

**Pfizer Medical Education Group
Request for Proposals (RFP):
Improve Outcomes and Optimize Healthcare Utilization for
Patients with Chronic Pain in a Primary Care Setting**

I. Background

The Pfizer Medical Education Group or MEG is the unit within Pfizer that provides independent grants to facilitate patient care improvements by supporting initiatives aimed at exploring approaches to closing gaps in clinical practice. The term “Independent” means that the initiatives that the grants help to support are the full responsibility of the receiving organization. Pfizer has no influence over any aspect of the project, and only asks for reports about the results and impact of the projects in order to share them publicly.

A gap in clinical practice is considered to be the difference between what is currently happening and what should be happening to meet the highest optimal standard of care.

Gaps may relate to:

- the ability or competencies of the healthcare professionals themselves,
- the abilities of the systems in which they work to promote or allow proper treatment and
- other factors related to the external environment or patient population.

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

The Pfizer Medical Education Group posts RFPs related to addressing gaps in practice in order to identify and support initiatives designed to impact these gaps. RFPs generally identify a clinical challenge and encourage applicants to address this challenge using strategies that address the development, adoption and/or integration of evidence-based health interventions to impact practice within specific settings. Examples of approaches might include:

- Identification of strategies to encourage provision and use of effective health services
- Identification of strategies to promote the integration of evidence into policy and program decisions.
- Appropriate adaptation of interventions according to population and setting
- Identification of approaches to scale-up effective interventions
- Development of innovative approaches to improve healthcare delivery
- Setting up an impact evaluation for a population based intervention

Pfizer is particularly vested in supporting programs that develop and implement interventions that are followed by rigorous assessment of the “efficacy” of the intervention examining outcomes that may include both short and long term improvements in physician behavior and patient care. The objective of this RFP is to develop and implement an educational or quality

improvement intervention that addresses current gaps in the treatment of chronic pain and leads to an improvement in patient outcome and/or optimization of health care utilization.

The intent of this RFP is to encourage organizations with a focus in healthcare professional education and quality improvement to submit Letters of Intent (LOIs) related to the gaps described on the following pages. ***Successful applicants will be able to describe the specific quality gaps or problems in practice that exist for their own learners, or system, or community, and describe what they will do to close these gaps or problems.***

This RFP model employs 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.

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II. Requirements

Date RFP Issued:	1/28/2013
Clinical Area:	Chronic Pain Care
Specific Area of Interest for this RFP:	<p>Design and implement a comprehensive learning and change interventional strategy for the primary care setting, targeting <u>primary care physicians</u>, that promotes improved management of adults with <u>chronic pain</u> to enhance patient outcomes, such as improvements in pain or function and reductions in misuse and abuse of prescription opioid medications, and/or optimize healthcare utilization. Programs should incorporate use of diagnostic tools to aid diagnosis of the underlying pain condition(s) and utilize current evidence-based treatment guidelines to guide appropriate <i>first line</i> treatment selection based on the underlying pain condition and include non-pharmacological treatment modalities. In addition, programs should incorporate current opioid guidelines and screening tools to ensure appropriate utilization of opioid medications, that balances need with risk, should other treatment options not provide sufficient relief. The program should utilize systems within the patient electronic health record (EHR) to document patient history, to aid in patient assessment, guide and track PCP intervention, and monitor patient response. The “efficacy” of the educational intervention on PCP behavior and patient outcomes should be assessed by measuring changes in relevant clinical outcomes as outlined below.</p> <p>Successful proposals will include a detailed plan to generate quantitative evidence that the educational intervention has a long lasting impact on physician behavior and that this change in behavior is associated with changes in both clinical and/or safety outcomes. In addition, assessment of health economic (e.g., health care resource utilization, per patient cost, overall direct & indirect cost) outcomes should be considered. This proposed approach should include a pre- and post-intervention assessment or a comparison to a control group receiving no education and tools.</p> <p>Programs must describe how the intervention, 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 REMS program mandated by the FDA.</p>

Disease Burden Overview:

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.¹ When chronic pain is poorly managed, patients report a substantial burden of illness regardless of the type of pain condition.^{2,3} Continuous, unrelieved pain can have negative effects on the immune, cardiovascular, gastrointestinal, and renal systems and can reduce patient mobility. It can lead to anxiety disorders including panic, generalized anxiety and post traumatic stress disorder.^{3,4} , On-going and unrelieved pain can create a cycle of increased anxiety and depression which, in turn, can amplify the pain.⁵ Patients with greater pain severity report increased difficulties with functioning, sleep, and overall health status.⁶ Finally, inadequately managed pain can lead to unfavorable physical and psychological outcomes not only for individual patients, but also for their families.³ 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).¹

Management of chronic pain can be considered within the context of a chronic care model, where improved outcomes are achieved when patients are informed and engaged in their care, providers are proactive, care is patient-centric and collaborative, and community and other resources are appropriately accessed. As with other chronic conditions such as diabetes, hypertension and COPD, patient education and coordination of care are essential and need to be integrated with the diagnosis and continued throughout chronic pain management. Integration of non-pharmacologic treatment approaches early in the assessment and treatment plan helps to reinforce the importance of the patient's role in his or her own care.⁷

Diagnosis of the underlying pain condition can be guided by the patients descriptions of the pain as well as by the use of diagnostic tools. Selection of the *initial* pharmacological treatment should be guided by the underlying pain pathology(s) and use of evidence-based guidelines that have been developed for specific chronic pain conditions such as osteoarthritis, low back pain, fibromyalgia and different neuropathic pain conditions. As chronic pain often involves multiple symptom domains in addition to pain the assessment and treatment plan should be individualized to reflect the individual patient's underlying chronic pain disorder, the particular mix of symptoms, the patient's priorities and preferences, cognitive / emotional and social support, and financial circumstances.

While prescription opioid medications can be an effective component of a multidisciplinary approach to management of moderate to severe chronic pain, they should be reserved for use only when other first line treatment options have been proven to be inadequate, or if first line treatments are contraindicated.^{8,9} Moreover, 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 prescription opioid abuse, addiction, and diversion. To provide guidance to clinicians, the American Pain Society and Academy of Pain Medicine have issued clinical practice guidelines to assist clinicians in prescribing potent opioid pain medications for patients with chronic non-cancer, and similar clinical guidelines for opioid use have been developed by others.^{8,9} Finally, opioids formulated with tamper resistant technologies (TRTs) have recently been approved. Misuse and abuse of the TRT formulation of Oxycontin is reduced compared with the previous non-TRT version of oxycontin.¹⁰

Gaps and Possible Reasons for Gaps

Based on a national mail survey of primary care physicians, pain specialists, chiropractors, and acupuncturists primary care physicians treat the majority of chronic pain patients in the US.¹¹ In addition, primary care is typically where people first report pain to the health care system and in a national survey conducted in the late 1990s, 80% of people currently experiencing severe pain said they had never been referred to a specialized pain program or clinic (American Pain Society, 1999); thus the primary care practitioner's response may be crucial in providing timely relief and preventing acute or early chronic pain from progressing to a persistent or severe chronic state.¹² Thus, it is important that primary care physicians make every effort to address both the non-pharmacologic and pharmacologic aspects of pain management.

However, there is a striking discrepancy between the high prevalence, cost, and complexity of pain and the sparse efforts to educate primary care physicians pain and pain management. Based on their own self-report, PCPs do not receive enough pain management education and training.^{1, 13} In addition, a large number of U.S. medical schools do not teach pain or pain management, or devote fewer than 5 hours to the topic.¹⁴

In addition to lack of education and training, a number of barriers to effective pain care involve the attitudes and training of the providers of care. First, health professionals may hold negative attitudes toward people reporting pain and may regard pain as not worth their serious attention. Second, the profession and culture of medicine generally focus on biological rather than psychosocial causes and effects of illnesses. Third, although pain is one of the most common reasons people seek treatment; clinicians may not ask about or thoroughly investigate pain. Fourth, while evidence-based protocols and guidelines exist to assist primary care practitioners in treating people with chronic pain these protocols are used only rarely to treat pain in primary care practice. Finally, while interdisciplinary, team approaches can facilitate high-quality pain care such team approaches are not consistently used in pain care.

Recommendations and Target Metrics:	<p>The impact of the program on improving the diagnosis and management of chronic pain should be assessed including an increase in utilization of guideline-recommended treatment options and corresponding reduction in utilization of opioids as a first line treatment option. The impact of the program on patient outcome should be assessed including reduction in pain severity, and/or improvement in function. The program should also measure the impact on prescription opioid medication misuse and abuse of incorporating a “universal precaution” approach to assess and monitor for risk of prescription opioid abuse and misuse for patients where opioids are a needed treatment option due to lack of sufficient response to non-opioid therapy. Finally, the program should assess the impact of the intervention on health care costs.</p> <p>Other suggested metrics include assessment of the impact of the educational intervention on the following:</p> <p>Clinical Outcome Measures:</p> <ol style="list-style-type: none"> 1. Clinical outcome measures: <ul style="list-style-type: none"> • Objective measure of improvement in quality of life • Patient reported outcome of satisfaction • Increased utilization of elements in opioid guidelines including patient agreements, urine drug screens, risk assessment tools, prescription monitoring programs etc. • Incorporation of opioids with tamper resistant technologies to mitigate risk of tampering when opioids are prescribed • Increase use of EMR to track access of tools to aid diagnosis, guide treatment, monitor response, assess risk of misuse & abuse etc 2. Cost Measures: <ul style="list-style-type: none"> • Total pain related healthcare utilization and costs, including but not limited to inpatient, ER, outpatient, pharmacy, and physical therapy expenses • Total pain related indirect costs due to lost productivity, absenteeism, presenteeism, etc
Target Audience	The focus of the program should be generating meaningful change among primary care physicians
Geographic Scope:	<input checked="" type="checkbox"/> United States Only <input type="checkbox"/> International (specify country/countries)_____
Applicant Eligibility Criteria:	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>Expected Approximate Monetary Range of Grant Applications:</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 \$2,000,000</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>Key Dates:</p>	<p>RFP release date: 01/28/13</p> <p>Letter of Intent due date: 02/22/2013.</p> <p>Anticipated LOI Notification Date: April 2013</p> <p>Please note, full proposals can only be submitted following acceptance of an LOI</p> <p>Full Proposal Deadline: To be communicated on acceptance of an LOI</p> <p>Anticipated Full Proposal Notification Date: June 2013</p> <p>Anticipated award delivered following execution of fully signed LOA</p> <p>Period of Performance: 7/2013 to 7/2015</p>
<p>How to Submit:</p>	<p>Please go to the website at www.pfizer.com/independentsupport and click on the button "Go to the Grant System".</p> <p>You will be prompted to take the <i>Eligibility Quiz</i> to determine the type of support you are seeking. Please ensure you identify yourself as a first-time user.</p> <p>Submit LOIs in the clinical area: Chronic Pain Care</p> <p>Requirements for submission: Complete all required sections of the online application and upload the completed letter of intent template. (<i>see Appendix</i>)</p>
<p>Questions:</p>	<p>If you have questions regarding this RFP, please direct them in writing to the Grant Officer for this clinical area, Robert Kristofco at (robert.kristofco@pfizer.com), with the subject line "RFP Chronic Pain Care 1/28/13"</p>
<p>Date Grant Award Decisions Will Be Made:</p>	<p>June 2013</p>

Mechanism by Which Applicants will be Notified:	All applicants will be notified via email by the dates noted above. Providers may be asked for additional clarification or to make a summary presentation during the review period.
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III. 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.pfizer.com/independentsupport
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.

IV. 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.

V. 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. Cole BE. Pain Management: Classifying, understanding, and treating pain. *Hosp Physician*. 2002;38:23-30.
3. Winterowd C, Beck AT, Gruener, D. *Cognitive Therapy for Chronic Pain Patients*. New York: Springer Publishing Company; 2003.

4. Buenaver LF, Edwards RR, Haythornthwaite JA. Pain-related catastrophizing and perceived social responses: interrelationships in the context of chronic pain. *Pain*. 2007;127:234-42.
5. Wells N, Pasero C, McCaffery M. Improving the Quality of Care through Pain Assessment and Management. In: Hughes RG, ed. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville, MD: Agency for Healthcare Research and Quality (US); 2008.
6. Hoffman DL, Sadosky A, Dukes EM, Alvir J. How do changes in pain severity levels correspond to changes in health status and function in patients with painful diabetic peripheral neuropathy? *Pain*. 2010;149:194-201.
7. Argoff CE, Albrecht P, Irving G, Rice F. Multimodal analgesia for chronic pain: rationale and future directions. *Pain Med*. 2009;10(Suppl 2):S53-66.
8. Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain. *J Pain*. 2009;10:113-130.
9. VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain. 2012.
10. Butler SF, Cassidy TA, Chilcoat H, Black RA, Landau C, Budman SH, Coplan PM. Abuse Rates and Routes of Administration of Reformulated Extended-Release Oxycodone: Initial Findings From a Sentinel Surveillance Sample of Individuals Assessed for Substance Abuse Treatment. *J Pain*. 2012 (epub)
11. Breuer B, Cruciani R, Portenoy RK. Pain management by primary care physicians, pain physicians, chiropractors, and acupuncturists: a national survey. *South Med J*. 2010 Aug;103:738-47.
12. Dobkin PL, Boothroyd LJ. Organizing health services for patients with chronic pain: when there is a will there is a way. *Pain Med*. 2008; 9:881-9
13. Pizzo PA, Clark NM. Alleviating suffering 101 – pain relief in the United States. *N Engl J Med*. 2012;366:197-199.
14. Mezei N, Murinson B, Johns Hopkins Pain Curriculum Development Team. Pain education in north american medical schools. *J Pain*. 2011;12:1199-1208.

Appendix: Letter of Intent Submission Guidance

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. Note that the main section of the LOI has a 3-page limit. ***Any proposals not meeting these standards will not be considered.***

LOIs will include the following sections

Main Section (not to exceed 3 pages):

A. Title

B. Goal

1. Briefly state the overall goal of the intervention

C. Objectives

1. List the *overall* objectives you plan to meet with your intervention both in terms of learning and expected outcomes. Do not include learner objectives.

D. Assessment of Need for the Intervention

1. Please include quantitative baseline data summary, initial metrics (e.g., quality measures), or project starting point (please cite data on gap analyses or relevant patient-level data that informs the stated objectives) in *your* target area. Describe the source and method used to collect the data. Describe how the data was analyzed to determine that a gap existed. The RFP includes a national assessment of the need for the intervention. Please do not repeat this information within the LOI (you may reference the RFP if needed). Only include information that impacts your specific intervention, linking regional or local needs to those identified on the national basis if appropriate.

2. Describe the primary audience(s) targeted for this intervention. Also indicate who you believe will directly benefit from the project outcomes..

E. Intervention Design and Methods

1. Describe the planned intervention and the way it addresses the established need.

2. Describe the overall population size as well as the size of your sample population.

F. Innovation

1. Explain what measures you have taken to assure that this project idea is original and does not duplicate other programs or materials already developed.

2. Describe how this initiative builds upon existing work, pilot projects, or ongoing programs, etc developed both by your institution or other institutions related to this program

G. Design of Outcomes Evaluation

1. Describe how you will determine if the practice gap identified in the needs assessment was addressed for the target group in terms of the metrics used for the needs assessment.

- Identify the sources of data that you anticipate using to make the determination.
- Describe how you expect to collect and analyze the data.
- Explain the method used to control for other factors outside this intervention (e.g., use of a control group, comparison with baseline data)

2. Quantify the amount of change expected from this intervention in terms of your target audience

3. Describe how you will determine if the target audience was fully engaged in the Intervention.

4. Describe how the project outcomes might be broadly disseminated.

H. Project Timeline

I. Requested Budget

J. Additional Information

1. If there is any additional information you feel Pfizer should be aware of concerning the importance of this project, please note it in within the page limitations

Organizational Detail (not to exceed 1 page)

Describe the attributes of the institutions/organizations/associations that will support and facilitate the execution of the project and the leadership of the proposed intervention.

LOIs should be single spaced using Calibri 12-point font and 1-inch margins. There is a 3-page limit for the main section and 1 page limit for organizational detail. If extensive, references may be included on 1 additional page.

*Please note the formatting and page limit for the LOI. The LOI is inclusive of additional information of any kind. A submission exceeding the page limit **WILL BE REJECTED and RETURNED UNREVIEWED.***