REQUEST FOR APPLICATIONS
Last Revised: July 6, 2015

Enhancing Performance in Primary Care Medical Practice
Through Implementation of Comprehensive Medication Management

Overview

The American College of Clinical Pharmacy (ACCP) has integrated the practice framework of comprehensive medication management (CMM)\(^1\) into its strategic plan, including organizational policy and advocacy agenda, professional development initiatives, and research agenda. The practice of CMM is aligned with the core values of the College, has been incorporated into Standards II and III of the Standards of Practice for Clinical Pharmacists,\(^2\) and is gaining increasing support of policy makers, medical and other professional organizations, primary care providers, and clinical pharmacists.

CMM is built upon a foundation of pharmaceutical care practice.\(^3\) It places explicit and enhanced emphasis on patient-centered and formalized team-based delivery systems. Using a consistent process of direct patient care provided by qualified clinical pharmacists, CMM achieves outcomes that align directly with the overall clinical goals of care for patients. CMM is wholly different from and more complete than the Medication Therapy Management (MTM) activities required of Medicare Part D prescription drug plans.

Peer-reviewed, published evidence demonstrating the clinical and economic outcomes of MTM has been disappointing.\(^4\) This is largely due to variation in study design, inconsistent practice models of pharmacists involved in published studies, ill-defined terminology around MTM and drug therapy problems (DTPs), vague performance and outcome metrics, and the limited scalability and sustainability of the services.

As medical practice continues its rapid transition toward value and outcomes based accountability, together with payment reform efforts that reward the quality rather than quantity of services, important opportunities exist to support enhanced practice performance by integrating CMM into primary care practices. It is widely recognized that strategies to address the safe, effective, and affordable use of medications in primary care are critical to enhance care transitions, improve health, and control costs. CMM holds promise as an effective, value-added strategy to optimize medication use; however,

\(^3\) Cipolle and Strand. Pharmaceutical Care Practice, 3rd edition (2013).
\(^4\) JAMA Intern Med. 2015;175(1):76-87.
several questions must be addressed to advance CMM implementation and ensure its widespread uptake and sustainability in primary care medical practices:

- Which patients and populations within primary care practices would benefit most from CMM?
- Among those who receive CMM, what is the impact on quality of care and cost? Are the patients in greatest need of medication optimization receiving CMM and, if so, what are best practices around the duration and frequency of follow-up?
- How can/should CMM be delivered, replicated, scaled, and sustained? In other words, how can medical practices do this most effectively?
- What are the medication-related, clinical, and economic performance metrics most relevant to today’s primary care practices? What are the contributions of the clinical pharmacist to helping the practice achieve these metrics?
- What are the contributions of the clinical pharmacist to the net revenue generated by the practice and the relative return on investment of having the clinical pharmacist embedded in the office or clinic?

ACCP has committed up to $2.5 million to fund research that seeks to answer these questions by examining the impact of CMM provided by qualified clinical pharmacists embedded in primary care practices as integral members of the health care team.

ACCP is interested in applications that focus on both effectiveness and implementation science. While it is important to test the effectiveness of CMM within the context of primary care delivery, it is also imperative that investigators critically examine how to implement CMM into busy medical practices in order to facilitate uptake and scalability in routine health care practice. Implementation science seeks to generate knowledge about “how” programs (i.e., CMM) can be delivered effectively and efficiently in real-world practices, how primary care practices finance such programs, and the processes of care by which health care professionals and office staff within busy practices work together to improve outcomes and facilitate the sustainable uptake, adoption, and implementation of a service like CMM.

Achieving the answers to these questions will require highly collaborative efforts focused on CMM design and implementation in primary care, rigorous evaluation, and a process of continuous quality improvement that generates real-time learning and informs continuous practice change.

**Funding Guidelines**

**Eligibility and Minimum Qualifications**

The following minimum qualifications must be met to apply for the award.

- Applicants must have and include existing primary care medical practices as participants in the application and conduct of the research.
- The application should include a large number of diverse primary care sites. Potential settings may include academic and non-academic sites (e.g., community-based health centers, safety net clinics, independent primary care clinics, etc.). Inclusion of non-academic sites is highly desirable. Federal/governmental sites may be included.
- The primary care practices must have established team-based relationships with clinical pharmacists authorized by collaborative practice agreements and/or by a documented privileging process to engage in patient encounters. While most practices should have
established relationships with an embedded clinical pharmacist, practices without a clinical pharmacist may be included as long as the practice embeds a pharmacist as part of this grant, adheres to the requirements of the application, and plans to continue to embed the clinical pharmacist after the grant funding ends.

- The primary care practices must have an electronic patient registry or a means of identifying patients most in need of comprehensive medication management.
- Clinical pharmacists must have read/write access in the electronic medical records at the primary care practice sites.
- All primary care practice sites participating in the study must obtain/submit a letter of commitment from the Chief Medical Officer, Medical Director, or other appropriate administrator endorsing participation in the study.
- Primary care practice(s) participating in the study must have existing quality measures that are reported on a regular basis for practice improvement (e.g., hospitalizations, emergency department visits, clinical care gaps, clinic revenue).
- The primary care practice(s) must provide or have the commitment to provide comprehensive medication management services (in accordance with ACCP standards regarding care process and documentation) in the context of team-based care delivery.
- Preference will be given to primary care practice sites that utilize clinical pharmacists certified by the Board of Pharmacy Specialties (BPS) or who are eligible for BPS certification.
- All applicants will be expected to obtain approval from an Institutional Review Board (IRB) or Boards, as applicable. Applicants are strongly encouraged to apply for IRB approval at the time of full proposal submission to avoid delay in project initiation.

Selection Criteria

Applications meeting the minimum qualifications will be reviewed by an expert panel. Applications will be assessed on the following:

- Whether high-risk, high cost patients can be identified and stratified to receive CMM.
- Whether the approaches employed are novel or innovative, could drive system change improvements, and catalyze efforts to improve primary care performance through CMM.
- Whether the approach to delivery of CMM follows a consistent patient care process and is aligned with the ACCP Standards of Practice, particularly standards II & III.²
- Whether the aims, methods, strategies, analyses, number and diversity of practices, and contextual environment are realistically appropriate to address CMM implementation in the context of primary care delivery.
- Whether the work proposed is aligned with the focus on implementation science (as described above) and can be assessed through a “plan-do-study-act” cycle of continuous quality improvement to generate timely, real-world learnings that inform continual change, sustainability, and scalability. That is, investigators are expected to indicate how their proposed study will advance CMM and ensure more widespread uptake and implementation in real-world practices.
- The involvement of stakeholders (e.g., providers, office staff and managers, practice administrators, payers, and policymakers) in determining the relevant outcomes and approach to pursuing this research.
• The robustness and meaningfulness of the clinical outcomes and practice performance measures, including the ability to provide comparator data to assess the impact on outcomes.
• Applicants’ demonstrated credibility and influence in their targeted communities based on the types and quality of partnerships and coalitions presented.
• The anticipated deliverables.
• The plan for scalability and sustainability.
• The reasonableness of the budget and a timeline for completing the proposed work within 2 years.

Applications also will be reviewed for completeness of the project plan, organizational capacity, and the appropriate representation and participation of stakeholders, partners, and collaborators.

General Provisions

ACCP reserves the right to:
• Reject any or all letters of intent or proposals submitted.
• Request additional information from any applicant.
• Conduct discussions with applicants for the purpose of clarification to assure full understanding of and responsiveness to the solicitation requirements.
• Modify/reduce portions of the applicant’s budget submission.

Timetable

Online inquiries and letters of intent will be accepted until June 1, 2015. Notification of the invitation to submit a full proposal will be sent on June 15, 2015.

If invited to submit, proposals will be due on or before August 1, 2015 and applicants will be notified of a final decision by September 15, 2015.

Inquiries

Online inquiries will be accepted through the RFA Web site at www.accpri.org/CMMRFA.

How to Apply

Online Letter of Intent: Submit at the RFA Web site (www.accpri.org/CMMRFA).
Applicant Organization(s).
State your proposed partners and collaborators and briefly describe the value they bring to the proposed work.
State your anticipated specific aims/research questions.
Briefly describe your approach to study design, measures, and evaluation.
Briefly describe your approach to ensure continuous quality improvement and fidelity of the CMM intervention?
What makes your team uniquely positioned to do this work?
Contact Information
Name of Program Director(s)/Principal Investigator(s) and Co-Investigator(s), as appropriate.
E-mail address(es).
Phone number(s).
PD/PI Biosketches.

Submitting Organization Description.
Key Partner Organizations and Collaborators (provide names of major partners and collaborating entities only; specific personnel should be listed in the budget and budget justification. Note that the budget and budget justification are required at the time of full application only, not as a part of the LOI).

Definition of Program Director(s)/Principal Investigator(s) (PD/PI)
The individual(s) designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the applicant organization, or as appropriate, to a collaborating organization for the proper conduct of the project or program including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI. Although all PD/PIs are responsible for the content of all reports, only one PD/PI (contact PD/PI) should submit a report to ACCP.

Definition of Co-Investigator
An individual involved with the PD/PI in the scientific development or execution of a project. The Co-Investigator (collaborator) may be employed by, or be affiliated with, the applicant/recipient organization or another organization participating in the project under a consortium agreement. A Co-Investigator typically devotes a specified percentage of time to the project and is considered senior/key personnel. The designation of a Co-Investigator, if applicable, does not affect the PD/PI's roles and responsibilities, nor is it a role implying multiple PD/PI.

Online Application
Upon notification to submit a full proposal, applicants must complete the online application process. The research proposal should not exceed 12 pages and the proposed budget and budget justification should not exceed 3 pages. These page limits do not include letters of commitment or letters of support.

Research Proposal (12 pages)

1. Overview and Specific Aims (1 page).

2. Relevant Background and Prior Work (1 page).
   Describe your individual or team experience as it relates to A) understanding the current problem and B) your evaluation and implementation of the proposed intervention.
3. Innovation (1 page).
   Briefly describe what it is about your approach to addressing this problem that makes your proposal unique and innovative, and well-suited to significantly advance CMM in the context of primary care delivery. Explain your approach to involving stakeholders (e.g., providers, patients, primary care practice staff, practice administrators, payers, policymakers) and incorporating stakeholder relevant outcomes into this research.

4. Primary Care Practice Site Descriptions, Clinical Pharmacist Descriptions, and Resources Available to Support the Practice (up to 3 pages total).
   Include a description of each practice site participating in the study (e.g., total patient population registered to the practice, patient mix, payer mix, number of providers, other personnel staffing in clinic, type of clinic, PCMH certification, resources available within the clinic to facilitate this work). Include a description of the clinical pharmacist(s) in the practice (e.g., qualifications and training, amount of time they are or will be devoted to providing CMM). Describe any collaborative practice agreements or scopes of work that exist or will be established, if necessary.

5. Patient Identification and Intervention Design (2 pages).
   Describe how the practice will identify, stratify, and target patients in need of CMM. Describe the CMM intervention that you will employ and study. How will you arrange for patients to receive CMM? Where will CMM be delivered? How and where will you document your encounters? How will you coordinate care and ensure collaboration and communication with care team members internal and external to the practice? How does the practice generate clinical queries and reports and monitor the quality of care delivered?

   Describe your study design, sample size considerations, process and outcome measures, and evaluation plan, considering the focus on both effectiveness and, importantly, real-world implementation science as described in the RFA. Describe your approach to ensuring data quality, security, and confidentiality. How will you ensure the fidelity of the CMM intervention in the context of care delivery? Describe your approach to incorporating a plan-do-study-act cycle of improvement.

7. Plan for Sustainability (0.5 page).
   Outline your plans for sustaining the CMM services delivered by a clinical pharmacist embedded in the primary care practice as an integral member of the health care team.

8. Plan for Dissemination and Scalability (0.5 page).
   Outline your plans for disseminating and scaling the CMM service beyond the primary care practices participating in this project.

9. Deliverables (0.5 page).
   Outline the deliverables that will be produced throughout and at the end of the proposed study.

Timeline (1 page).

Provide a timeline for the proposed study.
Proposed budget and budget justification (3 pages).

Include the budget requested per year, budget justification, and a brief overview of in-kind support. No more than 10% indirect costs are allowable. In-kind contributions will be weighed positively in application evaluation.

Letters of commitment.

Submit a letter of commitment from each primary care practice site's Chief Medical Officer, Medical Director, or other appropriate administrator endorsing its participation in the study. If the number of practice sites makes it impractical to include a letter from each site administrator with the full application, PIs should list each practice site from which you have received a written or verbal commitment to participate in the study, understanding that upon awarding the grant ACCP may ask to review written letters of commitment for each site as a part of the grantee’s acceptance and confirmation process.

Letters of support.

Submit a letter of support from each of the principal investigator's primary supervisors attesting to the availability of the necessary time and resources to successfully fulfill the objectives of the application.

Post-Award Administration

If multiple PD/PIs are from multiple organizations, ACCP’s preference is to issue the award to the applicant organization which will administer the award using consortium or subaward arrangements. Budgets, including F&A costs associated with subawards, will be subject to ACCP's policy of no more than 10% overall indirect costs. Responsibility for all required reports is shared by the PD/PIs and the recipient institution.

Appendix

ACCP will allow an appendix to the CMM application. It is important to note that the Appendix may not be used to circumvent the page limitations of the Research Proposal.

Materials Allowed in the Appendix

Publications:
• Applicants may submit up to 3 of the following types of publications.
  ◦ Manuscripts and/or abstracts accepted for publication but not yet published.
  ◦ Published manuscripts and/or abstracts only when a free, online, publicly available journal link is not available.
  ◦ Patent materials directly relevant to the project.
Other:
• Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents may be submitted in the Appendix as necessary.