

**Pfizer Medical Education Group  
Request for Proposals (RFP)  
The Role for Appropriate Opioid Medication Use as Part of a Comprehensive Pain  
Management Approach**

**I. Background**

The mission of the Pfizer Medical Education Group is to accelerate the adoption of evidence-based innovations that align the mutual interests of the healthcare professional, patients, and Pfizer, through support of independent professional education activities.

The intent of this document is to encourage organizations with a focus in healthcare professional (HCP) education and/or quality improvement to submit letters of intent (LOIs) in response to a Request for Proposal (RFP) that is related to education in a specific disease state, therapeutic area, or broader area of educational need. The new RFP model is a two stage process: Stage 1 is the submission of the LOI. If, after review, your LOI is accepted, then you are invited to submit your full program proposal. Stage 2 is the submission of the Full Grant Proposal.

When a RFP is issued, it is posted on the Pfizer Medical Education Group website ([www.Pfizermededgrants.com](http://www.Pfizermededgrants.com)) as well as those of other relevant organizations and is sent via e-mail to internal lists of all registered organizations and users in our grants system.

## II. Requirements

<b>Date RFP Issued:</b>	7/26/2012
<b>Clinical Area:</b>	Opioid Pain
<b>Specific Area of Interest for this RFP:</b>	<p>Assess the impact of a comprehensive program that would apply evidence based clinical guidelines to improve appropriate prescribing of prescription opioid medications. Pain types which are within scope of this proposal include moderate to severe acute and chronic non-cancer pain.</p> <p>Programs should strive to balance successful pain management with risk management, including risk of misuse, abuse, and diversion. Effort should be made to incorporate and or complement previously established evidence based guidelines and diagnostic tools, and to incorporate opioid medication use into a multidisciplinary pain program.</p> <p>Successful proposals will demonstrate a plan to generate evidence that health care provider education combined with other quality improvement measures has had an impact on clinical and/or safety outcomes (e.g., pain scales, functional or quality of life measures, discontinuation of treatment due to adverse events, or reductions in abuse and misuse). In addition, health economic (e.g., health care resource utilization, per patient cost, overall direct &amp; indirect cost) outcomes should be considered.</p> <p>Programs must describe how interventions, when implemented, will directly impact patient care and provide evidence of scalability (e.g., integration with an electronic medical record system) and sustainability (e.g., plan to extend beyond the proposed institution).</p> <p>NOTE: This initiative is not associated with the ER/LA Opioid REMS program mandated by the FDA.</p>

<p><b>Disease Burden Overview:</b></p>	<p>According to the 2011 IOM Report on Pain, as many as 100 million adults in the US report having a common chronic pain condition, exceeding the number affected by heart disease, cancer, and diabetes.<sup>1</sup> When pain is poorly managed, patients report a substantial burden of illness regardless of the type of pain condition. Inadequately managed pain can lead to unfavorable physical and psychological outcomes not only for individual patients, but also for their families.<sup>2</sup> In addition, acute pain is regarded as the most common symptom of many illnesses and if left untreated it can produce acute neurohumoral changes, neuronal remodeling, and long-lasting psychologic and emotional distress which may lead to prolonged chronic pain states.<sup>[1]</sup> Untreated acute post operative pain can also result in subsequent increase in morbidity and mortality.<sup>4, 5</sup></p> <p>The economic burden of pain to society is staggering. The 2011 IOM Report on Pain suggests that annual health economic impact of pain represents a \$560 to \$635 billion burden in the US (in 2010 dollars).<sup>1</sup></p> <p>Prescription opioid medications can be an effective component of a multidisciplinary approach to management of moderate to severe acute and chronic pain. Safe and effective opioid therapy requires clinical skills and knowledge in both the principles of opioid prescribing and on the assessment and management of risks associated with opioid abuse, addiction, and diversion. To provide guidance to clinicians, the American Pain Society and Academy of Pain Medicine issued evidence based clinical practice guideline to assist clinicians in prescribing potent opioid pain medications for patients with chronic non-cancer<sup>6</sup> and similar clinical guidelines for opioid use have been developed by others.</p>
<p><b>Barriers:</b></p>	<p><b>Physician Barriers:</b></p> <p>Despite being an appropriate therapeutic modality for many non-cancer patients with pain, some clinicians have been hesitant to prescribe opioids for several reasons: the perceived and real legal ramifications of prescribing controlled substances; known adverse-effects of opioid therapy; the potential need for increasing doses related to tolerance to therapy or disease progression; the potential for addiction and abuse of opioids; the inability to predict when an opioid will be effective; incomplete relief or need for relatively higher doses when chronic opioids are used to treat non-cancer pain; lack of belief in patient subjective reports of pain; complexity of having to write monthly prescriptions for controlled substances; difficulty dealing with co-morbidities in the chronic pain population. These beliefs can form barriers to the use of opioids for appropriate patients.<sup>7</sup></p>

**Recommendations  
and Target  
Metrics:**

**System Barriers:**

There is growing recognition that optimal pain management requires a interdisciplinary approach.<sup>8</sup> This is particularly true when opioid medications are part of the treatment approach. Physicians, nurses, physician assistants, pharmacists and others should work together to ensure patients understand their medication regimen, potential side effects, what to do if pain is not managed, and to screen for potential misuse and abuse<sup>9</sup> However, many physician practices are not designed for the level of patient education required for pain patients, nor do they have ready access to validated screening tools, or if they do, they may not use them or are not able to interpret them accurately. Compounding the issue is the lack of reimbursement for time spent in patient education and screening.<sup>1</sup>

**Clinical/safety outcome measures:**

- 1) Pain rating scale reduction (e.g., VAS, NRS, etc), either a total reduction value or percentage value (e.g., 50% from baseline rating)
- 2) Objective measure of return to functional improvement
- 3) Patient reported outcome of satisfaction
- 4) Reductions in abuse & misuse

**Health economic measures:**

- 1) Total pain-related healthcare resource utilization and costs, including but not limited to inpatient, ED, outpatient, pharmacy, and physical therapy expenses
- 2) Indirect costs due to lost productivity, absenteeism
- 3) Opioid-related healthcare resource utilization and costs

Process measures such as adherence to guidelines, adherence to REMS programs, utilization of prescription drug monitoring programs (PDMPs), percent of patients receiving opioid medication counseling, and percent of patients screened for relative risk related to abuse or misuse should also be considered.

Novel ways to measure impact of the interventions employed are also encouraged.

**Gaps Between  
Actual and Target  
and Possible  
Reasons for Gaps:**

Although a recent survey of 117 US and Canadian medical schools found that approximately 80% of US medical schools require 1 or more pain sessions in their curricula, the average of 1.4 teaching hrs for clinical assessment, and 0.7 hrs for pharmacological medication management, suggests that training is not optimal.<sup>10</sup> Based on these results, the Johns Hopkins Pain Curriculum Development Team concluded that US medical education on pain is limited, variable, and often fragmentary. Hence, the incorporation of existing evidence based guidelines into practice, as well as advances in patient care at a practical level, are needed.

<p><b>Current Models of Pain Care</b></p>	<p>Pain management, including utilization of opioid medications, occurs throughout the healthcare system including in primary care physician offices, dental offices, emergency departments, hospitals, and pain management centers. While there are some excellent examples of comprehensive, evidence-based pain care systems, often each component has its own approach to pain management and may not communicate with other members of the healthcare system.</p> <p>Implementation of existing evidence based guidelines in everyday practice is necessary. Education and quality improvement initiatives aimed at timely diagnosis, appropriate screening/risk assessment, management of both chronic and acute pain through a multidisciplinary approach, and the benefits and risks of opioid medications including misuse, abuse, and diversion, is essential to making measureable improvements in the care of patients with pain.<sup>10</sup></p>
<p><b>Target Audience</b></p>	<p>Primary Care Providers</p>
<p><b>Geographic Scope:</b></p>	<p><input checked="" type="checkbox"/> United States Only  <input type="checkbox"/> International (specify country/countries)_____</p>
<p><b>Applicant Eligibility Criteria:</b></p>	<p>Medical, dental, nursing, allied health, and/or pharmacy professional schools, healthcare institutions, for-profit health systems, professional associations and other not-for-profit entities may apply. Collaborations between organizations are encouraged.</p>
<p><b>Expected Approximate Monetary Range of Grant Applications:</b></p>	<p>Individual grants requesting up to \$1,000,000 will be considered. Preference will be given to applications requesting \$500,000 or less in order to permit support for more than one proposal. The total available budget related to this RFP is \$1,000,000.</p> <p>The amount of the grant Pfizer will be prepared to fund for any full proposal will depend upon Pfizer’s evaluation of the proposal and costs involved and will be clearly stated in the grant approval notification.</p>

<p><b>Key Dates:</b></p>	<p><b>RFP release date:</b> 7/26/2012</p> <p><b>Letter of Intent due date:</b> 8/23/2012  <i>(Please note you must be registered in the system to submit an LOI. Please attempt to complete this process at least one week prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted).</i></p> <p><b>Anticipated LOI Notification Date:</b> 10/10/2012</p> <p><b>Please note, full proposals can only be submitted following acceptance of an LOI</b></p> <p><b>Full Proposal Deadline:</b> To be communicated on acceptance of an LOI.</p> <p><b>Anticipated Full Proposal Notification Date:</b> 12/14/2012</p> <p><b>Anticipated award delivered following execution of fully signed LOA</b></p> <p><b>Period of Performance:</b> 12/2012 to 12/2014</p>
<p><b>How to Submit:</b></p>	<p>Submit LOIs online via the Pfizer Medical Education Group website <a href="http://www.pfizermededgrants.com">www.pfizermededgrants.com</a></p> <p>Submit LOIs in the clinical area: LOI-RFP Opioid Pain</p> <p><b>Requirements for submission:</b>  If not already registered, register in the system to submit an LOI. Please attempt to complete this process at least one week prior to submission in order to avoid delays as all registrations must be approved before access to the system is granted.</p> <p>Complete all applicable sections of the online application and upload the completed LOI guidance template.</p> <p>Note that only certain sections/questions of the application are applicable to the Letter of Intent submission <i>(see details in LOI guidance below)</i>.</p>
<p><b>Questions:</b></p>	<p>If you have questions, please submit them in writing so that if appropriate Questions and Answers can be posted on the website. Send questions to <a href="mailto:MedEdGrants@Pfizer.com">MedEdGrants@Pfizer.com</a> with the subject line "RFP Opioid Pain 7/26/2012"</p> <p>.</p> <p>Other communications may also be directed to the Education Director for this clinical area, Robert E. Kristofco, via email <a href="mailto:robert.kristofco@pfizer.com">robert.kristofco@pfizer.com</a></p>

<b>Date Grant Award Decisions Will Be Made:</b>	12/14/2012
<b>Mechanism by Which Applicants will be Notified:</b>	All applicants will be notified via email on or before 12/14/2012. Providers may be asked for additional clarification or to make a summary presentation during the review period.

### **III. References**

1. Committee on Advancing Pain Research, C.a.E. and M. Institute of, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*: The National Academies Press.
2. Jack Hadley, J.H., Teresa Coughlin and Dawn Miller, *Covering The Uninsured In 2008: Current Costs, Sources Of Payment, And Incremental Costs*. Health Aff, 2008. 27 (5): p. w399-w415.
3. Dunwoody, C.J., et al., *Assessment, physiological monitoring, and consequences of inadequately treated acute pain*. Pain Manag Nurs, 2008. 9(1 Suppl): p. S11-21.
4. Sharrock, N.E., et al., *Changes in mortality after total hip and knee arthroplasty over a ten-year period*. Anesth Analg, 1995. 80(2): p. 242-8.
5. Katz, J., et al., *Acute pain after thoracic surgery predicts long-term post-thoracotomy pain*. Clin J Pain, 1996. 12(1): p. 50-5.
6. Chou, R., et al., *Clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain*. The Journal of Pain, 2009. 10(2): p. 113-30.
7. The Management of Opioid Therapy for Chronic Pain Working Group. *The VA/DoD Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain*. May, 2010.
8. American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Practice Guidelines for Chronic Pain Management*. Anesthesiology, 2010. 112: p. 810-33.
9. Turk, D.C., et al., *Interdisciplinary Pain Management*. APS Position Statement. <http://www.ampainsoc.org/advocacy/downloads/2010%20Interdisciplinary%20White%20Paper-FINAL.pdf>. Accessed June 10, 2012.
10. Mezei, L. and B.B. Murinson, *Pain education in North American medical schools*. J Pain. 12(12): p. 1199-208.

### **IV. Terms and Conditions**

1. Complete TERMS AND CONDITIONS for Certified and/or Independent Professional Healthcare Educational Activities are available upon submission of a grant application on the Medical Education Group website [www.Pfizermededgrants.com](http://www.Pfizermededgrants.com).

2. This RFP does not commit Pfizer to award a grant, or to pay any costs incurred in the preparation of a response to this request.
3. Pfizer reserves the right to accept or reject any or all applications received as a result of this request, or to cancel in part or in its entirety this RFP, if it is in the best interest of Pfizer to do so.
4. Pfizer reserves the right to announce the details of successful grant application(s) by whatever means insures transparency, such as on the Pfizer website, in presentations, and/or in other public media.
5. For compliance reasons and in fairness to all providers, all communications about the RFP must come exclusively to the Medical Education Group. Failure to comply will automatically disqualify providers.

## **V. Transparency**

Consistent with our commitment to openness and transparency, Pfizer reports its medical educational grants and support for medical and patient organizations in the United States. In the case of this RFP, a list of all LOIs selected to move forward will be publicly disclosed. In addition, all approved full proposals, as well as all resulting material (e.g., status updates, outcomes reports etc) will be posted on the website.

## **VI. Letter of Intent Guidance**

The Letter of Intent (LOI) is intended to be a brief concept document, describing the proposed project at a high level. The External Review Panel will select LOIs that best align with the intent of the Request for Proposal. All applicants will be notified with either an acceptance or a declination. Successful applicants will be asked to submit a full grant proposal for consideration for funding. **LOIs must be single spaced using Calibri 12-point font and 1-inch margins.**

**There is a 3-page limit.**

Please include the following information in the LOI:

- A. Project Title
- B. List of the organization(s), department(s), or team members involved in project, as well as principal investigator.
- C. Primary goal(s) and brief description of project
- D. Baseline data summary, initial metrics or project starting point. What is the practice gap that will be addressed or improved?
- E. Technical Approach. What educational or quality improvement methods will be used as part of the project?
- F. Describe how this initiative builds upon existing work, pilot projects, prior collaborations, or ongoing programs.



G. Explain how the impact of the project would be evaluated. What are the goals or target measures of success? How might the program/project be sustained after the funding expires? To what extent is the program/project disseminable?

H. Project Timeline I. Requested Amount J. CV of PI (does not count toward 3-page limit)

***Please note that the three (3) page limit for the Letter of Intent (LOI is inclusive of additional information of any kind. A submission of any more than three (3) pages WILL BE REJECTED and RETURNED UNREVIEWED. The CV of the PI should be the only additional documentation beyond the three (3) page LOI.***

## **VII. Full Proposal Grant Review and Decision Making Criteria**

In order to provide some guidance for applicants considering submission of a LOI, some of the criteria that will ultimately be used to evaluate full grant proposals will be:

- The clarity and convincing nature of the “needs and gaps” analysis of the current practice and the metrics by which the applicant will assess their success and achievement of their goals and objectives.
- The assessment of current practice including aggregate patient level data, including a description of what quality indicators or performance measures will be utilized to measure the impact of the initiative proposed, and the rationale of why these were chosen.
- The assessment of barriers and possible solutions, including an approach for addressing unexpected contingencies.
- The inclusion of integrated, comprehensive approaches to change that addresses not only performance gaps of individual healthcare providers but also the performance of the entire team and the healthcare delivery system.
- The extent of intra-organization and/or inter-organization collaboration.
- The extent to which tools, resources, educational materials, or courses will be open-source and available for others to use following the completion of proposed initiative.
- Evidence of sustainability and/or exportability and the degree to which the proposal provides a model that could be disseminated or replicated. Successful LOI applicants will be asked to include in their full proposals: biographical sketches of project team members; and also to the extent possible flow charts of specimen flow and patient flow.