time to complete activity) ➤ Average number of CE credit hours for each activity ➤ Education methods and tools for each activity (case-based, multimedia, didactic, interactive, adaptive, etc.) <ul style="list-style-type: none"> — For more information on education methods and tools definitions, please reference Appendix A. ➤ Criteria for successful completion (passing) ➤ Total proposed number of participants and completers taking REMS-compliant accredited CE, as defined by the FDA: <ul style="list-style-type: none"> — Participant (partial completer): An individual who has registered for a CE activity but has only partially completed the CE activity at the time of data reporting — Completer: An individual who has completed all components of an educational activity and meets the education provider’s criteria for passing ▪ The CE activity is subject to independent audit conducted by an accrediting body not involved in the creation, production, or delivery of educational content or the determination of delivery method/platform. <ul style="list-style-type: none"> ➤ This audit ideally occurs prior to individuals encountering the CE activity. Therefore, the RPC-supported CE provider should report the CE activity via the reporting mechanism for the applicable accrediting body as soon as possible so that it can be subject to audit before the scheduled date of release or presentation to individuals. ➤ If the accrediting body selects the CE activity, the CE provider should submit all requested documentation to ensure that all RPC-supported activities are fully REMS-compliant. <ul style="list-style-type: none"> — Documentation in which a medical expert (independent of but chosen by the RPC-supported CE provider) attests that the CE activity meets the REMS-compliant accredited CE requirements should be made available if a CE activity is selected by an accreditor for audit. The CE provider must also submit this
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	<p>content validation documentation as part of Milestone 2 specified in the CE Letter of Agreement (LOA).</p> <p>The CE activity must be conducted in accordance with the standards for accredited CE set by any appropriate specialty accrediting body, including but not limited to the following: ACCME, American Academy of Family Physicians (AAFP), American Association of Nurse Practitioners (AANP), American Academy of Physician Assistants (AAPA), ACPE, American Dental Association (ADA), ANCC, and American Osteopathic Association (AOA).</p>
<p>FDA- Requested Learner Level Data Information (continued on next page)</p>	<p>The FDA has requested that RPC-supported CE providers collect CE learner level data for those individuals who complete REMS-compliant accredited CE activities. Specifically, the FDA requested RPC-supported CE providers to collect the CE learner data listed below.</p> <p>Note: While learner response is optional for some data fields, RPC-supported CE providers are required to request all of the below information from learners as part of the REMS-compliant CE activity.</p> <ol style="list-style-type: none"> 1. Geographic location (learner response optional) <ol style="list-style-type: none"> a. State of primary practice 2. Prescribers (learner response optional) <ul style="list-style-type: none"> ➤ Indicate if you are able (licensed) to prescribe controlled substances (CS) (yes/no) ➤ If so, what type of registration allows you to do so? (individual, institutional, none) 3. Profession <ol style="list-style-type: none"> a. Physician b. Advanced practice nurse (e.g., APRN, CNS, NP, DNP, CRNA, CNMW, other) c. Physician Assistant d. Dentist e. Podiatrist f. Nurse g. Pharmacist h. Optometrist i. Psychologist j. Other health care professional k. Other 4. Practice area (learner response optional) <ol style="list-style-type: none"> a. Which best describes your practice area? <ol style="list-style-type: none"> i. Anesthesiology ii. Critical Care iii. Dentistry iv. Emergency v. Family Medicine vi. Geriatric vii. Hematology viii. Hospice and/or Palliative Care ix. Internal Medicine x. Neurology xi. Obstetrics/Gynecology

	<ul style="list-style-type: none"> xii. Oncology xiii. Ophthalmology xiv. Pain xv. Pediatric xvi. Physical Medicine and Rehabilitation xvii. Psychiatry xviii. Substance Use Disorder xix. Surgery <ul style="list-style-type: none"> 1) General surgery 2) Orthopedic surgery 3) Other surgical specialty xx. Urology xxi. Other xxii. N/A <p>b. Do you perform surgical procedures? (yes/no)</p> <p>5. Length of time learner has been in practice (learner response optional)</p> <ul style="list-style-type: none"> a. Trainee (e.g., student, intern, resident, fellow) b. 0-5 years post training c. 6-10 years d. 11-15 years e. 16-20 years f. 21+ years <p><i>For more information on the technical specifications for CE learner level data, please see the MedBiquitous specifications in Appendix A.</i></p>
Key Dates	<p>CE RFA Posted: January 14, 2021</p> <p>Application Due Date: 11:59pm ET March 11, 2021</p> <p>Award Notification Date: Q3 2021</p>
CE RFA Response Document Parameters	<p>Grant applicants should submit applications in MS Word. Please limit application submission to 50 pages.</p>
Submission Link	<p>Grant applications must be submitted via the Grant Management System (GMS), which will be accepting grant applications in response to this CE RFA beginning on January 14, 2021. The GMS may be accessed on the RPC website via the right side link, "Accredited CE Provider Information." For this CE RFA, the appropriate code is 110121.</p>
Questions on CE RFA?	<p>Please contact the Grant Coordinator at grants@opioidanalgesicrems.com.</p>

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Section 1: Scope of the Problem and Background on the REMS

The Intersection of Dual Public Health Issues

The nation is facing competing public health issues: the need to adequately treat a large number of Americans with acute and chronic pain, and a crisis of prescription opioid abuse. As described in the 2011 report by the National Academies of Science, Engineering, and Medicine (NASEM), *Relieving PAIN in America, A Blueprint for Transforming Prevention, Care, Education, and Research*, 100 million Americans suffer from common chronic pain conditions; fewer than half of Americans undergoing surgery report adequate pain relief; and 60% of Americans visiting the emergency department with acute painful conditions receive analgesics.

It is critical that HCPs are knowledgeable about the risks associated with opioid analgesics as they pertain to their patients as well as from a public health perspective. The data continue to show problems associated with certain prescribing of opioid analgesics.

- In 2016, over 63,632 Americans died from drug poisonings, and of these, approximately 66% or 42,249 deaths involved illicit and/or prescription opioids, likely driven by illicitly manufactured fentanyl.¹
- Based on the 2016 National Survey on Drug Use and Health (NSDUH), an estimated 11.5 million Americans aged 12 or older misused a prescription pain reliever during the previous year — with hydrocodone, oxycodone, and codeine products being the most commonly reported.²
- The most common source of pain relievers reported in the 2016 NSDUH was “a friend or relative” (53%). “A physician’s prescription” was the second most common source, reported by approximately 35% of respondents.³

It is critically important that HCPs have all the information they need to properly treat their patients and safely manage their pain. It is also critical for HCPs to understand when opioid analgesics may be an appropriate treatment and how to implement best practices to ensure their patients’ safety. A 2017 report by NASEM, *Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use*, describes the challenges of providing adequate pain management and calls for the establishment of “comprehensive pain education materials and curricula” for HCPs.⁴

Having broad knowledge about how to manage patients with pain can enable HCPs to consider *all* options for pain management, including non-pharmacologic and non-opioid pharmacologic options, and to reserve opioids for when non-opioid options are inadequate and when the benefits of the opioids are expected to outweigh the risks. This information can also aid HCPs in identifying and intervening when encountering obstacles that may reduce access to non-pharmacological and non-opioid medication options. Fully informed HCPs can help contribute to national efforts to address opioid addiction and reduce opioid misuse and abuse.

¹ Spencer, Merianne Rose, et al. “Drug Overdose Deaths Involving Fentanyl.” *National Vital Statistics Reports*, vol. 68, no.3, 21 Mar. 2019.

² FDA. “FDA’s Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain”. https://www.accessdata.fda.gov/drugsatfda_docs/remis/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf.

³ Id.

⁴ Id.

REMS and the RPC

The Opioid Analgesic REMS is designed to ensure that the benefits of opioid analgesics outweigh the risks (in patients whose clinicians have determined opioid analgesics to be an appropriate treatment option). The goal of the Opioid Analgesic REMS is to educate prescribers and other HCPs, including pharmacists and nurses, on the treatment and monitoring of patients with pain. Through education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with non-pharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies, which is intended to assist HCPs in reducing adverse outcomes of addiction/substance use disorder, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse of opioid analgesics.⁵

The FDA determined that a shared system REMS was to be implemented for all extended-release / long-acting (ER/LA) opioid products within this drug class. On September 27, 2017, the FDA formally notified holders of new drug applications and/or abbreviated new drug applications for immediate-release / short-acting opioid (IR/SA) analgesic products that those products were to be included in the REMS moving forward.

A component of the Opioid Analgesic REMS is the provision of REMS-compliant accredited CE to educate HCPs on the treatment and monitoring of patients with pain. RPC-supported REMS-compliant accredited CE is provided through accredited CE activities supported by independent educational grants from the RPC. For a current listing of the RPC member companies, please reference [Appendix C](#).

In order to be considered REMS-compliant (and eligible for RPC support), CE activities must include all elements of the FDA Blueprint.

Desired Outcomes and FDA Expectations of RPC-supported REMS-compliant Accredited CE

The FDA is seeking analysis of educational outcomes of RPC-supported REMS-compliant accredited CE that evaluates participants' knowledge, attitudes, and behavior relating to pain management, as well as to appropriate opioid prescribing and understanding of key elements from all sections of the FDA Blueprint. Multiple methodologies should be used, including but not limited to pre-and post-activity knowledge assessments, long-term follow-up evaluation of learners to assess retention of knowledge and skills, application of learning to clinical practice, self-reported changes in behavior, and barriers to change.

The expected results of the REMS-compliant accredited CE, as described in the "Purpose of the Opioid Analgesic REMS HCP Educational Effort" section in the FDA Blueprint, are that HCPs of opioid analgesics should be knowledgeable about the following:

- Understanding the fundamental concepts of pain management, including definitions and mechanisms of pain
- Assessing patients with pain and identifying potential risk factors for abuse and addiction
- Utilizing the range of therapeutic options for managing pain, including non-pharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies
- Integrating opioid analgesics into a pain treatment plan individualized to meet the needs of the patient
- Managing patients on opioid analgesics safely and effectively in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics, if appropriate and necessary
- Counseling patients and caregivers on the safe use of opioid analgesics, including proper storage and disposal

⁵ Id.

- Counseling patients and caregivers about the use of naloxone for opioid overdose
- Referring patients to a pain specialist, as appropriate
- Utilizing the fundamental elements of addiction medicine
- Identifying and managing patients with opioid use disorder

In addition, HCPs will gain an understanding of current information about safe opioid practices and current federal and state regulations, national guidelines, and professional organization and medical specialty guidelines on treating pain and prescribing opioids. HCPs will also become familiar with the use of naloxone and the importance of its availability for use by patients and caregivers in the community and home.⁶

In order to be REMS-compliant, and therefore eligible for educational grant support from the RPC, CE activities and material(s) must address all elements of the FDA Blueprint. While this represents FDA's overall expectation for RPC-supported CE activities, successful grant applications should translate such expectation into REMS-compliant accredited CE-compliant objectives and educational outcomes.

Key Learnings and Challenges

Since the inception of REMS-compliant accredited CE activities in early 2013, RPC-supported CE providers have been accruing information on both challenges in providing REMS-compliant accredited CE, as well as key learnings. In the interest of optimizing REMS-compliant accredited CE for individuals and achieving the education goals for the Opioid Analgesic REMS, RPC-supported CE providers have worked collaboratively to share this information within the CE community and with all Opioid Analgesic REMS stakeholders. Highlights of key learnings and challenges can be found in [Appendix B](#).

Definitions and Clarifications

As part of the Opioid Analgesic REMS, the FDA identified HCPs as the intended audience for REMS-compliant accredited CE. REMS-compliant accredited CE learner level data specifications were developed and finalized by the MedBiquitous Metrics Working Group, which includes representation from accreditors, national CE provider organizations, RPC-supported CE providers, the FDA, the RPC, and other Opioid Analgesic REMS CE-related stakeholders. For a current list of learner level data specifications, please reference the [MedBiquitous specifications](#) on Opioid Analgesic REMS-related definitions developed by the MedBiquitous Metrics Working Group, which can be found in [Appendix A](#).

The FDA Blueprint and additional information on REMS-compliant accredited CE can be found on the [FDA's website](#).

⁶ Id.

Section 2: Funding Opportunity and Award Information

<p>Anticipated Number of Awards</p>	<p>The number of grants awarded in 2021 will depend on the number and quality of grant applications submitted. Grants may be awarded for various CE delivery methods/platforms, including adaptive learning / personalized CE learning modalities and/or traditional CE delivery methods. CE activities must fully address the Opioid Analgesic REMS requirements and the FDA Blueprint, as well as outline the grant applicants' ability to engage HCPs.</p>
<p>Grant Budget</p>	<p>Budgets should be consistent with the <u>realistic</u> total number of individuals that the grant applicant estimates will successfully complete REMS-compliant accredited CE activities.</p> <ul style="list-style-type: none"> ▪ Please outline how the proposed number of participants and completers were determined, including any external factors such as the impacts of COVID-19. <p>The RPC CE Subteam is interested in grant applications that are cost effective and collaborative, and that provide innovative CE activities or platforms and minimize redundancies in development costs.</p> <p>Grant applicants may propose budget models with multiple levels of support, allowing the RPC to review and potentially award funds for a subset of CE activities.</p> <p>As part of the application, grant applicants should include a breakdown of the total budget so that funds are appropriated based on the following planned schedule:</p> <ul style="list-style-type: none"> ▪ Milestone 1: 50% of total grant budget ▪ Milestone 2: 20% of total grant budget ▪ Milestone 3: 20% of total grant budget ▪ Milestone 4: 10% of total grant budget <p style="margin-left: 40px;">➤ <i>Note: During submission of the grant application in the GMS, input of this information is not required; however, it should be included in the detailed program information contained in your grant application. The final breakdown of Milestones and associated payments will be determined upon receipt of award notification.</i></p> <p>Once the RPC-supported CE provider has submitted a Milestone Report, Milestone payment will be provided within 30 days following RPC CE Subteam approval. Grant applicants should include timelines that reflect this Milestone payment timeframe.</p> <p>Note:</p> <ul style="list-style-type: none"> ▪ To be eligible to receive an RPC-funded grant, grant applicants must comply with applicable requirements of the Transparency Reports and Reporting of Physician Ownership Interests provisions of the Social Security Act 1128G (42 U.S.C.1320a-7h) (Physician Payments Sunshine Act). ▪ Grant applications may not use grant funds from the RPC for payments associated with the provision of food, beverages, travel, or lodging to meeting participants. ▪ RPC-supported CE providers must only use grant funds from the RPC to provide REMS-compliant accredited CE activities. <p>RPC-supported CE providers are responsible for being aware of and abiding by applicable state-specific payment reporting requirements.</p>

<p>CE Activity Period</p>	<p>Because of the need to report ongoing progress to the FDA, general expectations of RPC-supported CE providers are as outlined below:</p> <ul style="list-style-type: none"> ▪ The initial activity within the proposed training must begin within three months of execution of the CE LOA. ▪ Unless otherwise noted in the application, all activities should begin by October 2021 and be completed no later than October 2022. Please see Appendix D for the 2021 CE Grant Cycle timeline. ▪ The RPC will accept grant applications from accredited CE providers to extend grant support for currently funded activities and/or for new proposed activities, if the content adheres to the FDA Blueprint. <p>The RPC will endeavor to complete the application review process and notify selected grantees during Q3 of 2021.</p>
<p>Other Award Information</p>	<p>To optimize learning opportunities, the RPC intends to fund multiple CE providers and educational partners with different, yet complementary, initiatives. The RPC CE Subteam is interested in funding grant applications that propose high quality, creative activities that will enable achievement of educational outcomes.</p> <p>Grant applicants must demonstrate how the proposed accredited CE will fully meet or exceed the requirements for compliance with the Opioid Analgesic REMS. The proposed activities must be cost-effective for the scope of the application, and include all of the information outlined in Section 4.</p>

Section 3: Grant Applicant Eligibility Criteria

- Must be an accredited CE provider that will serve as the CE provider of record for the proposed activities
- Must be accredited by a national specialty accrediting body to provide CE, including but not limited to ACCME, AAFP, AANP, AAPA, ACPE, ADA, ANCC, and AOA, or an equivalent accrediting body, or by an official state accrediting agency; the grant applicant must be in good standing at the time of submission

Section 4: CE RFA Submission Information

Grant applications **must** include all of the following components listed below:

Application Component		Description
1	CE Provider of Record	Name of accredited CE provider and individual(s) responsible for the grant application, including contact information.
2	Partner Organizations	<p>Name of any confirmed partner organizations to be involved in the proposed education, along with respective roles/responsibilities, contact information, and how the confirmed partner will assist in attracting new individuals to REMS-compliant accredited CE.</p> <p>If there are any partner organizations with which you are planning to collaborate in connection with your CE program, please indicate the following in your grant application:</p> <ul style="list-style-type: none"> ▪ The planned partner organization name(s) ▪ The estimated time to secure the partnership ▪ Contingency plans to secure a subsequent partner if the original partner organization is unable to collaborate with your CE program ▪ How you plan to keep the RPC apprised of any changes to partnerships
3	Overview of Proposed Educational Activities	<p>One to two page summary/abstract describing:</p> <ul style="list-style-type: none"> ▪ Overall project goals and the CE delivery method/platform, including adaptive learning, personalized CE models and/or traditional CE delivery methods ▪ Intended audiences that have been previously educated, as well as additional audiences that are planned as part of this application (see Overview section for specifications on audiences) <ul style="list-style-type: none"> ➤ Prescribers that have an individual registration with the Drug Enforcement Administration (DEA) to prescribe controlled substances (CS) and/or are authorized to prescribe controlled substances under an institutional (hospital/clinic) DEA registration ➤ Other members of the healthcare team without authorization to prescribe ▪ <u>Realistic</u> estimate of the number of all individuals who will participate in the REMS-compliant accredited CE ▪ <u>Realistic</u> estimate of the number of all individuals who will complete the REMS-compliant accredited CE ▪ Cost per individual who will complete the REMS-compliant accredited CE ▪ Grant amount sought ▪ Timeline of planned activities that aligns with the 2021 CE Grant Cycle, including the date of the first planned CE activity (i.e., Milestone 2) and completion of the last CE activity (i.e., Milestone 4); please refer to Appendix D for a detailed timeline
4	Faculty Selection Criteria/Team Member Qualifications	<ul style="list-style-type: none"> ▪ Description of methods and criteria to be used to select proposed faculty and/or individuals involved in the development and implementation of proposed educational initiatives

		<p>➤ <i>Do not provide the names and credentials of proposed faculty members; applications will be rejected if names of faculty are listed</i></p> <ul style="list-style-type: none"> ▪ Description and qualifications of team members responsible for implementing the project
5	Audience(s)	<p>The audiences for REMS-compliant accredited CE, as outlined by the FDA, are those involved with direct patient care, including HCPs registered with the DEA and are eligible to prescribe all opioid analgesics, as well as non-prescribers involved in the care of patients receiving opioid analgesic therapy, non-pharmacologic therapies, and non-opioid medication therapies.</p> <ul style="list-style-type: none"> ▪ Within this broadly defined audience, clearly identify your specific audience(s) ▪ Why this/these particular audience(s)? Include whether prior activities have not reached this audience and/or how you will be more successful in reaching this audience ▪ What expertise do you have motivating audiences to complete relevant components of accredited educational training (including assessment of learning)? <p>Note: See the FDA Blueprint for the types of HCPs that are considered as acceptable target audiences for grant funding.</p>
6	Scope/Populations	<p>Specify the intended reach of your CE activity/offering:</p> <ul style="list-style-type: none"> ▪ National ▪ Regional (multi-city, multi-state) ▪ State (local) ▪ Health system or integrated delivery networks ▪ Hospital or medical Center ▪ Other community practice collaborations <p>The RPC CE Subteam is interested in funding grant applicants that plan to provide REMS-compliant accredited CE in areas most affected by opioid abuse, as outlined by the Centers for Disease Control and Prevention (CDC). The RPC is particularly interested in funding grants that can provide REMS-compliant accredited CE in the following states: West Virginia, Ohio, Pennsylvania, Kentucky, New Hampshire, Delaware, Maryland, and Maine.</p>
7	Needs Assessment	<p>Needs Assessment should be concise (one to two pages - 12-point font; one -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 specific audiences b) Evidence of knowledge, practice, and/or educational modality gaps specific to audiences in the geographic area where the proposed activities will occur c) Results from any surveys or assessments that have been executed with your specific audiences, in which the survey tool was specifically based on the FDA Blueprint <p>Note: A lengthy overview of general needs related to opioid risk and safety is not necessary, as this has been previously established and</p>

		<p>described in published literature. The needs assessment should be specific to the knowledge, audience and educational modality gaps addressed in your application.</p> <p>The RPC CE Subteam is interested in funding grant applicants that can bridge gaps in learner knowledge of key messages in the FDA Blueprint, as well as assess educational outcomes by factoring in a diverse group of individuals and the impact of the REMS-compliant accredited CE.</p> <p>Please outline the assessment process and how data/assessment educational outcomes will be provided to the RPC.</p>
8	<p>Description of Educational Training and Design</p> <p>Note: See Section 5 for details on how applications will be reviewed and evaluated</p>	<p>Detailed description of proposed educational training, and if appropriate, how the activities will:</p> <ul style="list-style-type: none"> ▪ Incorporate adaptive learning / personalized CE and/or traditional CE delivery methods ▪ Align with all elements of the FDA Blueprint ▪ Meet all REMS-compliant accredited CE requirements (See Overview) ▪ Close gaps in knowledge, competence, and performance for audiences based on the needs assessment ▪ Incorporate adult learning principles, utilize innovative instructional design principles, and employ best educational practices/methods to attract individuals and optimize both knowledge acquisition and the transfer of that knowledge into clinical practice ▪ Reinforce the value of including a multidisciplinary team in patient care ▪ Propose how the impact of REMS-compliant accredited CE will be measured by assessing individuals' knowledge and behaviors, preferably, utilizing a pre- and post-activity knowledge assessment, including long-term follow-up <ul style="list-style-type: none"> ➢ The RPC will consider grant applications that provide alternative methods for assessing the impact of REMS-compliant accredited CE. ▪ Outline how the CE activities are planned to be implemented given the impacts of COVID-19 <p>Please include an attestation regarding full compliance with all applicable standards of your accrediting body, as well as other relevant standards, guidelines, and requirements as applicable to the conduct of independent CE/CME (including certification of good standing with the relevant accreditor(s) at the time of application).</p>
9	RPC-supported CE Provider of Record	<p>A detailed description of the relevant process should be included outlining which of the following will be validated prior to individuals encountering the CE activities:</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 aligns with the FDA Blueprint ▪ There is a fair balance and bias control within the content.

		<p>Prior to finalizing content, the RPC-supported CE provider should check the FDA REMS website for any new information that may affect the content of the REMS-compliant accredited CE.</p> <p>Validation of clinical content and confirmation of other independent audit-related requirements apply to all REMS-compliant accredited CE activities, regardless of CE activity selection for independent audit by the relevant accreditor. Accredited CE providers must agree to provide documentation to the RPC in which a medical expert independent of, but chosen by, the accredited CE provider attests that the activity meets the REMS-compliant accredited CE requirements described in the Overview, whether or not the activity is selected for audit by an accrediting body.</p>
10	Educational Outcomes Evaluation/Knowledge Assessment	<p>Provide a detailed description of how you intend to assess the educational success associated with educational activities, including the valid and reliable measures intended for utilization in the evaluation of activities/assessment of learning. Educational impact on HCPs' knowledge, competence, and performance may include attitudes, perceptions, and skills.</p> <p>In addition to educational activities covering all elements of the FDA Blueprint, the activities must:</p> <ul style="list-style-type: none"> ▪ Include an assessment that covers all elements 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 individuals completing the assessment ▪ Be subject to an independent audit by accreditors to confirm that requirements of the REMS-compliant accredited CE have been met
11	Marketing Plan for the Proposed Accredited CE Activities	<p>Detail a marketing strategy for reaching individuals that are motivated to participate and complete all components of the REMS-compliant accredited CE, including an assessment of learning. Please include any specific marketing strategies for reaching individuals given the impacts of COVID-19.</p> <p>Note: Refer to Appendix B when developing the marketing strategy.</p>
12	Budget	<p>Submit a detailed budget using the template found within the GMS.</p> <p>The RPC will cover the cost of REMS service fees for accreditors that require reimbursement of costs incurred in conjunction with FDA-mandated independent audits and data aggregation/reporting. The budget template requests the estimated total REMS service fees for the proposed CE activities. <i>The following REMS service fees are applicable for the 2021 CE Grant Cycle:</i></p> <ul style="list-style-type: none"> ▪ <i>ACCME: \$2,000 per ACCME-accredited activity</i> <p>In the detailed program information section of the grant application, please explain the rationale for the proposed budget, including efficiencies, cost-effective approaches to RPC-supported CE activities, and an estimated cost per completer. <i>The rationale should</i></p>

		<p><i>include an explanation of how the estimated number of completers was determined.</i></p> <p>Include a statement indicating that:</p> <ul style="list-style-type: none"> ▪ The training meets the accreditation/certification requirements and standards of the specialty accrediting bodies (e.g., ACCME, AAFP, AANP, AAPA, ACPE, ADA, ANCC, and AOA). ▪ No RPC member company or representative has selected or provided suggestions for any speaker involved in the activities. ▪ The grant monies provided are for the activities as a whole and are not meant to be a direct payment to any speaker, as ultimate disbursement of grant monies is within the sole control of the RPC-supported CE provider. <p>Proposed <u>cost per completer</u> for the entire project should be calculated and included as part of the budget.</p>
13	Timeline of Project	<p>The detailed project timeline for each phase and Milestone will serve as the basis for the Milestone payments in the awarded grant, as outlined below:</p> <p>Milestone 1: 50% of total grant budget</p> <ul style="list-style-type: none"> ▪ Thirty (30) days after execution of the CE LOA, submission and acceptance of initial activity listing, and provision of listing of RPC-supported activities to accrediting organizations, including entry of all activities into ACCME’s program activity and reporting system <p>Milestone 2: 20% of total grant budget</p> <ul style="list-style-type: none"> ▪ Start of first activity and upon acceptance of update report, content validation document and/or audit report(s) <ul style="list-style-type: none"> ➢ Note that the content validation document must include the CE provider name, grant ID, program title, confirmation that the CE activities fully align with the FDA Blueprint, and attestation that the reviewer is independent of the CE provider. <p>Milestone 3: 20% of total grant budget</p> <ul style="list-style-type: none"> ▪ Mid-term of activity timeline and upon acceptance of update report (including progress towards the grant metrics that the RPC-supported CE provider submitted in the approved application) <p>Milestone 4: 10% of total grant budget</p> <ul style="list-style-type: none"> ▪ Completion of last activity and submission/acceptance of required grant-related documentation (including final metrics for the education activity and budget reconciliation) <p>Grant applicants are expected to understand and agree to adhere to this Milestone payment schedule.</p> <p>The RPC-supported CE provider recognizes that upon submission of an invoice for a Milestone payment, the RPC-supported CE provider may receive a request for additional information from the RPC, either in</p>

		writing, or in the form of a request for a teleconference, prior to RPC approval of the payment.
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Section 5: Grant Application Review Criteria

Grant applications will be thoroughly and critically reviewed by members of the Independent GRC, RPC GRC, and RPC Oversight Committee (OC) to ensure that applications are aligned with the FDA Blueprint and additional criteria noted below.

Grant applications should include a description of CE activities and audiences that have not been successfully reached in the past. The RPC is interested in advancing opportunities for REMS-compliant accredited CE within integrated delivery systems, accountable care organizations (ACOs), various health plans or third-party payers, worker’s compensation organizations, insurers (if not listed above), professional organizations, organizations that administer state licensure requirements, and institutional accrediting bodies.

The RPC is most interested in activities that were not planned and executed in previous CE grant cycles. Grant applicants should examine completed CE activities and strive to include new or creative ideas for expanding audiences and various activities. The RPC reiterates the need for inclusion of all elements of the FDA Blueprint in the grant application.

Awarded grants applicants will include elements in the grant application that clearly and sufficiently address the following criteria:

Criteria	Description
Compliance	The grant applicant (CE provider of record) continues to meet eligibility criteria outlined in Section 3 .
Adaptive Learning or Personalized Education / Traditional CE Delivery Methods	In addition to detailing current CE activities, the grant applicant should incorporate adaptive learning/personalized CE and/or traditional CE learning methods, as applicable.
Alignment	<p>To demonstrate how the CE activity will include all elements of the FDA Blueprint, the grant application should:</p> <ul style="list-style-type: none"> ▪ Present a detailed mapping of how all elements will be covered in educational activities and training materials <ul style="list-style-type: none"> ➢ Grant application submission requires an attestation that all elements of the FDA Blueprint will be addressed as part of the CE activities and training materials, as well as a review of each core message of the FDA Blueprint to confirm alignment. ▪ Explicitly state that each of the sections of the FDA Blueprint will be covered in the assessment
Learner Data	<p>Relative to FDA goals and MedBiquitous specifications /definitions, the grant application should include a <u>realistic</u> estimate of the number of individuals expected to complete the CE activities. See Overview for information on FDA-requested learner level data information.</p> <p>Grant applications should consider whether the intended audience(s) have been previously engaged by your organization and/or other RPC-supported CE providers.</p>

	<p>Completing REMS-compliant accredited CE means that individuals have, at minimum:</p> <ul style="list-style-type: none"> ▪ Received information/instruction that covers all elements of the FDA Blueprint ▪ Completed and passed an assessment of learning that covers all sections of the FDA Blueprint <p>Note: Refer to Key Learnings and Challenges (Appendix B) when determining the number of individuals expected to complete the REMS-compliant accredited CE. The grant applicant should detail how the estimated number of participants and completers was determined.</p> <p><i>Grant applicants must outline in detail how they plan to meet the proposed number of participants and completers by the close of the grant (i.e., Milestone 4). Note that the RPC CE Subteam regularly tracks the reported number of participants and completers at each Milestone Report compared to the expected number of such completers per the grant application.</i></p> <p>The RPC CE Subteam considers past performance of previously awarded RPC-supported CE providers, including the reported number of participants and completers compared to the expected number of participants and completers, when reviewing grant applications.</p>
Qualifications of CE Provider and Partners	<p>Grant applications should identify and describe any relevant novel confirmed partnerships/coalitions across professional, governmental, and/or healthcare organizations that can achieve broad reach, engagement, and impact, and consider the inclusion of groups such as ACOs, integrated delivery networks, state licensing boards, and group health organizations. Additionally, grant applications should include a description of how the educators, collaborators, and other team members are suited for the educational activities outlined in the grant application, including relevant experience and/or training.</p>
Needs Assessment ^{7,8,9}	<p>The needs assessment should be specific to the target audience and determine the goals of the CE activities, ensuring that the content of the educational material is relevant and adapted to the needs and clinical practice circumstances of the individuals participating in the REMS-compliant accredited CE.</p> <p>The overall strategy, methodology, and analyses should consider the specific aims of the education planned to be provided, as well as potential problems, alternatives strategies, and benchmarks for success.</p>

⁷ 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.

⁸ 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.

⁹ 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.

<p>Educational Design / Methods^{10,11,12,13,14,15,16}</p>	<p>Grant applicants should ensure that the proposed educational design/methods fill a void, consider currently available REMS-compliant accredited live and online CE activities (e.g., electronic activities for mobile devices, engaging print format), and/or utilize adaptive learning, simulation-based training, or other personalized education to encourage completion and promote participation in activities.</p> <p>Grant applicants should deliver content using evidence-based methods and multiple formats including, but not limited to, audio, visual, case discussions, role-plays, print materials, and other features of active learning and problem-based learning approaches, to guide individuals in reflection and application of new knowledge to their practice settings.</p> <p>CE activities should be innovative and creative in nature, motivating individuals to participate in and complete activities, including the requisite learning assessment inherent in REMS-compliant accredited CE, as well as utilizing novel concepts, approaches, formats, and methodologies that seek to shift current strategies for educating HCPs.</p> <p>Grant applicants should consider delivering content in digestible “chunks” or modules in ways that optimize learning.</p> <p>The implementation approach should include details about the utilization of support systems, as well as the dissemination approach available to the RPC-supported CE provider.</p>
<p>Knowledge Transfer¹⁷</p>	<p>Grant applicants should consider the incorporation of principles from the field of implementation science into overall learning activities. This incorporation should seek to address barriers to the application of the knowledge conveyed in the activities and improve overall HCP performance. Successful completion of the REMS-compliant accredited CE should lead to changes in the concepts, methods, technologies, treatments, services, and/or preventative interventions that drive meaningful behavior change.</p>

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 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.

¹² Chiauzzi, 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.

¹³ 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.

¹⁴ Institute of Medicine. *Redesigning Continuing Education in the Health Professions*. National Academies Press, 2010.

¹⁵ 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]

¹⁶ 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.

¹⁷ 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.

	Application of REMS-compliant educational outcomes measures should encompass knowledge, competence, and performance.
Interprofessional Education ^{18,19}	Grant applicants should outline the provision of interprofessional education and CE activities particularly for HCPs practicing in settings with multidisciplinary teams.
Valid and Reliable Outcome Measures ^{20,21,22}	Evidence of the validity and reliability of CE evaluation and outcome assessment methods should be provided; particular consideration will be given to grant applications that integrate assessments throughout the educational activity (versus waiting until the end of the entire activity) to optimize HCP completion.
Budget	The total proposed grant budget should include a reasonable cost per completer given the proposed educational activities (see Section 2).
Marketing Plan for CE Activities	Grant applications should include a detailed marketing strategy outlining: outreach to audiences, including new audiences, CE activities, and methods; how audiences will be motivated to participate in the CE activity and engaged to complete all components of the educational activity; and how to meet the CE provider's criteria for completing the accredited CE.

¹⁸ 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.

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 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.

²¹ 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/TechnologyAssessment 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.

²² 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.

Appendix A: Definitions - Medical Education Metrics and Educational Methods

Medical Education Metrics

Medical Education Metrics provides a standard XML format for accredited CE educational outcomes data, including data related to REMS-compliant accredited CE. Please reference the related [MedBiquitous specifications](#) for a full list of REMS-related definitions developed by the MedBiquitous Metrics Working Group.

Note: Users should login or sign up to access the full specifications. Additional resources on activity reporting can be found via: https://medbiq.org/activity_report.

Individual

The participant has an individual registration with the DEA to prescribe controlled substances.

Institutional

The participant is authorized to prescribe controlled substances under an institutional (hospital/clinic) DEA registration.

None

The participant is not authorized to prescribe controlled substances.

RPC-supported CE providers are encouraged to check the MedBiquitous website periodically for updates:

<https://www.medbiq.org/mems/definitions>

Educational Methods and Tools

- Didactic: A teaching method that follows a consistent scientific approach or educational style to engage the student's mind
- Case-based: A first person account of an individualized evaluation, assessment, diagnosis, and treatment is presented, and discussion may or may not conclude the presentation
- Multimedia: Education that may include film, internet, didactic classroom presentation and other modalities, as well as immersive multimedia, which is the learning of digital media tools that requires a student to navigate a virtual environment and engage in multiple tasks while working through a digital simulation
- Interactive: A hands-on, real-world approach to education; interactive learning actively engages students through lectures that are changed into discussions where students and teachers become partners in knowledge acquisition
- Adaptive: Also known as adaptive teaching, an educational method that uses computer algorithms to orchestrate the interaction with the learner and deliver customized resources and learning activities to address the unique needs of each learner; in professional learning contexts, individuals may "test out" of some training to ensure they engage with novel instruction

Appendix B: Key Learnings and Challenges

While there are currently more than 75 different risk evaluation and mitigation strategies approved by the FDA, the Opioid Analgesic REMS represents the **first use of accredited CE** to fulfill a REMS “training” requirement.

Key Learnings

- CE providers have shared that an adaptive learning approach can provide insights into the learner’s capability when taking REMS-compliant accredited CE, as well as concepts that may be more challenging to understand and why.
- Some form of pain/opioid CE is required for at least one discipline in every state, and CE activities based on the FDA Blueprint fully meets the CE requirements in a majority (69%) of states.²³

REMS CE Learner Challenges

- REMS-compliant CE requirements can be daunting to HCPs.
 - Participating in REMS-compliant accredited CE can require a substantial investment of time.
- Relatively low “REMS awareness,” as well as uncertainty about REMS can contribute to lack of motivation for HCPs to complete REMS-compliant accredited CE.
 - While HCPs are aware of the patient safety/public health issues related to opioids, the term “REMS” itself may not be particularly meaningful to HCPs.
 - There is existing available opioid education that competes with REMS-compliant accredited CE.

RPC-supported CE Provider Challenges with REMS-compliant Accredited CE

- The prescriptive nature of REMS-compliant accredited CE, as well as the lack of ability of knowledgeable clinicians to demonstrate evidence of prior learning/competence, may reduce an individual’s incentive to complete REMS-compliant CE.
- Concurrent non-REMS-compliant accredited CE targets the same audience as REMS-compliant accredited CE.
- Reduction in the numbers of HCPs prescribing opioids may limit the number of HCPs interested in completing REMS-compliant accredited CE.
- REMS-compliant accredited CE can include a “greater-than-usual number of registration questions required of REMS activity participants,” which may contribute to the length of the content.
- Competing activities from other agencies (e.g., CDC, state medical societies) may result in confusion by HCPs, which may reduce the number of individuals participating in REMS-compliant accredited CE.

²³ Duensing, Kathryn, Robert Twillman, Stephen Ziegler, M. Soledad Cepeda, David Kern, Maribel Salas, and Gregory Wedin. "An Examination of State and Federal Opioid Analgesic and Continuing Education Policies: 2016-2018." *Journal of Pain Research* (2020).

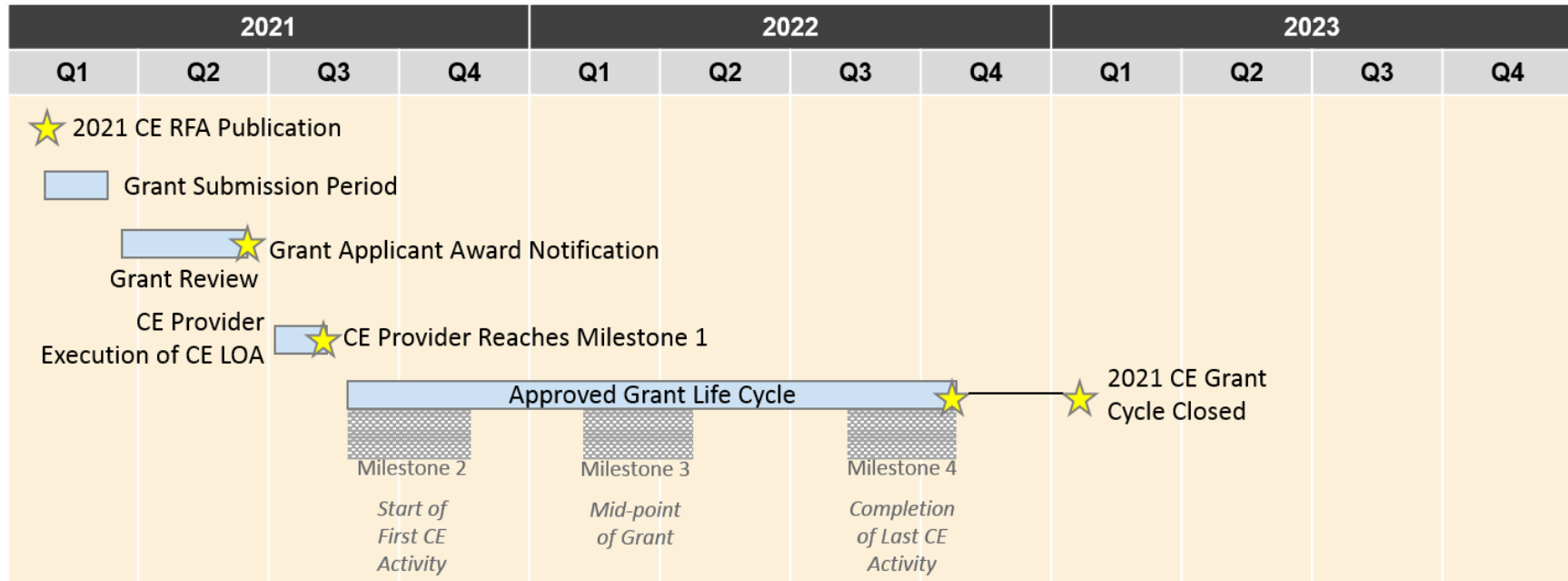
- In some states, there are specific state education requirements, and HCPs are therefore more likely to complete activities that enable them to meet state requirements.
- Limited REMS awareness, coupled with the time investment required, demands a strategic, innovative approach to attracting HCPs to complete REMS-compliant CE.
- Innovative partnerships with professional organizations and institutional credentialing bodies, e.g., may increase awareness of REMS, as well as enhance participation and increase the likelihood that participants will “successfully complete” the REMS-compliant accredited CE.
 - Providing REMS-compliant accredited CE within health systems may create challenges due to existing internal system processes and subsequently lead to lower numbers of participants and completers.
- Some RPC-supported CE providers have noted that acknowledgement of completion and receipt of a certificate may increase the likelihood that individuals will successfully complete the full activity, while others have not seen any impact on overall participation.
- External factors such as COVID-19 may impact participation in REMS-compliant accredited CE, and CE providers with web-based CE activities may be well positioned to continue offering CE activities in a format that is accessible for HCPs.

Note: Please reference the [Frequently Asked Questions \(FAQs\)](#) for more information on responding to the 2021 CE RFA.

Appendix C: Current Listing of the RPC Member Companies

1. Abhai, LLC	35. Megalith Pharmaceuticals Inc.
2. ACI Healthcare Limited	36. Microlabs USA, Inc.
3. Akorn, Inc.	37. Mikart, LLC
4. Allergan Sales, LLC	38. Mylan Inc.
5. Alvogen	39. Neshor Pharmaceuticals USA LLC
6. Amneal Pharmaceuticals, LLC	40. Nexgen Pharma, Inc.
7. ANI Pharmaceuticals, LLC	41. Nostrum Laboratories, Inc.
8. Apotex, Inc.	42. Novitium Pharma LLC
9. Ascent Pharmaceuticals, Inc.	43. Nuvo Pharmaceuticals, Inc.
10. Athena Bioscience, LLC	44. Osmotica Pharmaceutical Corp.
11. Aurolife Pharma LLC	45. Paddock Laboratories, LLC, a subsidiary of Perrigo Company PLC
12. Avanthi, Inc.	46. Persion Pharmaceuticals LLC
13. Biodelivery Sciences International, Inc.	47. Pharmaceutical Associates, Inc.
14. Cipher Pharmaceuticals Inc.	48. Purdue Pharma L.P.
15. Collegium Pharmaceutical, Inc.	49. Rhodes Pharmaceuticals L.P.
16. Daiichi Sankyo, Inc.	50. Rubicon Research Private Limited
17. Elite Laboratories Inc.	51. Sandoz Inc.
18. Endo Pharmaceuticals Inc.	52. Sentynt Therapeutics, Inc.
19. Epic Pharma, LLC	53. Sun Pharmaceutical USA, Inc.
20. Fosun Pharma USA Inc.	54. Teva Pharmaceuticals USA, Inc.
21. Genus Lifesciences Inc.	55. ThePharmaNetwork, LLC
22. Hikma Pharmaceuticals USA Inc.	56. Tris Pharma, Inc.
23. Ingenus Pharmaceuticals NJ, LLC	57. Unichem Laboratories Limited
24. Ipca Laboratories Limited	58. Upsher-Smith Laboratories, LLC
25. Janssen Pharmaceuticals Inc.	59. Validus Pharmaceuticals LLC
26. Jerome Stevens Pharmaceuticals, Inc.	60. Virtus Pharmaceuticals, LLC
27. Kindeva Drug Delivery L.P.	61. VistaPharm, Inc.
28. KVK-Tech, Inc.	62. WES Pharma Inc
29. Lannett Company, Inc.	63. Wockhardt Bio AG
30. Larken Laboratories, Inc.	64. Wraser Pharmaceuticals, LLC
31. Lupin Pharmaceuticals Inc. / Novel Laboratories, Inc.	65. Xiromed / Chemo Research S.L.
32. Macleods Pharmaceuticals Limited	66. Zydus Pharmaceuticals (USA) Inc.
33. Mallinckrodt LLC	67. Zyla Life Sciences
34. Mayne Pharma Inc.	

Appendix D: Sample Timeline for 2021 CE Grant Cycle



2021 CE Grant Cycle Activities	Tentative Dates for Grant Applicants
CE RFA Publication	January 2021
Application Submission Period Closed	March 2021 (<i>see Overview for specific date</i>)
Grant Review Process*	March 2021 – July 2021
Grantee Award Notification	July 2021
Grantee Reaches Milestone 1	August 2021
Grantee Reaches Milestone 2	August 2021 – November 2021
Grantee Reaches Milestone 3	February 2022 – May 2022
Grantee Reaches Milestone 4	October 2022
Grant Closed	January 2023

*Grant Review Process time includes review of grant applications by the Independent GRC and the RPC GRC.

Note: The timeline presented is an example of a CE grant cycle to help grant applicants prepare their grant applications.

Appendix E: Moore's Levels of Outcomes

The impact of a REMS-compliant accredited CE activity can be measured using [Moore's Levels of Outcomes](#). Please consider the seven levels outlined below when determining educational outcomes measures in the grant application:



FAQs

Milestones

- Following submission of a Milestone Report, when can I expect to receive payment?
 - Each RPC-supported CE provider executes a CE LOA that outlines Milestone payment-related details. There are four Milestones in a grant's life cycle, and each Milestone includes specific requirements. Once the RPC-supported CE provider completes a Milestone, a Milestone Report, relevant documentation, and an associated invoice are submitted through the GMS for RPC CE Subteam review. Following RPC CE Subteam review and approval, it can take up to 30 days for the RPC-supported CE provider to receive the Milestone payment.
- How are the Milestone dates calculated?
 - Milestone 1 is reached upon completion of these activities:
 - CE LOA is fully executed.
 - Accrediting organization(s) are notified of RPC-reported activities.
 - ***While the RPC CE Subteam provides RPC-supported CE providers with the Milestone 1 date, the RPC-supported CE provider should consider the timing of the Milestone 1 payment when planning REMS-compliant accredited CE activities as well as the timing of subsequent Milestone dates.***
 - Milestone 2 occurs upon the start of the first CE activity and RPC CE Subteam acceptance of the Milestone 2 report, content validation documents, and/or audit report(s). To provide the most accurate projected Milestone 2/CE activity start date, please consider a realistic project timeline, taking into account availability of funds and project resources.
 - Milestone 3 is the midpoint of the grant and can be calculated by finding the midpoint between the projected Milestone 1 and Milestone 4 dates.
 - Milestone 4 is the completion of the last REMS-compliant accredited CE activity and RPC receipt/acceptance of required grant-related documentation. Please note that closure of the grant occurs following approval of Milestone 4 and the subsequent associated payment.
- Can you provide a high-level timeline of expected Milestone dates?
 - Please see [Appendix D](#) for an overview of the Milestone dates for the 2021 CE Grant Cycle.
- What if my activity is not tracking to the number of proposed completers outlined in the grant application?
 - Grant applicants should provide a clear plan for reaching the number of proposed completers outlined in the grant application, including a contingency plan(s). Therefore, if the CE activity is not tracking to the number of proposed completers outlined in the grant application, the RPC-supported CE provider should implement the contingency plan(s) outlined in the grant application in order to reach the number of proposed completers by closure of the grant (i.e., Milestone 4).

CE Activity Search Page

- Does the RPC provide a list of REMS-compliant accredited CE activities offered by previously awarded and current RPC-supported CE providers?
 - The [CE Activity Search Page](#) includes currently ongoing enduring and live REMS-compliant accredited CE activities for RPC-supported CE providers. The goal of the CE Activity Search Page is to provide HCPs with access to available REMS-compliant accredited CE activities supported by the RPC.
- Can you provide more information about the requirements of the program title?
 - RPC-supported CE providers are encouraged to create a unique, specific program title. Please note that the CE activity displays on the [CE Activity Search Page](#) and provides individuals with an understanding of the program offerings. The program title submitted in the CE RFA should align with the program title in the CE LOA and other grant-related documentation.

REMS requirements

- What does the “FDA Blueprint” cover, as noted throughout the CE RFA?
 - Per the FDA requirements for the Opioid Analgesic REMS, REMS-compliant accredited CE should be based solely on the [FDA’s Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain](#) approved in September 2018. The goal of the education is to optimize knowledge acquisition and translate that knowledge into practice. Please review the [RFA Elements Essential to Meeting REMS-Compliant Accredited CE Requirements](#) in the [Overview](#) section, which outlines expectations of REMS-compliant accredited CE per the FDA Blueprint.
 - **Note:** While the RPC does not anticipate changes in the FDA Blueprint, the RPC-supported CE provider should check the FDA REMS website for any new information that may affect the content of REMS-compliant accredited CE prior to finalizing CE activity content.

CE RFA submission

- Can I receive an extension for submitting an application if it is not complete by the specified deadline?
 - No. The application due date is 11:59pm ET on March 11, 2021. To avoid any technical delays, grant applicants should submit their grant application prior to the deadline, as the submission portal closes at 11:59pm ET on March 11, 2021.
- How can supporting materials be submitted with the grant application?
 - Grant applicants are able to submit supporting materials to accompany their grant application via the GMS as part of the detailed program information. Please limit the detailed program information to no more than 50 pages.
- I have additional questions regarding submission via the GMS. Whom should I contact?
 - Please first review [FAQs](#) related to the GMS. If you have additional questions regarding the submission of your application in the GMS, you may contact the Grant Coordinator at grants@opioidanalgesicrems.com.