Mycophenolate REMS Program

Continuing Education (CE) Request for Grant Application (RFA)

Overview Information

Independent Commercial Organization	Mycophenolate Applicants (Mycophenolate REMS Group, MRG)
CE RFA Title	Mycophenolate Shared System Risk Evaluation and Mitigation Strategy (Mycophenolate REMS)
CE RFA Code[1]	040426
CE RFA Goal	The goal of this Request for Grant Application (RFA) for Continuing Education (CE) is to support REMS-compliant, accredited, continuing medical education (CME) / continuing education (CE) for healthcare providers (HCPs) who prescribe mycophenolate to improve patient understanding of certain risks associated with mycophenolate. The U.S. Food and Drug Administration (FDA) believes there is an opportunity to mitigate the risks associated with mycophenolate use by expanding the educational reach of training using alternate options such as REMS-compliant accredited CE to educate HCPs. REMS-based CE training can be effective in improving stakeholder participation in REMS programs even when training is voluntary for HCPs, such as in the Mycophenolate REMS (MREMS). The MRG is issuing this CE RFA to meet the FDA requirements for REMS-compliant accredited CE. Successful grant applications will recommend REMS-compliant CE activities that adhere to the accreditation standards of the CE Providers and will include educational designs that optimize knowledge acquisition and translate that knowledge into practice. REMS-compliant accredited CE should be available to HCPs who prescribe and/or participate in the treatment of patients taking mycophenolate products. REMS-compliant CE must include all elements of the "FDA's Mycophenolate REMS Education Blueprint for Healthcare Providers Who Prescribe" (FDA Blueprint) that the FDA approved on January 19, 2024. Applications should detail educational initiatives as outlined here and in accordance with the detailed plans in Section 4 of this CE RFA.

[1] The RFA Code is a six-digit number generated using the number / version associated with publishing the RFA (e.g., "04" for the fourth RFA published), and the RFA publication month/year (e.g., "04" for April, "26" for 2026), making the RFA Code 040426.

CE RFA Elements Essential to Meet REMS-Compliant Accredited CE Requirements	Accrediting bodies and CE Providers must ensure that CE activities comply with the standards for CE of the Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE), American Nurses Credentialing Center (ANCC), or another CE accrediting body, depending on the target audience's medical specialty or healthcare profession. ***Educational design of proposed CE activities utilized for REMS training must incorporate all of the below requirements to be considered REMS-compliant:*** ▪ Includes all elements of the FDA Blueprint ▪ Is offered by an accredited CE Provider and supported by independent commercially supported educational grants from the MRG ▪ Includes, at a minimum, a knowledge assessment of all sections of the FDA Blueprint ▪ Includes collection of pre- and post-knowledge HCP assessment data stratified by HCP specialty, as well as whether the HCP has reported prescribing mycophenolate in the past year ▪ Is subject to independent audit to confirm that conditions of the REMS training have been met ▪ Is verified via written attestation from a third-party independent subject matter expert (SME) that each CE activity fully covers all elements of the FDA Blueprint ***In order for CE grants supported by the MRG to meet the FDA-mandated REMS requirements, all applications must:*** ▪ Describe how a CE Provider will ascertain whether an HCP who has completed REMS-compliant CE has prescribed mycophenolate in the last 12 months ▪ Outline how the content of the REMS-compliant accredited CE will cover all elements of the FDA Blueprint ▪ Confirm that the integrated or post-course assessment will cover, at a minimum, knowledge of all sections of the FDA Blueprint ▪ Describe the planned educational outcomes for the CE activity and how your organization intends to measure them ▪ Outline how educational outcomes data can be collected as required by the FDA ▪ Include an overview of your organization's ability to provide the following assessment elements: ➢ Confirmation that the CE Provider can provide data on the number of HCPs who complete REMS-compliant accredited CE stratified by specialty, degree, and geographic region (defined by US Census), as well as whether the HCP has reported prescribing mycophenolate in the past year (see additional details outlined in the FDA-requested Data Requirements section below) ➢ Total proposed number of learners and anticipated "completers" of the REMS-compliant accredited CE ("completers" are defined as learners who finish a CE activity covering the full FDA Blueprint, who successfully complete, at minimum, an assessment confirming knowledge of all sections of the FDA Blueprint, and meet the CE Provider's criteria for successful completion) ➢ Details on CE Provider's plan to disseminate CE programs The MedBiquitous Medical Education Metrics (MEMS) provide a standard XML format for accredited CE educational outcomes data, including data related to

	REMS-compliant accredited CE. Please reference the MedBiquitous specifications for a full list of REMS-related definitions developed by the MedBiquitous Working Group. ▪ CE activities must be conducted in accordance with the standards for accredited CE set by any appropriate accrediting body (ACCME, ACPE, ANCC, or another CE accrediting body). ▪ For CE Providers requesting grant support for this CE RFA, provide a detailed description of how your organization intends to measure educational outcomes associated with the CE activities, and include the following information: ➢ Moore's level of outcomes the activity is designed to impact ➢ CE format (live, online, webinar, etc) ➢ Date(s) of CE activity ➢ Duration of activity for live, online, or webinar activities ➢ Average time to complete for online/enduring activities ➢ Average number of CE credit hours for each live, online/enduring, and webinar activity ➢ Educational methods and tools for each activity (case-based, multimedia, didactic, interactive, etc.) — For more information on educational methods and tools definitions, please reference Appendix A. ➢ 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 MRG-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 MRG-supported activities are fully REMS-compliant. — Documentation in which a medical expert (independent of but chosen by the MRG-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 MRG-funded grant recipients. ▪ CE activities must be conducted in accordance with the standards for accredited CE set by an appropriate accrediting body (ACCME, ACPE, ANCC, or another CE accrediting body).

FDA-requested Data Requirements	The FDA has requested that MRG-supported CE Providers collect data on the number of HCPs who complete REMS-compliant accredited CE stratified by ***degree, specialty, and geographic region (as defined by US Census)***. For reference, the HCP specialty and HCP degrees fields are outlined below for reference: **HCP Specialty** ▪ Allergy and Immunology ▪ Cardiology ▪ Dermatology ▪ Family Medicine ▪ Gastroenterology ▪ Hepatology ▪ Internal Medicine ▪ Nephrology ▪ Neurology ▪ Obstetrics/Gynecology ▪ Pediatrics ▪ Pulmonology ▪ Rheumatology ▪ Surgery ▪ Transplantation ▪ Other ▪ N/A **HCP Degree** ▪ Physician ▪ Advanced Practice Nurse ▪ Dentist ▪ Nurse ▪ Optometrist ▪ Other ▪ Other Healthcare Professional ▪ Pharmacist ▪ Physician Assistant ▪ Podiatrist ▪ Psychologist
Key Dates	CE RFA Posted: **April 10, 2026** Application Due Date: **11:59 pm ET June 5, 2026** Award Notification Date: **July 2026**
CE RFA Document Parameters	Grant applicants should complete the Needs Assessment and Detailed Program Information in MS Word. Please limit application submission to no more than 50 pages.
Submission Information	Grant applications must be submitted via the Grant Management System (GMS) beginning on **April 10, 2026.** The deadline for submitting applications is **11:59 pm ET** on **June 5, 2026.** **The GMS Portal can be accessed here:** https://webportalapp.com/sp/login/mycophenolate_rems_grants
Questions on CE RFA?	Please contact Myco_CE@REMS-PMO.com.

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Section 1: Background on the REMS

In September 2012, the FDA approved the Mycophenolate Shared System Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of mycophenolate outweigh the risks. The Mycophenolate REMS (MREMS) covers the following products: CellCept® (mycophenolate mofetil), Myfortic® (mycophenolic acid), MYHIBBIN™ (mycophenolate mofetil oral suspension), generic mycophenolate mofetil, and generic mycophenolic acid.

The goal of the MREMS is to mitigate the risk of embryofetal toxicity associated with the use of mycophenolate by educating healthcare providers (HCPs) and informing female patients of reproductive potential who are prescribed mycophenolate about the risks. In August 2020, the FDA found that the REMS was not meeting its goals and determined that modifications, including implementation of accredited continuing education (CE) were necessary. ***The MRG must provide education for HCPs who prescribe and/or participate in the treatment of patients taking mycophenolate products.*** For a current listing of the Mycophenolate REMS Group (MRG) companies, please reference Appendix B.

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

The FDA believes there is an opportunity to expand the educational reach of the training by including alternate options for educating HCPs, such as CE. REMS-based accredited CE as a means of accomplishing FDA-required training can be effective in improving learner participation in REMS programs when training is voluntary for HCPs, such as in the MREMS.

In order to encourage HCP participation and expand the educational reach of REMS training, the MRG is issuing this CE RFA. Through independent educational grants to accredited CE Providers, the MRG will make REMS-compliant accredited CE available to HCPs who prescribe and/or participate in the treatment of patients taking mycophenolate products.

The expected results of the REMS-compliant accredited CE, as described in the "Purpose of the Mycophenolate Healthcare Provider Educational Effort" section in the FDA Blueprint, are that following completion of educational activities under the MREMS, HCPs should be knowledgeable about the following:

- The increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate
- Importance of educating females of reproductive potential about the increased risk of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy
- Importance of prescribers providing or facilitating patient education about pregnancy prevention and planning, including acceptable methods of contraception during mycophenolate treatment
- When treating a pregnant patient or a patient who is considering pregnancy, consider alternative immunosuppressants with less potential for embryofetal toxicity
- Importance of reporting to the Mycophenolate Pregnancy Registry any pregnancies that occur during mycophenolate treatment or within 6 weeks following discontinuation of treatment
- Importance of encouraging pregnant patients to participate in the Mycophenolate Pregnancy Registry

In order to be REMS-compliant, and therefore eligible for independent educational grant support from the MRG, the educational activities and material(s) must address all elements of the FDA Blueprint, include an assessment covering all sections of the FDA Blueprint, and conform to the "RFA Elements Essential to Meeting REMS-Compliant Accredited CE Requirements". While these criteria represent the FDA's overall expectation for MRG-supported CE activities, successful applications should translate such expectations into REMS-compliant accredited CE objectives and educational outcomes.

Section 2: Funding Opportunity and Award Information

Anticipated Number of Awards	The number of grants awarded under the 2026 CE Grant Cycle will depend on the number and quality of grant applications submitted. Grants may be awarded for various CE delivery methods/platforms, including innovative learning modalities and/or traditional CE delivery methods. These grants must fully address the REMS requirements for CE and the FDA Blueprint, outline the ability to engage HCPs to complete the REMS-compliant CE, and include an assessment covering all sections of the FDA Blueprint.
Grant Budget	***Budgets should be consistent with the realistic total number of learners that the CE Provider estimates will "successfully complete" REMS-compliant accredited CE activities. Successful completers are those learners who finish a CE activity covering all elements of the FDA Blueprint, and an assessment that covers all sections of the FDA Blueprint.*** Consideration will be given to grant applications that are cost effective and collaborative, as well as provide innovative educational activities or platforms and minimize redundancies in development costs. CE Providers may propose budget models with multiple levels of support, allowing the MRG to potentially approve a grant level of support that is consistent with funding availability. As part of the application, 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 plus ACCME fees ▪ Milestone 2: 25% of total grant budget exclusive of ACCME fees ▪ Milestone 3: 30% of total grant budget exclusive of ACCME fees ▪ Milestone 4: 10% of total grant budget exclusive of ACCME fees ➢ Note: During submission of the grant application, input of this information is not required; however, it should be included in the detailed program information contained in the grant application. Please reference Section 4 of this CE RFA for an explanation of the milestone criteria. The final breakdown of milestones will be determined upon receipt of award notification. Milestone payments will be made to the MRG-supported CE provider within 75 days pending receipt and approval by the MRG of the applicable milestone report and corresponding invoice. Grant applicants should include timelines that factor in this milestone payment timeframe. Note: ▪ To be eligible to receive an MRG-funded grant, CE Providers submitting applications 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). ▪ MRG-supported CE Providers must ensure that grant funds from the MRG are not used for payments associated with the provision of food, beverages, travel, or lodging to meeting participants. ▪ Awarded grant funds must only be used to provide REMS-compliant accredited CE activities that meet the requirements of the REMS.

	MRG-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 MRG-supported CE Providers are as outlined below: ▪ Unless otherwise noted in the grant application, all CE activities should begin by November 2026 and be completed no later than November 2027. Please see Appendix C for the 2026 CE Grant Cycle timeline. ▪ The MRG will complete the grant application review process and notify grantees selected to receive funding by July 2026.
Other Award Information	To optimize learning opportunities, the MRG intends to fund multiple accredited CE Providers and educational partners with different, yet complementary, initiatives. Consideration will be given to grant applications that propose high-quality, creative CE activities that will enable achievement of educational outcomes, Grant applicants must demonstrate how the proposed CE activities will fully meet or exceed the requirements for REMS compliance. The proposed CE activities must be cost-effective for the scope of the application, designed to support learner completion, demonstrate broad reach, and satisfy the CE RFA criteria outlined in Section 4.

Section 3: 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, ACPE, ANCC, or an equivalent accrediting body, or by an official state accrediting agency; the applicant must be in good standing with the relevant accreditor at the time of grant submission
- Should provide a description of your organization's past experience and demonstrated success in the design and implementation of innovative, interactive, engaging, multimodal educational activities, such as developing electronic activities for mobile devices or implementing adaptive learning education; effective communication skills, as evidenced by solid partnerships and collaborations, are highly valued

Section 4: CE RFA Submission Information

Grant applications **must** include all of the following components, preferably in the sequence listed below.

Application Component		Description
1	CE Provider of Record	Name of accredited CE Provider, name of CE Provider's authorized signatory and individual(s) responsible for the grant application, including contact information.
2	Partner Organizations	Name of any partner organizations to be involved in the proposed education, along with respective roles/responsibilities, contact information, and how the partner will assist in attracting learners to engage in and complete REMS-compliant accredited CE.
3	Overview of Proposed Educational Activities	One (1) to two (2) page summary/abstract describing: ▪ Overall project goals and the CE delivery method/platform, including rationale for the selection of delivery methods/platforms, innovative means of reaching and engaging learners, as well as retaining learners through completion of the REMS-compliant accredited CE activity and assessment ▪ Intended audiences that will be reached through the REMS-compliant accredited CE ➢ The FDA mandates that CE must be available and accessible to HCPs who prescribe and/or participate in the treatment of all patients taking mycophenolate products, including those HCPs prescribing to non-transplant patients ➢ Applicants are encouraged to design programs that ensure outreach to broad and diverse target audiences.Realistic estimate of the total proposed number of learners and anticipated "completers" of the REMS-compliant accredited CE ▪ "Completers" are defined as learners who finish a CE activity covering all elements of the FDA Blueprint, who successfully complete, at minimum, an assessment confirming knowledge of all sections of the FDA Blueprint, and meet the CE Provider's criteria for successful completion.Cost per completer ▪ Amount of grant funds being sought ▪ Timeline of planned activities that aligns with the 2026 CE Grant Cycle, including the date of the first planned CE activity and completion of the last CE activity
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 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

Application Component		Description
5	Audience(s)	The audiences for REMS-compliant accredited CE, as outlined by the FDA in the REMS documents, are those who prescribe and/or participate in the treatment of all patients taking mycophenolate products. ▪ Within this broadly defined audience, clearly identify the target audience(s). ▪ Why this/these particular audience(s)? ▪ What expertise does your organization have motivating learners to not only engage in, but also complete the full CE activity (including the assessment, which is required in all REMS-compliant CE)? ▪ The FDA requires that the CE RFA includes the provision that Providers of REMS-compliant CE must be able to ascertain whether an HCP who has completed REMS-compliant CE has prescribed mycophenolate in the last 12 months. Describe how your organization will ascertain this. **Note**: The MRG invites grant applications targeting prescribers of mycophenolate for both transplant and non-transplant patients to ensure proper patient education on its correct use, regardless of patient type.
6	Scope/Populations	Specify the intended reach of your activity/offering: ▪ National ▪ Regional (Multi-City, Multi-State) ▪ State ▪ Health System or Integrated Delivery Networks ▪ Hospital or Medical Center ▪ Other Community Practice Collaborations The MRG is particularly interested in funding grants that can provide REMS-compliant accredited CE contributing to broader and diverse audience engagement and completion, especially with prescribers of mycophenolate.
7	Needs Assessment	The Needs Assessment should be properly referenced and include one or more of the following: a) Evidence and rationale for choosing the target audiences b) Evidence of knowledge, practice, and/or educational modality gaps specific to audiences for whom the proposed activities are designed c) Results from any surveys or assessments that have been executed with your specific audiences, in which the survey tool addressed mycophenolate-related risks described in the FDA Blueprint Consideration will be given to applicants who can bridge gaps in learner knowledge and clinical application of key messages based on the FDA Blueprint. As appropriate for the audiences being proposed in the grant application, CE Providers should factor in the gaps/needs of a diverse group of learners. Planned educational outcomes/impact of the REMS-compliant accredited CE should be linked back to the Needs Assessment.

Application Component		Description
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 REMS-compliant accredited CE will: ▪ Align with all elements of the FDA Blueprint ▪ Meet all REMS-compliant accredited CE requirements (See Overview Information) ▪ Close gaps in knowledge, competence, and performance for audiences based on the Needs Assessment ▪ Incorporate adult learning and innovative instructional design principles ▪ Employ best educational practices/methods to attract learners, retain them through completion of the CE activity as well as the assessment, and optimize both knowledge acquisition and the application of that knowledge into clinical practice ▪ Reinforce the value of including a multidisciplinary team in patient care ▪ Measure learner knowledge and behaviors ▪ Incorporate adaptive learning/personalized CE and/or traditional CE delivery methods **Note**: The MRG is interested in funding grant proposals that provide prescribers with the knowledge and communication strategies needed to effectively convey the correct use of mycophenolate, particularly as it relates to pregnancy risks and birth control options during treatment.

Application Component		Description
9	CE Provider of Record	MRG-supported CE Providers will ensure that REMS-compliant accredited CE activities comply with ACCME's *Standards for Integrity and Independence in Accredited Continuing Education* or another CE accrediting body's standards, depending on the target audience's medical specialty or healthcare profession. 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 that the CE Provider of Record is in good standing with the relevant accreditor(s) at the time of application). Include a statement indicating that no MRG member company or representative has selected or provided suggestions for any speaker involved in the CE activities. One of the requirements for REMS-compliant CE supported by educational grants from the MRG is that all CE activities are subject to audit by a SME, independent of, but chosen by, the accredited CE Provider; the independent SME will provide written attestation to confirm that the FDA requirements for the accredited CE activity have been met. MRG-supported CE Providers must agree to provide documentation to the MRG confirming the CE activity is fully REMS-compliant. In addition to written attestation of this by the independent SME, this documentation shall also include a detailed description of the independent subject matter expert review process outlining how the following will be validated prior to learners encountering the CE activities: ▪ All elements of each section of the FDA Blueprint are covered in the educational activity/materials to ensure completeness of content, and all sections of the FDA Blueprint are covered in the assessment. ▪ The content of the CE activity reflects the most current evidence-based information and aligns with the FDA Blueprint. ▪ The CE activity complies with ACCME's *Standards for Integrity and Independence in Accredited Continuing Education* or another CE accrediting body's standards, depending on the target audience's medical specialty or healthcare profession. Prior to finalizing CE activity content, it is the MRG-supported CE Provider's responsibility to check the FDA website for any new information that may affect the content of the REMS-compliant accredited CE. Note: Grant applicants must complete the FDA Blueprint Attestation requested in the GMS application to attest that all CE activities fully align with the FDA Blueprint.

10	Educational Outcomes Evaluation/Knowledge Assessment	Please describe how the assessment will be conducted and how CE data / assessment of educational outcomes will be provided to the MRG. Provide a detailed description of how your organization intends to measure educational outcomes associated with REMS-compliant accredited CE, 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 CE activities covering all elements of the FDA Blueprint, the activities must: ▪ Include an assessment that covers all sections of the FDA Blueprint; preferred consideration will be given to grant applications that integrate the assessment throughout the CE activity in order to increase the likelihood of learners 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 and CE dissemination plan for how audiences will be reached, motivated to participate, and engaged to complete all components of the REMS-compliant accredited CE activities, including an assessment of the learning. Include steps your organization will take if it appears that the estimated number of proposed HCPs outlined in the grant application may not be met.
12	Budget	Submit a detailed budget using the template found within the GMS. The MRG will cover the cost of REMS service fees for accreditors who require reimbursement of costs incurred in conjunction with the CE data aggregation/reporting. There is a specific line on the budget template that indicates how to estimate REMS service fees for the proposed activities. ➢ ***ACCME: $1,600 per ACCME-accredited CE activity*** In the detailed program information section of the grant application, please explain the rationale for the proposed budget, including efficiencies, cost-effective approaches to live and/or enduring activities, and an estimated cost per completer. The rationale should include an explanation of how the estimated number of learners and anticipated numbers of completers was calculated. ***The proposed cost per completer for the entire project should be calculated and provided as part of the budget.*** Include a statement indicating that: ▪ 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 MRG-supported CE Provider.

Application Component		Description
13	Timeline of Project	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: Milestone 1: 35% of total grant budget ▪ Following execution of the CE LOA, submission and acceptance of initial activity listing, and notification of MRG-supported activities to accrediting organizations, including entry of all activities into ACCME's Program Activity and Reporting System (PARS) / Joint Accreditors' PARS (JA-PARS), as applicable Milestone 2: 25% of total grant budget ▪ Initiation of the first CE activity and upon acceptance of milestone report and content validation document ➢ 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: 30% of total grant budget ▪ Midpoint of the activity timeline and upon acceptance of the milestone report (including progress towards the grant metrics that the CE Provider submitted in the approved application). Milestone 3 can be calculated by finding the midpoint between the projected Milestone 1 and Milestone 4 dates. Milestone 4: 10% of total grant budget ▪ Completion of the last CE activity and MRG receipt/acceptance of required grant-related documentation (including final metrics for the educational activity and budget reconciliation) ***Grant applicants are expected to understand and agree to adhere to the milestone payment schedule.*** The MRG-supported CE Provider recognizes that upon submission of an invoice for a milestone payment, the MRG-supported CE Provider may receive a request for additional information from the MRG, either in writing, or in the form of a request for a teleconference, prior to MRG approval of the payment.

Section 5: Grant Application Review Criteria

Grant applications will be thoroughly and critically reviewed by members of the MRG Grant Review Committee (GRC) to ensure that applications are fully aligned with the FDA Blueprint and additional criteria noted below.

The MRG is interested in advancing opportunities for REMS education of HCPs who prescribe and/or participate in the treatment of patients taking mycophenolate products.

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

Criteria	Description
Compliance	Applicant (CE Provider of Record) continues to meet eligibility criteria outlined in Section 3.
Alignment	Includes all elements of the FDA Blueprint: ▪ Presents a detailed mapping of how all elements will be covered in educational activities/training materials ▪ Explicitly states that each of the sections of the FDA Blueprint will be covered in the assessment ▪ Alignment with the FDA Blueprint is verified by written attestation from third-party independent SME and submitted via a content validation document
Qualifications of CE Provider and Partners	Identify and describe any relevant novel partnerships/coalitions across professional, governmental, and/or healthcare organizations that can achieve broad reach, engagement, and impact. Consider the inclusion of such groups as Accountable Care Organizations (ACOs), integrated delivery networks, state licensing boards, and group health organizations.
Needs Assessment[2,3]	The Needs Assessment should be specific to your proposed audience(s) and determine the goals of the activities, ensuring the content of the educational material is relevant and adapted to the needs and clinical practice circumstances of the learners. **Note**: The MRG is interested in funding grant applications that target ***all*** prescribers of mycophenolate to ensure both transplant and non-transplant patients are educated on its correct use.

[2] 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.
[3] 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.

Criteria	Description
Educational Design / Methods[4,5,6,7,8,9]	Ensure that the proposed educational design/methods fill a void, appeal to broader audiences, consider innovative approaches (e.g., electronic activities for mobile devices, engaging print format) or other modalities to encourage completion of the activity/assessment, and promote participation in the REMS-compliant accredited CE activities. Content should be delivered 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 learners in reflection and application of new knowledge to their practice settings. REMS-compliant accredited CE activities should be innovative and creative in nature, motivating learners to participate in and complete activities, including the requisite learning assessment inherent in REMS-compliant accredited CE. Formats in which learners receive content over time should be delivered in digestible "chunks" or modules in ways that optimize learning.
Knowledge Transfer[10]	Principles from the field of implementation science are incorporated into overall learning activities to address barriers to the application of the knowledge conveyed in the activities. Application of REMS-compliant accredited CE outcomes measures should encompass knowledge, competence, and performance.
Interprofessional Education[11,12]	Facilitate interprofessional education and educational CE activities, particularly for HCPs practicing in settings in which care is delivered by multidisciplinary teams
Valid and Reliable Outcome	Provide a description of learner to completer ratio from previous/current CE initiatives in addition to evidence of the validity and reliability of the CE evaluation and outcome assessment methods; consideration will be given to

[4] 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.

[5] 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.

[6] 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.

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

[8] 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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[10] 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.

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Measures[13,14,15]	grant applications that integrate assessments throughout the educational activity (versus waiting until the end of the entire activity) to optimize HCP completion
Budget	Reasonable cost per completer given the proposed educational activities (see Section 2)
Marketing Plan for CE Activities	Detailed marketing strategy outlining the following: ➢ How diverse audiences for various types of activities will be reached ➢ CE dissemination plans ➢ How audiences will be motivated to participate in the educational activity and engaged to complete all components, including, at a minimum, an assessment of knowledge and competence which meets the accredited CE Provider's criteria for "successful completion"

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Appendix A: Definitions - Medical Education Metrics and Educational Methods

Medical Education Metrics

MedBiquitous is developing a technology standard to enable exchange of educational outcomes data across organizations. This standard, MEMS 2.0, will allow accreditors to collect CE data from MRG-supported CE Providers in a common format, allowing that data to be compiled across accreditation systems. Please access the MedBiquitous specifications relevant to the MREMS.

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 the 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: Current Listing of the MRG Companies

Accord Healthcare Inc.
Alkem Laboratories, Ltd.
Amneal Pharmaceuticals LLC
AMTA
Apotex Corp
Aurobindo Pharma
Avet Pharmaceuticals Inc.
Azurity Pharmaceuticals
Biocon Pharma Limited
Cadista
Concord Biotech Limited
Genentech, Inc.
Hetero USA, Inc.
Hikma Pharmaceuticals USA Inc.
Hisun Pharmaceuticals USA, Inc.
Jubilant Cadista Pharmaceuticals Inc.
Lannett Company, Inc.
Meitheal Pharmaceuticals, Inc.
Mylan Pharmaceuticals Inc.
Novartis Pharmaceuticals Corporation
Par Health USA, LLC
Rising Pharma Holdings, Inc
RK Pharma, Inc.
Sandoz Inc.
Strides Pharma Science Limited
Teva Pharmaceuticals USA, Inc.
TWi Pharma USA
VistaPharm, Inc.
Wuxi Fortune Pharmaceutical Co., Ltd.
Zydus Pharmaceuticals (USA) Inc.

Appendix C: Sample Timing for 2026 CE Grant Cycle

2026 CE Grant Cycle Activities	Tentative Dates for Applicants/Grantees
CE RFA Publication	April 2026
Application Submission Period Closed	June 2026 (*see* Overview Information *for specific date*)
Grant Review Process	June 2026 – July 2026
Grantee Award Notification	July 2026
Grantee Reaches Milestone 1	Upon completion of all Milestone 1 requirements (See FAQs), including submission and acceptance of initial activity listing in PARS/JA-PARS, to be completed no later than August 2026
Grantee Reaches Milestone 2	Upon initiation of first CE activity and acceptance of milestone report and content validation documents; extends through mid-term of CE grant cycle, to be completed no later than November 2026
Grantee Reaches Milestone 3	Upon acceptance of Milestone 3 Report, to be completed no later than May 2027
Grantee Reaches Milestone 4	Upon completion of last activity and receipt/acceptance of required documentation including final grant metrics, budget reconciliation, and report no later than November 2027
Grant Closed	February 2028

Frequently Asked Questions (FAQs)

Milestones

- Following submission of a milestone report, when can I expect to receive payment?
  - Milestone payment-related details are outlined in the CE LOA, which is provided to each MRG-supported CE Provider that is awarded a grant for a particular grant cycle. There are four milestones in a grant's life cycle, and each milestone includes specific requirements. Once the MRG-supported CE Provider completes a milestone, a milestone report, relevant documentation, and an associated invoice should be submitted by the CE Provider for review by the MRG CE Subteam. Following MRG CE Subteam review and acceptance, it can take up to 75 days for the milestone payment to be processed and received, as outlined in the CE LOA.
- How are the milestone dates calculated?
  - Milestone 1 is reached upon completion of the following activities:
    - CE LOA is fully executed.
    - CE Provider submits the initial activity listing in PARS/JA-PARS (as applicable), and the MRG CE Subteam confirms all activity listing columns have been completed.
    - Accrediting organization has been notified of the MRG-reported activities by the MRG-supported CE Provider.
    - ***While the MRG CE Subteam provides MRG-supported CE Providers with the Milestone 1 date, the MRG-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 is the start of the first activity and MRG CE Subteam acceptance of the milestone report and content validation documents. 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 MRG receipt/acceptance of required grant-related documentation. Please note that the grant will be considered closed following completion of Milestone 4, receipt/acceptance of required grant-related documentation, including budget reconciliation, and the subsequent distribution of funds.
- Can you provide a high-level timeline of expected milestone dates?
  - Please see Appendix C for an overview of the milestone dates for the 2026 CE Grant Cycle.

CE Activity Page

- Does the MRG provide a list of REMS-compliant accredited CE activities offered by current CE Providers?
  - The CE Activity Page includes REMS-compliant accredited CE information for MRG-supported CE Providers. The goal of the CE Activity Page is to provide prospective HCP learners with access to available REMS-compliant accredited CE activities supported by the MRG.
- Can you provide more information about the requirements of the program title?

- CE Providers are encouraged to create a unique, specific program title to provide learners 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 REMS, REMS-compliant accredited CE should be based solely on the FDA Blueprint (January 2024). Please review the RFA Elements Essential to Meeting REMS-Compliant Accredited CE Requirements section within the CE RFA, which outlines expectations of REMS-compliant accredited CE per the FDA Blueprint.

Note: While the MRG does not anticipate changes in the FDA Blueprint, it is the CE Provider's responsibility to check the FDA website for any new information that may affect the content of the REMS-compliant accredited CE prior to finalizing 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 11:59 pm ET on June 5, 2026. To avoid any technical delays, it is recommended that applicants submit the application prior to the deadline, as any applications received after 11:59 pm ET on June 5, 2026, will not be eligible for funding consideration.
- How can supporting materials be submitted with the grant application?
  - Applicants are requested to provide all supporting materials via the GMS as part of their application (W9, Needs Assessment, Detailed Program Information, and Proof of Tax Status).
- I have additional questions regarding submission. Who should I contact?
  - Please reach out to Myco_CE@REMS-PMO.com with any additional questions.