RPC CONTINUING EDUCATION GRANT REQUEST FOR APPLICATION

Overview

Sponsoring Organizations	Opioid Analgesic (OA) Risk Evaluation and Mitigation Strategy (REMS) Program Companies (RPC)
CE RFA Title	Opioid Analgesic Risk Evaluation and Mitigation Strategy (Opioid Analgesic REMS, or the REMS)
CE RFA Code	OA 120125
CE RFA Goal	The goal of the RPC's Continuing Education Request for Application (CE RFA) is to support high-quality REMS-compliant accredited continuing medical education (CME) or continuing education (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 of this Overview. Through education, the healthcare team will have an improved understanding of how to manage pain, along with the role of opioid analgesics and the use of 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 and nonmedical use of opioid analgesics. 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. ***Such education is to be based solely on the updated FDA's*** Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ***dated October 2023 (FDA Blueprint). The education should seek to optimize knowledge acquisition and translate that knowledge into practice. Please note the FDA Blueprint includes information on safe disposal options of unused opioid analgesics and removal of stigmatizing language.*** Grant applications submitted in response to the 2025 CE RFA should detail educational initiatives as outlined in Section 4 of this CE RFA. As part of the 2025 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 (IGRC). The purpose of the IGRC is to provide feedback to the RPC on the quality of grant applications submitted in response to the 2025 CE RFA and to recommend grant applications for funding by the RPC. The IGRC will be comprised of individuals who: ▪ Have relevant subject matter expertise ▪ Are not affiliated with the grant applicants under consideration ▪ Have no affiliation to the RPC or any of the REMS Program Agreement (RPA) Participants ▪ Are not currently on the board or staff of any accreditors
CE RFA Elements Essential to Be REMS-	For a proposed CE activity to be eligible for CE credit awarded by the accrediting body, the educational design of proposed CE activities must incorporate all of the requirements for REMS-compliant accredited CE training:

	▪ All CE activities must cover all elements of the FDA Blueprint.
Compliant Accredited CE	▪ Each CE activity must include an assessment that covers all sections of the FDA Blueprint. ➢ Grant applications should include strategies 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 these data are reported annually to FDA by the RPC.*** ➢ The RPC encourages grant applicants to outline plans for measuring HCP retention of the FDA Blueprint elements, as well as translating knowledge into practice. ➢ Grant applicants are encouraged to outline the development of interprofessional education and CE activities (i.e., representatives of targeted learner groups, case examples of pain problems addressed by an interdisciplinary team, interdisciplinary competencies described in the literature), particularly for HCPs practicing in settings with multidisciplinary healthcare teams. *Please reference the* MedBiquitous specifications *for a full list of REMS-related definitions currently under revision by the MedBiquitous Metrics Working Group* (Appendix A). ▪ 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: ➢ Moore's levels of outcomes the CE activity is designed to impact — For more information on Moore's levels of outcomes, please reference Appendix E. ➢ CE format (live or enduring) ➢ 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.) — For more information on education methods and tools definitions, please reference Appendix A. ➢ Criteria for successful completion (passing) ➢ Total proposed number of completers taking REMS-compliant accredited CE, as defined by the FDA: — 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. Accrediting bodies involved in any way with the development and / or implementation of any educational programming should refrain from auditing such programs ➢ 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 for audit, the CE provider should submit all requested documentation to ensure that all RPC-supported activities are fully REMS-compliant. – 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 content validation documentation as part of Milestone 2 specified in the CE Letter of Agreement (LOA) executed by all RPC-funded grant recipients. 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).
FDA-Requested Learner Level Data Information (*continued on next page*)	FDA has requested that RPC-supported CE providers collect CE learner level data for those individuals who complete REMS-compliant accredited CE activities. Specifically, FDA has asked that RPC-supported CE providers collect the CE learner data listed below. **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. 1. Geographic location (learner response optional) a. State of primary practice 2. Prescribers (learner response optional) ➢ 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 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) a. Which best describes your practice area? 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 xii. Oncology xiii. Ophthalmology xiv. Pain xv. Pediatric xvi. Physical Medicine and Rehabilitation xvii. Psychiatry xviii. Substance Use Disorder xix. Surgery 1) General Surgery 2) Orthopedic Surgery 3) Other Surgical Specialty xx. Urology xxi. Other (e.g., pharmacy, radiology, dermatology, cardiology, ambulatory care) xxii. N/A b. Do you perform surgical procedures? (yes/no) 5. Length of time learner has been in practice (learner response optional) 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 *For more information on the technical specifications for CE learner level data, please see the* MedBiquitous specifications in Appendix A.
Key Dates	CE RFA Posted: January 9, 2025 Application Due Date: 11:59pm ET March 6, 2025 Award Notification Date: Q3 2025
CE RFA Response Document Parameters	Grant applicants should submit applications in MS Word. Please limit application submission to fifty (50) pages.
Submission Link	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 9, 2025. 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 120125.
Questions on CE RFA?	Please contact the Grant Coordinator at RPC_CE@rems-pmo.com.

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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 overdoses, many still involving prescription opioid analgesics, often in combination with other substances. An analysis of 2019-2021 National Health Interview Survey (NHIS) data found that in 2021, an estimated 20.9% or 51.6 million adults in the United States experienced chronic pain, and 6.9% or 17.1 million adults in the United States experienced chronic pain that resulted in substantial restrictions to daily activities. By 2022, approximately 54.6 million Americans needed substance use disorder treatment, but only 13.1 million people received it.[1,2]

It is critical that HCPs are knowledgeable about the risks associated with opioid analgesics as data continue to show problems associated with these medications.

- In 2022, 107,941 drug overdose deaths occurred in the United States; of these, approximately 76% involved an opioid; 73,838 or 68% of opioid-involved overdose deaths involved synthetic opioids.[3]
- Based on the 2021 National Survey on Drug Use and Health (NSDUH), 1.8 million people aged 12 or older initiated prescription pain reliever nonmedical use in the past year; 8.7 million people aged 12 or older misused prescription pain relievers in the past year.[4]
- Provisional data from the Centers for Disease Control and Prevention (CDC) indicate that the number of overdose deaths rose to 107,622 in the 12-month period ending in December 2021. The 2021 increase was half of what it was a year ago, when overdose deaths rose 30% from 2019 to 2020.[5]
- In 2021, an average of 45 people died each day from overdoses involving prescription opioids, totaling more than 17,000 deaths, but in 2022, that number decreased to just over 14,000. While prescription opioids were involved in nearly 21% of all opioid overdose deaths in 2021, a 12% decrease in death rates was noted from 2021-2022.[6]

It is critically important that HCPs have all the information they need to properly treat and safely manage their patients' 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 the National Academies of Science, Engineering, and Medicine (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 establishing "comprehensive pain education materials and curricula" for HCPs. [7]

The goal of the Opioid Analgesic REMS is to mitigate the risks of addiction, abuse and misuse which can lead to overdose and death. The Opioid Analgesic REMS is one of many national, state, and local efforts to address the risks of prescription opioid analgesics.

FDA approved labeling for OA products define misuse, abuse, and addiction in the following ways:

- Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed.
- Abuse is the intentional non-therapeutic use of a prescription drug, even once, for its rewarding psychological or physiological effects.
- Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful

consequences, giving a higher priority to drug use than to other activities and obligations), and possible tolerance or physical dependence.

As of 2024, the FDA adopted the term ‘‘**nonmedical use**’’ to refer to use of a medication in a way other than as directed by a health care provider, including both misuse and abuse, as defined above. FDA is also encouraging use of the medical terms “substance use disorder” and “opioid use disorder” rather than “addiction.”

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 also help contribute to national efforts to reduce nonmedical use of opioids and address the ongoing public health crisis involving opioid use disorder and overdoses.

[1] CDC. “ Chronic Pain Among Adults — United States, 2019–2021”. https://www.cdc.gov/mmwr/volumes/72/wr/mm7215a1.htm?s_cid=mm7215a1 w
[2] CDC. “Drug Overdose Deaths https://www.cdc.gov/overdose-prevention/prevention/
[3] Id
[4] NSDUH. “Key Substance Use and Mental Health Indicators in the United States: Results from the 2021 National Survey on Drug Use and Health”. https://www.samhsa.gov/data/sites/default/files/reports/rpt39443/2021NSDUHFFRRev010323.pdf.
[5] CDC. “U.S. Overdose Deaths In 2021 Increased Half as Much as in 2020 – But Are Still Up 15%.” https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm
[6] CDC. “Opioid Overdose”. https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates#Fig4
[7] FDA. “FDA’s Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain’”. https://www.fda.gov/OA_REMS_FDA_Blueprint

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 opioid use disorder, unintentional or intentional overdose, and death resulting from inappropriate prescribing and nonmedical use of opioid analgesics.[8]

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 (NDAs) and/or abbreviated new drug applications (ANDAs) for immediate-release/short-acting opioid (IR/SA) analgesic products that those products were to be included in the REMS moving forward. On April 3, 2023, the FDA formally notified all manufacturers of opioid analgesics used in outpatient settings that they are required to submit a proposed modification to the Opioid Analgesic to include a safe disposal option. At the time of this RFA publication, the modification has not yet been approved by FDA or implemented.

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 completer 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:

- The fundamental concepts of pain management, including definitions and mechanisms of pain
- How to assess patients in pain and identify risk factors for substance use disorders
- The range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies
- How to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient and evaluate for functional improvement
- How to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics
- How to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal
- How to counsel patients and caregivers about the use of naloxone for opioid overdose
- When referral to a pain specialist is appropriate
- The fundamental elements of addiction medicine
- How to identify and manage patients with opioid use disorder (OUD)

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 the home. [9]

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, 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.

[8]FDA. "Online Opioid Summits." https://www.fda.gov/drugs/news-events-human-drugs/online-opioid-summits.
[9] Id

Section 2: Funding Opportunity and Award Information

Anticipated Number of Awards	The number of grants awarded in 2025 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.
Grant Budget	Budgets should be consistent with the realistic total number of individuals that the grant applicant estimates will successfully complete REMS-compliant accredited CE activities. ▪ Please outline how the proposed expected number of completers were determined, including any external factors (e.g., increases in reported overdose deaths, increases in substance use disorder) and resultant changes in healthcare delivery. The RPC 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. Multiple grant applications from the same accredited CE provider will only be reviewed by the RPC Grant Review Committee (GRC) if the accredited education projects differ. Grant applicants are encouraged to propose budget models with multiple levels of support, allowing the RPC to review and potentially award funds for a subset of CE activities. CE providers submitting budget models exceeding $1,000,000 are required to include justification (i.e., how the activities conducted under the grant will target under-represented geographic regions / populations) and alternative budget options. Special purpose applications that target under-represented populations or geographic regions, and/or place special emphasis on education that address disparities in pain management, opioid prescribing, and substance use disorder with respect to patient demographic groups (e.g., race / ethnicity, age) are encouraged to be submitted and will be considered. 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: ▪ Milestone 1: 35% of total grant budget ▪ Milestone 2: 20% of total grant budget ▪ Milestone 3: 20% of total grant budget ▪ Milestone 4: 25% of total grant budget ➢ 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*. Once the RPC-supported CE provider has submitted a milestone report, milestone payment will be provided within seventy-five (75) days following RPC CE Subteam approval. Grant applicants should include timelines that reflect this milestone payment timeframe. **Note:** ▪ 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. ▪ RPC-supported CE providers are responsible for being aware of and abiding by applicable state-specific payment reporting requirements.
CE Activity Period	Because of the need to report ongoing progress to the FDA, general expectations of RPC-supported CE providers are as outlined below: ▪ The initial activity within the proposed training must begin within three (3) months of execution of the CE LOA. ▪ Unless otherwise noted in the application, all activities should begin by October 2025 and be completed no later than October 2026. Please see Appendix D for the 2025 CE Grant Cycle timeline. Please note that any changes in the timeline will be communicated to the CE Providers that are awarded under the 2025 CE Grant Cycle. ▪ 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. The RPC will endeavor to complete the application review process and notify selected grantees during Q3 of 2025.
Other Award Information	To optimize learning opportunities, the RPC intends to fund multiple CE providers and educational partners with different, yet complementary, initiatives. The RPC is interested in funding grant applications that propose high quality, creative activities that will enable achievement of educational outcomes. The IGRC, as subject matter experts, will provide initial review of applications and recommend those applications that demonstrate these characteristics for further review. 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 below.

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 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 application 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	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. 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: ▪ The planned partner organization name(s) ▪ How partners contribute to the CE program (i.e., partner role in grant development/implementation) ▪ The estimated time needed 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 ▪ Any qualifications / accreditation required to conduct education programs
3	Overview of Proposed Educational Activities	One to two-page summary/abstract describing: ▪ 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 to be targeted as part of this application (see Overview section for specifications on audiences) ➢ 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 ▪ Realistic estimate of the expected number of individuals who will participate in the REMS-compliant (i.e., fully FDA Blueprint-compliant) accredited CE ▪ Realistic estimate of the expected number of individuals who will complete the REMS-compliant (i.e., fully FDA Blueprint-compliant) accredited CE ▪ Cost per individual who completes the REMS-compliant (i.e., fully FDA Blueprint-compliant) accredited CE ▪ Total grant funding requested ▪ Specifics around development, use, and implementation of

		supplemental materials (e.g., relation to completer goals and coverage of the FDA Blueprint) ➢ **Note**: Any supplemental materials / reinforcement activities that do not cover the full FDA Blueprint may be described in the grant application, however, these materials / activities should not be listed with REMS-compliant activities. ▪ Timeline of planned activities that aligns with the 2025 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	▪ 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 ➢ ***Do not provide the names and credentials of proposed faculty members; applications will be rejected if names of faculty are listed*** ▪ Description and qualifications of team members responsible for implementing the project (i.e., disciplines or specific areas of expertise that will assist in developing the curriculum) ▪ Description of how faculty / team member(s) will contribute to the development, implementation and execution of the education ▪ The RPC is interested in programs involving pain management and substance abuse disorder specialists as expert faculty. Additionally, the RPC is interested in how the proposal emphasizes interprofessional education and the perspectives of patients and caregivers.
5	Audience(s)	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 who 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. ▪ 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)? Provide your plan for motivating audiences to complete all relevant components of the accredited educational training (including assessment of learning) **Note:** See the FDA Blueprint for the types of HCPs that are considered as acceptable target audiences for grant funding.

6	Scope/Populations	Specify the intended reach of your CE activity/offering: ▪ National ▪ Regional (multi-city, multi-state) ▪ State (local) ▪ Health system or integrated delivery networks ▪ Hospital or medical center ▪ Other community practice collaborations The RPC is interested in funding grant applicants that plan to provide REMS-compliant accredited CE in areas most affected by opioid use disorder, as outlined by the CDC. The RPC is particularly interested in funding grants that can provide REMS-compliant accredited CE in one or more of the following: ▪ States most affected by opioid use disorder, as outlined by the CDC ▪ Under-resourced states or regions/territories such as the District of Columbia, rural America, and Native American reservations / tribal lands. ▪ Under-resourced populations such as those affected by domestic violence and human trafficking
7	Needs Assessment	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 as evidence and rationale for choosing specific audiences: a) Evidence of knowledge, practice, and/or educational modality gaps specific to audiences in the geographic area where the proposed activities will occur b) 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 The needs assessment should provide rationale for targeted learners specifically related to the gaps among intended learner attitudes, what targeted learners may know, what targeted learners may be able to do, and standards that could improve intended learner performance. Based on the gaps identified in the needs assessment, provide a list of the learning objectives that will determine the program's content, learning formats, and assessments. These should reference expected changes in learners' attitudes, knowledge, competence, or standards to improve their performance. Based on a 2021 analysis of the literature partly published by the National Academy of Medicine, major causes for Patient Participation Groups (PPGs) were gaps in clinical knowledge (40%), attitudes and biases (30%), and/or failure to use/lack of available evidence-informed tools and resources (26%). Key themes included unexplained differences in prescribing practices between groups of clinicians, the presence of harmful negative

		attitudes or biases held by HCPs towards patients or the interprofessional team, and reports of insufficient time/resources and health system constraints exacerbating PPGs. Further details may be found here.[10] **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 published literature. The needs assessment should be specific to the knowledge, audience and educational modality gaps addressed in your application. The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) utilizes the diagnosis of opioid use disorder, replacing the terms opioid abuse and opioid dependence from the 4th Edition (DSM-IV). As such, grant applicants are encouraged to utilize DSM-5 terminology (i.e., opioid use disorder). Additionally, per the updated FDA Blueprint, grant applicants are encouraged to utilize the term nonmedical use of opioids instead of terms such as abuse or misuse of opioids. The RPC 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. Please outline the assessment process and how data/assessment educational outcomes will be provided to the RPC.
8	Description of Educational Training and Design **Note:** See Section 5 for details on how applications will be reviewed and evaluated	Detailed description of proposed educational training, and if appropriate, how the activities will: ▪ 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) ▪ Align with the proposed learning objectives to close the gaps in attitudes, knowledge, competence, and performance for audiences. 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 by utilizing a pre- and post-activity knowledge assessment, including long-term follow-up ➢ The RPC will consider grant applications that provide alternative methods for assessing the impact of REMS-compliant accredited CE. 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). ***CE providers are encouraged to include a complete list of all planned REMS-compliant activities as the RPC GRC will evaluate applications based solely on the activities provided.*** ➢ The RPC GRC will require a clear distinction between activities that cover the entire FDA Blueprint and those that are reinforcement / supplemental activities (e.g., fact sheets, presentations, etc.) as REMS-compliant activities are the primary consideration of the RPC GRC.
9	RPC-supported CE Provider of Record	A detailed description of the relevant process should be included outlining which of the following will be validated prior to individuals encountering each CE activity: ▪ 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. 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. 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.

10	Educational Outcomes Evaluation/Knowledge Assessment	Provide a detailed description of how you intend to assess the educational success associated with proposed learning objectives 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. In addition to educational activities covering all elements of the FDA Blueprint, each activity must: ▪ 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 the requirements of REMS-compliant accredited CE have been met
11	Marketing Plan for the Proposed Accredited CE Activities	Detail a marketing strategy for reaching individuals who are motivated to participate and complete all components of the REMS-compliant accredited CE, including an assessment of learning. CE providers should outline strategies for outreach, engagement, and recruitment including any partnerships that may facilitate reaching a large numbers of learners **Note:** Refer to Appendix B when developing the marketing strategy.
12	Budget	Submit a detailed budget using the template found within the GMS. ***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. ***The following REMS service fees are applicable for the 2025 CE Grant Cycle:*** ▪ ***ACCME: $2,000 per ACCME-accredited activity*** *Entry of activities into ACCME's Program Activity and Reporting System (PARS) / Joint Accreditors' Program Activity and Reporting System (JA-PARS) is strongly recommended for all CE providers, regardless of accrediting body, to facilitate consistency in data for aggregation and ensure impartial audits of the education*. 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 activities, and an estimated cost per completer. ***The rationale should include an explanation of how the estimated number of completers was determined.*** Include a statement confirming that: ▪ 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 an activity. 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. Proposed cost per completer for the entire project should be calculated and included as part of the budget.
13	Timeline of Project	Individual orientation sessions, required for new awardees and optional for those CE providers who have received grants in previous cycles, will be held prior to the start of program activities. In addition to providing an overview of the grant lifecycle and key activities, these orientation sessions will detail the project timeline for each phase and milestone which serves as the basis for the milestone payments in the awarded grant, as outlined below: Milestone 1: 35% of total grant budget ▪ Within 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 PARS / JA-PARS Milestone 2: 20% of total grant budget ▪ Start of first activity and upon acceptance of update report, content validation document and/or audit report(s) ➢ Note that the content validation document must include the CE provider name, grant ID, program title, confirmation that each CE activity fully aligns with the FDA Blueprint, and attestation that the reviewer is independent of the CE provider. Milestone 3: 20% of total grant budget ▪ Mid-term of activity timeline and upon acceptance of update report (including progress towards the grant metrics that the RPC-supported CE provider included in the approved application) Milestone 4: 25% of total grant budget ▪ Completion of last activity and submission/acceptance of required grant-related documentation (including final metrics for the education activity and budget reconciliation) Grant applicants are expected to understand and agree to adhere to this milestone payment schedule. 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 (RAI) from the RPC, either in writing, or in the form of a request for a teleconference, prior to RPC approval of the payment. CE providers are requested to provide the additional information within five (5) calendar days, however, if no response is received within seven (7) calendar days, the Grant Coordinator will confirm cancellation of the grant with the RPC GRC.

14	Guidelines for Change of Scope Requests	CE providers should submit Change of Scope (COS) requests via email to the Grant Coordinator for review / approval by the RPC CE Subteam. A COS request is required for changes to the following: ▪ Number of CE activities ▪ Format (e.g., live, enduring) ▪ CE activity title ▪ Increase/decrease in grant funding ▪ Milestone dates (i.e., start date of first CE activity (Milestone 2) and/or end date of last CE activity (Milestone 4)) *For updates to milestone dates, the COS request must be submitted **at least fifteen (15) days** prior to the original milestone completion date.* ***Please note that greater than a 1-month delay in submitting required milestone reports without notifying the Grant Coordinator, submitting a COS request, and/or updating the required timelines could result in CE LOA termination and loss of grant funding. If CE LOA is terminated, the Joint Accreditors would be made aware, and future RPC grant funding could be jeopardized.*** CE providers are encouraged to develop contingency plans to remedy any internal issues prohibiting timely submission of milestone reports (e.g., Provide Grant Coordinator a secondary point of contact.).

[10] Chappell, K., E. Holmboe, L. Poulin, S. Singer, E. Finkelman, and A. Salman, Editors. "Educating Together, Improving Together: Harmonizing Interprofessional Approaches to Address the Opioid Epidemic." *National Academy of Medicine,* (2021): 1

Section 5: Grant Application Review Criteria

Grant applications will be thoroughly and critically reviewed by members of the IGRC and RPC GRC 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 indicate whether the intended audience has 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, healthcare insurers (if not listed above), professional organizations, organizations that administer state licensure requirements, and institutional accrediting bodies.

The RPC is interested in supporting novel activities (i.e., those 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 that also aim to address disparities in opioid prescribing and pain management therapies. The RPC reiterates the need for inclusion of all elements of the FDA Blueprint in the grant application.

Awarded grant 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	To demonstrate how the CE activity will include all elements of the FDA Blueprint, the grant application should: ▪ Present a detailed mapping of how all elements will be covered in educational activities and training materials ➢ 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. ➢ **Note:** If grant application includes funding for multiple activities under the same grant, every activity must cover every section of the FDA Blueprint ▪ Explicitly state that each of the sections of the FDA Blueprint will be covered in the assessment ➢ An **FDA Blueprint Mapping Document Template** (Appendix F) must be completed and uploaded as part of each application to confirm that each section of the FDA Blueprint will be covered. ***Grant applicants must not include any CE activity content when completing the FDA Blueprint Mapping Document Template (i.e., please only provide yes/no answers).***

Learner Data	Relative to FDA goals and MedBiquitous specifications /definitions, the grant application should include a realistic estimate of the number of individuals expected to complete each REMS-compliant accredited CE activity. See Overview for information on FDA-requested learner level data information. Grant applications should consider whether the intended audience(s) have been previously engaged by the applicant and/or other RPC-supported CE providers. Completing REMS-compliant accredited CE means that individuals have at a minimum: ▪ 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 **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 completers was determined. ***Grant applicants must outline in detail how they plan to meet the proposed number of completers by the close of the grant (i.e., Milestone 4). Note that the RPC CE Subteam regularly tracks the reported number of REMS-compliant completers in each milestone report compared to the expected number of such completers per the grant application.*** ***The RPC GRC considers past performance of previously awarded RPC-supported CE providers***, including the reported number of completers compared to the expected number of completers, when reviewing grant applications. Previously awarded CE providers are encouraged to outline / describe any improvements since initial funding, which may include enhancements in program design, outcomes, participant feedback, and/or increases in completer numbers that may illustrate the effectiveness of the education.
Qualifications of CE Provider and Partners	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. CE providers must ensure that any partner organization meets the necessary criteria (e.g., proper accreditation, REMS service fees) for conducting any educational programming.

Needs Assessment[11,12,13]	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. The needs assessment should provide evidence about targeted learners specifically related to the gaps among intended learner attitudes, what targeted learners may know, what targeted learners may be able to do, and standards that could improve intended learner performance. The gaps should be clearly translated to proposed learning objectives that will be used to determine content, learning formats, and assessments. 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.
Educational Design / Methods[14,15,16,17,18,19,20]	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. 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. 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. Grant applicants should consider delivering content in digestible “chunks” or modules in ways that optimize learning. 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.

Knowledge Transfer[21]	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. Application of REMS-compliant educational outcomes measures should encompass knowledge, competence, and performance.
Interprofessional Education[22,23]	Grant applicants should outline the provision of interprofessional education (i.e., representatives of targeted learner groups, case examples of pain problems addressed by an interprofessional team, interprofessional competencies described in the literature) and CE activities particularly for HCPs practicing in settings with multidisciplinary teams.
Valid and Reliable Outcome Measures [24,25,26]	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 REMS-compliant completer given the proposed educational activities (see Section 2). CE providers submitting budget models exceeding $1,000,000 are required to include justification (i.e., how the activities conducted under the grant will target under-represented geographic regions / populations) and alternative budget options.
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.

[11] 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.

[12] 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.

[13] 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.

[14] 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.

[15] 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.

[16] 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.

[17] 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.

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

[19] 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]

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[21] 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.

[22] 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.

[23] 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): 167–17

[24] 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.

[25] Marinopoulos SS, Dorman T, Ratanawongsa N, Wilson LM, Ashar BH, Magaziner JL, Miller RG, 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.

[26] 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 learner has an individual registration with the DEA to prescribe controlled substances.

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

None
The learner 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/standards

Educational Methods and Tools

- Didactic: A teaching method that follows a consistent scientific approach or educational style to engage the learner'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 have been 310 REMS approved by the FDA, the Opioid Analgesic REMS represents the first to ***use REMS-compliant accredited CE*** to fulfill a REMS "training" requirement.[27]

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.[28]

<u>REMS CE Learner Challenges</u>

- REMS-compliant accredited 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.

<u>RPC-supported CE Provider Challenges with REMS-compliant Accredited CE</u>

- 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 participant," which may contribute to the length of the content.
- Competing activities offered by 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.

[27] FDA. "REMS Public Dashboard - FDA Risk Evaluation" https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/risk-evaluation-and-mitigation-strategy-rems-public-dashboard

[28] 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.

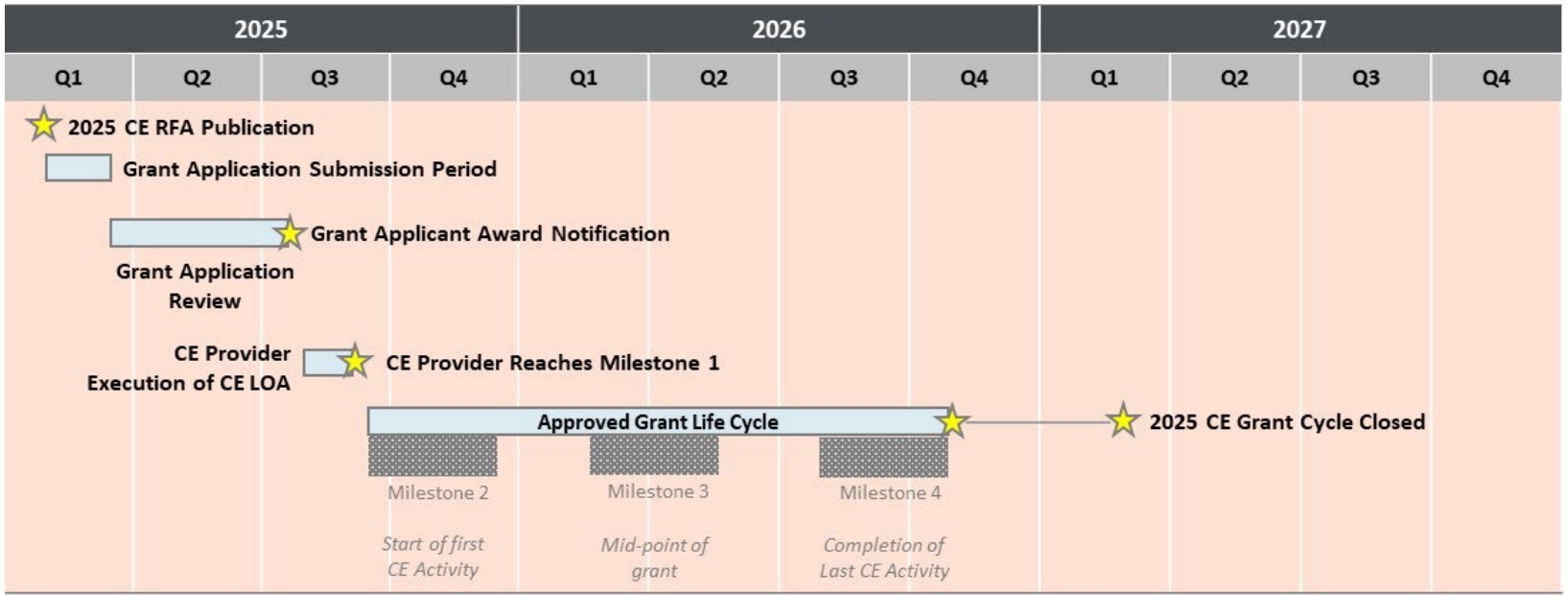
- Requirements for REMS-compliant accredited CE may not meet relevant CE requirements imposed by state licensing boards for various prescribing professions.
- Limited REMS awareness, coupled with the time investment required, demands a strategic, innovative approach to attracting HCPs to complete REMS-compliant 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 learners 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 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.

Note: Please reference the **Frequently Asked Questions (FAQs)** for more information on responding to the 2025 CE RFA.

Appendix C: Listing of RPC Member Companies as of November 2024

1. Abhai, LLC	33. Mikart, Inc.
2. ACI Healthcare Limited	34. Nortec Development Associates, Inc.
3. Alvogen, Inc.	35. Nostrum Laboratories, Inc.
4. Amneal Pharmaceuticals, LLC	36. Nuvo Pharmaceuticals, Inc.
5. ANI Pharmaceuticals, LLC	37. Osmotica Pharmaceutical US, LLC
6. Apotex, Inc.	38. Padagis US LLC
7. Ascent Pharmaceuticals, Inc.	39. Pharmaceutical Associates, Inc.
8. Athena Bioscience, LLC	40. Protega Pharmaceuticals
9. Aurolife Pharma LLC	41. Purdue Pharma L.P.
10. Avanthi, Inc.	42. Quagen Pharmaceuticals LLC
11. Cipher Pharmaceuticals Inc.	43. Rhodes Pharmaceuticals L.P.
12. Collegium Pharmaceutical, Inc.	44. Rising Pharma Holdings Inc.
13. DifGen Pharmaceuticals LLC	45. Rubicon Research Private Limited.
14. Elite Laboratories, Inc.	46. Sanaluz, LLC
15. Endo Pharmaceuticals Inc.	47. SpecGx
16. Epic Pharma, LLC	48. Strides Pharma Global Pte. Limited
17. Fosun Pharma USA Inc.	49. Sun Pharmaceutical Industries Inc.
18. Genus Lifesciences Inc.	50. Teva Pharmaceuticals USA, Inc.
19. Granules Pharmaceuticals Inc.	51. ThePharmaNetwork, LLC
20. Graviti Pharmaceuticals PVT. LTD.	52. Tris Pharma, Inc.
21. Hikma Pharmaceuticals USA Inc.	53. Unichem Laboratories Limited
22. Ingenus Pharmaceuticals NJ, LLC	54. Upsher-Smith Laboratories, LLC
23. Ipca Laboratories Limited	55. Validus Pharmaceuticals LLC
24. Jerome Stevens Pharmaceuticals, Inc.	56. Viatris Inc.
25. Kindeva Drug Delivery L.P.	57. Virtus Pharmaceuticals, LLC
26. Kowa Pharmaceuticals America, Inc.	58. VistaPharm, Inc.
27. Lannett Company, Inc.	59. WES Pharma Inc
28. LGM Pharma Solutions, LLC	60. Wockhardt Bio AG
29. Lupin Pharmaceuticals Inc. / Novel Laboratories, Inc.	61. Xttrium Laboratories, Inc.
30. Macleods Pharmaceuticals Limited	62. Zevra Therapeutics, Inc.
31. Megalith Pharmaceuticals Inc.	63. Zydus Pharmaceuticals (USA) Inc.
32. Micro Labs USA Inc.	64. Zyla Life Sciences

Appendix D: Sample Timeline for 2025 CE Grant Cycle



2025 CE Grant Cycle Activities	Tentative Dates for Grant Applicants
CE RFA Publication	January 2025
Application Submission Period Closed	March 2025 (*see* Overview *section for specific date*)
Grant Application Review Process*	March 2025 – July 2025
Grantee Award Notification	July 2025
Grantee Reaches Milestone 1	August 2025
Grantee Reaches Milestone 2	September 2025 – December 2025
Grantee Reaches Milestone 3	March 2026 – June 2026
Grantee Reaches Milestone 4	October 2026
Grant Closed	February 2027

*Grant Application Review Process time includes review of grant applications by the IGRC 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:

Appendix F: FDA Blueprint Mapping Document Template

All educational activities must fully cover the elements of the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (dated October 2023) recently released by the FDA, and must include an assessment that covers all sections of the approved FDA Blueprint. Please review each core message of the approved FDA Blueprint below and indicate whether this core message is planned to be included within the activity(ies) as part of the grant application.

FDA Blueprint Requirement	Will this core message be included in the CE activity(ies)?* (Yes/No)
Section 1	
I. The Need for Comprehensive Pain Education	
The FDA Blueprint was developed with two, competing, U.S. public health concerns in mind--(1) the large number of Americans with pain, and (2) nonmedical use of prescription opioids.	Yes/No
II. Definitions and Mechanisms of Pain	
Pain can be categorized according to its duration, underlying pathophysiology of the original insult, and whether a central sensitization component has been developed. An understanding of these different categorizations can help direct therapeutic decisions. When defining, and classifying pain, the following should be taken into consideration: 1. Biological significance of pain (survival value) 2. Relationship between acute and chronic pain 3. Distinction between nociceptive and neuropathic pain	Yes/No
III. Assessing Patients in Pain	
HCPs should be knowledgeable about how to assess each patient when initiating a pain management program. When appropriate, evidence-based, standardized scales and tools can be used to document pain characteristics and guide management decisions throughout treatment, noting the strengths and weaknesses regarding specificity and sensitivity of these scales. Important elements of an initial assessment should include the following: 1. Patient history	Yes/No

2. Screening tools to evaluate the known risk factors for development of chronic pain after an acute injury or disease 3. Screening tools to evaluate the known risk factors for nonmedical use of opioids and OUD 4. Queries of state prescription drug monitoring programs (PDMPs) 5. Pain assessment scales/tools 6. Functional assessment scales 7. Physical examination 8. Family planning, including information about use of contraceptives, pregnancy intent/status and plans to breastfeed 9. Psychological and social evaluation 10. Diagnostic studies when indicated	
Section 2	
I. Components of an Effective Treatment Plan	
1. The goals of treatment, including the degree of improvement in pain and function when function has been impaired by pain 2. Possible constituents of the treatment plan, including nonpharmacologic approaches and pharmacologic therapies 3. Patient/prescriber/health care team interactions, including ▪ Patient responsibilities/compliance with the plan ▪ Responsibilities of the prescriber and health care team, including patient monitoring ▪ Plans for reviewing functional goals ▪ Use of supplemental medication for intermittent increases in pain ▪ Use of patient provider agreements (PPAs)	Yes/No
II. General Principles of Nonpharmacologic Approaches	
Pain can arise from a wide variety of causes. There are a number of nonpharmacologic and self-management treatment options that have been found to be effective alone or as part of a comprehensive pain management plan, particularly for musculoskeletal pain and chronic pain. Examples include, but are not limited to, psychological, physical rehabilitative, and surgical approaches, complementary therapies, and use of approved/cleared medical devices for pain management. HCPs should be knowledgeable about the range of treatment options available, the types of pain that may be responsive to those options, and when they should be used as part of a	Yes/No

multidisciplinary approach to pain management. HCPs should also be aware that not all nonpharmacologic options have the same strength of evidence to support their utility in the management of pain, and some may be more applicable for some conditions than others.	
III. General Principles of Pharmacologic Analgesic Therapy	
When using non-opioid medications in pain management, HCPs should be knowledgeable about the following: 1. Mechanism of action of analgesic effect 2. Indications and uses for pain management 3. Routes of administration and formulations used in pain management 4. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia 5. Contraindications 6. Adverse events, with emphasis on labeled warnings 7. Drug interactions – both pharmacodynamic and pharmacokinetic	Yes/No
Opioid analgesic medications can be used successfully as a component of pain management. However, opioids carry risks greater than those of most non- opioid analgesics, specifically the risks of nonmedical use, OUD, respiratory depression, overdose and death. Therefore, it is the responsibility of HCPs to be knowledgeable, not just about the presence of such risks, but about how to weigh these risks before prescribing an opioid and about how to properly manage patients who are prescribed opioids, both for short-term and long-term use. When using opioid analgesics as part of pain management, HCPs should be knowledgeable about the following: 1. General precautions 2. Mechanism of action and analgesic effect 3. Types of opioids (full agonists, partial agonists) 4. Indications and uses for pain management 5. Range of opioid analgesic products available for pain management and their related safety concerns 6. Initial dosing, dose titration, dose tapering (when appropriate) for analgesia 7. Contraindications 8. Adverse events 9. Drug interactions	Yes/No

10. Key safety strategies for use with opioid medications	
IV. Managing Patients on Opioid Analgesics	
Initiating treatment with opioids – acute pain 1. Patient selection 2. Dosing 3. Naloxone for home use 4. Screening tools for risk of nonmedical use of opioids and OUD	Yes/No
Initiating treatment with opioids – chronic pain 1. Patient selection 2. Dosing 3. Considerations in opioid selection 4. When and how to use an opioid or non-opioid analgesic to supplement pain management	Yes/No
Ongoing management of patients on opioid analgesics 1. Periodic review of pain and functional goals 2. Review adverse events at each visit 3. Review refill history/review PDMP 4. How to determine when an opioid analgesic is no longer necessary/beneficial 5. Assess for changes in patients' psychiatric or medical conditions	Yes/No
Long-term management 1. Evaluation of the patient with worsening pain for changes in underlying condition and for signs of OUD before increasing opioid dosage 2. Changing opioid medications 3. Monitoring of patient adherence to the treatment plan, especially regarding nonmedical use of opioids	Yes/No
HCPs should understand how to monitor patients taking opioid analgesics and identify the signs and symptoms of opioid OUD and be knowledgeable about how to begin the process of evaluation and intervention upon suspicion of an OUD	Yes/No
HCPs should be knowledgeable about when referral to a pain management specialist is indicated, including identifying patients at high risk for OUD and patients unable to achieve adequate pain management	Yes/No

HCPs should be knowledgeable about how to safely taper opioid analgesics, including potential harms from sudden discontinuation or rapid dose decreases in patients who are physically dependent on opioids. HCPs should understand the need for shared decision-making with patients and be able to recognize and manage signs and symptoms of opioid withdrawal. HCPs should be knowledgeable about the particular risks associated with tapering during pregnancy.	Yes/No

HCPs should recognize their role in reducing the risks associated with opioid analgesics through patient education at initiation of an opioid and throughout long-term management. 1. Inform patients about pain management expectations and managing pain through different pharmacologic and nonpharmacologic modalities 2. Use the *Patient Counseling Guide: What You Need to Know About Opioid Pain Medicines* as part of discussions with patients and caregivers when prescribing opioid analgesics 3. Counsel the patient about the following: a) Importance of adherence to prescribed dosing regimen b) Patients should use the least amount of medication necessary to treat pain and for the shortest amount of time c) The risk of serious adverse events that can lead to death d) The risk of addiction that can occur even when product is used as recommended e) Known risk factors for serious adverse events, including signs and symptoms of overdose and opioid-induced respiratory depression, GI obstruction, and allergic reactions, among others f) The most common side effects, along with the risk of falls, working with heavy machinery, and driving g) When to call the prescriber (e.g., managing adverse events, ongoing pain) h) How to handle missed doses i) The importance of full disclosure of all medications and supplements to all HCPs and the risks associated with the use of alcohol and other opioids/benzodiazepines j) Product-specific concerns, such as not to crush or chew ER products; transdermal systems and buccal films should not be cut, torn, or damaged before use, etc. k) How to safely taper dose to avoid withdrawal symptoms l) Safe storage and disposal (e.g., in home disposal systems, kiosks, take back programs, mail back envelopes), risks of accidental exposure, and risks of diversion by family members and household visitors m) Never share any opioid analgesic with another person	Yes/No

n) How and when to use naloxone products and their various means of administration o) Seeking emergency medical treatment if an opioid overdose occurs p) How to report adverse events and medication errors to FDA	
V. Addiction Medicine Primer	
HCPs should be knowledgeable about the basic elements of addiction medicine and be familiar with the definition, neurobiology, and pharmacotherapy of OUDs. In particular, stigmatizing or blaming language (e.g., drug abuser, addict, "clean" versus "dirty") should be replaced with language that acknowledges that addiction, referred to as *substance use disorder* in the revised Diagnostic Statistical Manual-V, is a disease. The term *opioid use disorder* should be used when referring to the use of opioids, rather than other substances. HCPs should be familiar with the following: 1. The neurobiology of OUD (addictive cycle) and difference between physical dependence and addiction 2. Use of screening tools to identify patients at risk, based on known risk factors, and to identify patients developing signs of opioid dependence or addiction as early as possible 3. Management of OUD, including the types of pharmacologic and nonpharmacologic treatments available and when to refer to an addiction medicine specialist	Yes/No

*For individual activities with multiple modules, each module is not required to address the totality of the FDA Blueprint, however completion of all modules should address the totality of the FDA Blueprint.

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 75 days for the RPC-supported CE provider to receive the milestone payment.
- How are the milestone dates determined?
  - 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 2025 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 referenced 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 updated by the FDA in October 2023. 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.

FDA Blueprint Mapping Document Template

- Where can I find the FDA Blueprint Mapping Document Template?
  - The FDA Blueprint Mapping Document Template can be found in Appendix F of the CE RFA.

CE RFA submission

- Can I receive an extension for submitting an application if it is not complete by the specified deadline?
  - No. The application submission deadline is 11:59pm ET on March 6, 2025. 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 6, 2025.
- 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 application submission via the GMS. Whom should I contact?

If you have additional questions regarding the submission of your application in the GMS, you may contact the Grant Coordinator at RPC_CE@rems-pmo.com.

Reporting "Completer" Data

- What is the definition of a "Completer"?
  - An individual who has completed all components of an educational activity and meets the education provider's criteria for passing.
- How do I accurately report "Completer" numbers?
  - An individual should only be counted as a "Completer" if they have completed all components of an educational activity, *which fully covers the elements of the FDA's Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain dated October 2023* (FDA Blueprint) and meet the education provider's criteria for passing.