

C. Proposal Narrative: Main Section

1. Overall Goals and Objectives

The primary goals of this initiative are to improve patient safety and outcomes by improving the management and quality of care provided to patients with non-cancer chronic pain using the frameworks of the Chronic Care Model for improving chronic illness care and the Patient Centered Medical Home (PCMH) model for redesigning primary care practice. We will achieve these goals by bringing together a powerful partnership of primary care leaders in Maine with national experts in chronic pain management and leveraging existing PCMH efforts in the state, using the following primary two objectives:

(1) Provide structured quality improvement (QI) support to up to 10 Patient Centered Medical Home (PCMH) practice sites to implement standardized, systematic and team-based processes to improve comprehensive chronic pain management. This QI approach will focus on implementing consistent and reliable processes of care that promote adherence to current best practice guidelines that advance a comprehensive, multi-disciplinary, patient-centered approach to chronic pain management and safe prescribing of opioids.

(2) Provide education, peer support, and specialty expert consultation to primary care providers in these PCMH sites to increase their knowledge and self-efficacy to effectively manage chronic pain. This includes providing education from the Chronic Pain Curriculum developed by the Physician's Institute for Excellence in Medicine (PIEM); providing peer support to providers in participating PCMH practice sites through outreach, education, and collaborative learning opportunities; and offering expert consultation to primary care providers through the Project ECHO (Extension for Community Healthcare Outcomes) initiative for chronic pain management in partnership with the Community Health Center (Middletown, CT).

2. Technical Approach

This initiative will meet the goal of improving chronic pain management using a comprehensive, patient-centered and team-based approach to care by positioning our efforts within a Medical Home context, and leveraging the extensive and ongoing work to implement the Chronic Care and PCMH models in primary care practices in Maine.

Recognizing the essential role of primary care in our healthcare system, Maine Quality Counts (QC) leads several multi-stakeholder efforts to drive quality improvement in primary care, and offers structured learning opportunities and quality improvement assistance to promote adoption of both the Chronic Care and PCMH models of care. Since 2002, QC has led a statewide Learning Community to identify and share best practices for implementing the Chronic Care model.

Additionally, since 2009, Maine has been a leader in the PCMH movement through the Maine PCMH Pilot. Convened by the Dirigo Health Agency's Maine Quality Forum, Maine Quality Counts, and the Maine Health Management Coalition, the Maine PCMH Pilot is a multi-stakeholder statewide effort to implement the PCMH model as the first step in achieving statewide adoption of the model of care to improve quality and control costs of care. The Pilot

was initially launched in January 2010 with 26 practices that achieved NCQA PCMH recognition. Following Maine's selection to participate in the national CMS (Medicare) Multi-Payer Advanced Primary Care Practice (MAPCP) demonstration, the original 3-year timeline of the Pilot was extended to 5 years, and now continues through 2014. The Pilot was also expanded to include an additional 50 practices in 2012, and now includes a total of 75 practices. Additionally, under Section 2703 of the Affordable Care Act, Maine's Medicaid program introduced a Health Homes initiative aligned with the Pilot, adding an additional 80 primary care practices. Together, 155 practices statewide are now actively engaged in PCMH efforts.

The Maine PCMH Pilot and Health Homes initiatives both require that practices achieve NCQA PCMH recognition to participate. Participating practices also commit to implementing a set of ten PCMH "Core Expectations" outlining the key changes required by practices to move to a more patient-centered, high-value model of care, including provider leadership for change, team-based care, and commitment to improve integration of physical and behavioral health.

QC provides quality improvement (QI) support for practice transformation to the 155 PCMH Pilot and Health Homes practices through a range education and outreach efforts, including the Maine PCMH Learning Collaborative. This Collaborative is based on the Institute for Health Care Improvement's (IHIs) Breakthrough Series Learning Collaborative model, and includes 2-3, day-long learning sessions for practice teams each year that focus on one or more of the 10 PCMH "Core Expectations" for practice change. At each learning session, QC features national and/or local practice improvement experts, highlights best practices from participating teams, and provides opportunities for networking and collaborative learning across practices. Practice participation in the learning sessions has been excellent, with at least 3 practice leaders and over 400 individuals now attending each session. QC staff also provide direct QI assistance to practices between learning sessions both directly through practice outreach, site visits, and monthly webinars, and by supporting QI Coaches to work with each practice. QC also offers focused technical assistance related to specific areas of improvement, including health information technology assessment; assistance in engaging patients in their improvement efforts; and improving the integration of behavioral and physical health. Pilot teams report high levels of satisfaction with the transformation support, and have been strong advocates for promoting adoption of the PCMH model with other practices around the state.

As lead organization for this initiative, QC has direct access to and relationships with these 155 NCQA PCMH-recognized practices, as well as an additional 20-30 NCQA PCMH-recognized practices across the state not currently in the Pilot. QC will offer participation in this proposed chronic pain QI initiative by issuing a competitive application to all PCMH practices in Maine, and will select 5-10 practices to participate using pre-identified selection criteria and a multi-stakeholder selection group. Practice sites will be selected based on the strength of their commitment to implement a multifaceted, team-based QI approach to improving chronic pain management based on the elements of the Chronic Care and PCMH models.

Each participating site will also be asked to commit to collecting specific evaluation data through clinical records and their Electronic Health Records (EHR) that can be reviewed and analyzed by the project evaluation team. Baseline data will be generated at each site prior to

the project interventions, and the project evaluation team will analyze baseline data to evaluate provider and patient outcomes at the end of the 9-month period of intervention.

a. *Current Assessment of Need for Improving Chronic Pain Management in Maine*

Like many states, Maine faces enormous challenges with supporting the effective management of chronic pain and unsafe prescribing of prescription opioids. Our experience supporting primary care practices through the Maine PCMH Pilot and other quality improvement initiatives indicates that providers express a lack of confidence and high levels of frustration in managing chronic pain and safe use of opiates, and are eager for assistance to bring a quality improvement approach to this complex issue. In a recent PCMH Learning Session, providers responded overwhelmingly positively to a plenary session focused on chronic pain management and asked for additional assistance to implement QI workflows to support best practices.

Maine also has the unfortunate distinction of being the worst state in the nation for rates of diversion and misuse of prescription opioids. Despite this information, primary care providers inadvertently put patient safety at risk on a daily basis through unsafe prescribing practices that commonly include use of high dose opioids (i.e. greater than 100 morphine equivalents daily); concurrent use of opioids and benzodiazepines; and provision of chronic opioid prescriptions to people with history of addiction and other known high risk factors (e.g. sleep apnea, COPD).

According to the Centers for Disease Control and Prevention *Morbidity and Mortality Weekly Report* (MMWR), Vol. 60, No. 43 (Nov. 4, 2011) (available at www.cdc.gov/mmwr/PDF/wk/mm6043.pdf):

- In 2010, opioid pain relievers were sold at a higher rate in Maine than nationally. The Maine rate was 9.8 kilograms (kg) of OPR sold (in morphine equivalents) per 10,000 people, with the national rate at 7.1 kg per 10,000. Maine's rate was three times higher than nine of the best states.
- The percentage of people using opioid pain relievers (OPR) non-medically in Maine in 2008-2009 was 4.7%, slightly lower than the national rate (4.8%)

These statistics are even more concerning when recognizing that Maine has many assets that support safe and appropriate opioid prescribing. The State of Maine implemented a Prescription Monitoring Program (PMP) in 2003 that requires prescriptions for all controlled substances dispensed in the state to be submitted by pharmacies and other dispensers to a central database. Health care providers and other authorized users are able to register for access and once approved can view information through a secure web portal. Additionally, the Maine Board of Licensure in Medicine Rules, Chapter 21, requires that providers monitor patients for potential abuse/misuse of opioid prescriptions using multiple measures (e.g., use of urine drug screens, pill counts, provider/patient agreements, and use of PMP), though the degree to which providers adhere to these requirements varies widely.

The information available through the PMP can help providers avoid duplicative prescribing and dangerous drug interactions, and can help identify substance abuse or pain management issues and improve communications between PCPs and specialists. Maine's PMP data, however, indicate that providers could benefit from significant support and education including access to specialists and deeper knowledge about treating chronic pain in order to improve safe prescribing of opioids. According to the Maine State PMP 2013 report:

- Although PMP registration is required by law, only 60.8% of prescribers in Maine are currently registered to use it.
- Between 2008 and 2012, total number of opioid prescriptions rose by 6%. Additionally, the percent of primary hospital admissions related to heroin/morphine use rose 6%, and primary admissions for complications of opioid use rose 28%.
- In 2012, the national and Maine average number of opioid scripts per person was 1.91 prescriptions per person, but in several Maine counties, this number was well above that average, including Washington County at 2.28; Knox 2.08; Kennebec and Penobscot 2.04; Waldo 2.02.
- The number of hospital admissions related to inappropriate use of prescription opioids has increased much more quickly than admissions for heroin/morphine use: in 2008, 8% of admissions were related to heroin/morphine use and 27% for conditions associated with use of prescription opioids; by 2012, that number had increased to 10% for heroin/morphine use, and to 34% for conditions related to use of prescription opioids.
- The number of pharmacy robberies for narcotics has increased significantly over the past several years: in 2008, there were 2 pharmacy robberies in Maine. In 2012, there were 56.

The primary audience for the proposed intervention to improve chronic pain management will start with 5-10 PCMH practice care practices selected for participation in this effort, and ultimately is the statewide community of primary care providers in Maine. While the selected practices and their patients will receive the most immediate benefit from this effort, we also plan to share the learnings from this project with all 150 PCMH practices in the PCMH Pilot and Health Homes initiative, and eventually with all providers statewide.

b. *Intervention Design and Methods*

Our intervention design and methods will support our two primary objectives anchored in the Chronic Care and PCMH models, and will be implemented with set of highly motivated PCMH practice care practices selected for participation. We will offer participation in this chronic pain QI initiative by issuing a competitive application to all PCMH practices in Maine, and will select up to 5-10 practices to participate using pre-identified selection criteria and a multi-stakeholder selection group. Given the high importance and frequent requests for assistance that primary care practices have voiced regarding the issue of chronic pain management, we anticipate a high level of interest and do not anticipate difficulty recruiting at least 5-10 practices to participate.

Practices will be selected based on their commitment to using the Chronic Care and PCMH models to improve care, and their demonstrated capacity and willingness to use performance data to improve clinical quality, efficiency, and patient experience related to chronic pain management. These practices will be asked to sign a Memorandum of Agreement (MOA) outlining the specific expectations of their participation in the initiative, including identification of a leadership team to serve as practice “clinical champions” to lead and spread practice improvement efforts related to chronic pain management at their practice site, and to participate in collaborative learning activities with the other participating sites. Once selected,

we will engage the PCMH practices using the following methods within the framework of our primary objectives:

(1) **Provide structured quality improvement (QI) support to PCMH practices** to implement standardized, systematic and team-based processes to improve comprehensive chronic pain management, using the elements of the Chronic Care and PCMH models. This QI approach will focus on implementing consistent and reliable processes of care that promote consistent adherence to current best practice guidelines, including a comprehensive, multi-disciplinary, team-based and patient-centered approach that focuses on implementing a set of key changes reflecting best practices for chronic pain management and safe opioid prescribing within the framework of the Chronic Care model.

- a) **Self-Management Support:** Promote patient-centered approaches to the assessment and management of chronic pain, including efforts to engage patients in a multi-disciplinary approach focused on effective pain management. Efforts will focus on improving function (vs. simply controlling pain), and will use shared decision making and collaborative goal-setting, as well as patient agreements and informed consent forms to promote safety when prescribing opiate medications.
- b) **Delivery System Design:** Promote a systematic, patient-centered comprehensive approach to chronic pain management that includes team-based care, use of best practice guidelines, and implementing workflows that use standard processes and procedures. A multi-stakeholder steering group will identify a set of “key changes” that participating sites will be asked to implement; specific components of these key changes will be finalized by this group, but are expected at a minimum to include the following:
 - Promote a multi-disciplinary approach to assessing and managing chronic pain that focuses on improving function and quality of life through the use of multiple modalities including exercise, meditation, and other complementary therapies.
 - Apply “Universal Precautions” for chronic pain management that includes comprehensive assessment of chronic pain; assessment for potential addictive disorder; use of informed consent for patients when considering chronic opioid therapy; use of opioid trials; and regular reassessment (“4As”) of impact of therapy.
 - Promote use of PMP by all providers at the practice site, and identify team-based workflows that support routine use of the PMP.
 - Implement process and procedures that promote safe prescribing of opioids, including identification and case reviews for patients receiving high dose opioids (i.e. over 100 mg morphine equivalent dose daily) for chronic non-cancer pain; for all cases of premature patient deaths; and identified by providers with concerns.
 - Develop a team-based approach and workflows to ensure provider adherence to Maine Board of Licensure in Medicine Rules, Chapter 21 requirements including medication contracts, pill counts, urine drug screens, and use of PMP data.
 - Develop a tapering plan for patients receiving high dose opioids and those receiving opioids concomitantly with benzodiazepines or marijuana, or who are otherwise at high risk of respiratory arrest, diversion, abuse or addiction.

- c) **Decision Support:** Identify and implement decision support tools to support more effective assessment and management of chronic pain and safe prescribing, including standardized screening tools (e.g. Screener and Opioid Assessment for Patients with Pain (SOAPP) tool and Opioid Risk Tool (ORT)); dose calculators; taper calculators.
- d) **Clinical Information Systems:**
 - (i) Develop team-based workflows and system for monitoring reliable use and adherence to practice guidelines, including ad hoc chart reviews and staff interviews
 - (ii) Conduct real-time data collection and provide data feedback to providers reflecting adherence to the chronic pain management key changes and policies.
 - (i) Develop a plan to build supporting workflows and decision support into the practice EHR routine tracking and reporting to support quality of care for chronic pain management and safe opioid prescribing – e.g. reports on...
 - Use of functional assessments for patients with chronic pain
 - Patients receiving chronic and/or high-dose opioids for non-cancer pain
 - Patients at high risk of complications from chronic opioids – e.g. from concomitant use of high-risk medications (e.g. marijuana or benzodiazepines) or high-risk conditions (e.g. COPD)

(2) **Provide education, peer support, and specialty expert consultation for primary care providers** to increase their knowledge and self-efficacy of to deliver effective chronic pain management in 5-10 Patient Centered Medical Home (PCMH) practice sites through the following specific interventions:

- a) **Chronic Pain Curriculum** *developed by the Physician's Institute for Excellence in Medicine (PIEM):* We have identified three Maine physicians with expertise and interest in chronic pain management who will serve as our project "Provider Leaders". They will attend the two-day PIEM Pain Collaboratory in Atlanta, and then serve as core educators in a "train the trainer" approach to conduct education and training with the 5-10 PCMH practice sites. Each Provider Leader will work with the identified leadership team at up to 3-4 PCMH practice sites to provide education, outreach, and coaching to help them implement the key changes outlined above. Project staff will tailor the training to the particular site needs following initial interviews with the team at each site that will include review of baseline data and evaluating existing policies, processes and work flows.
- b) **Chronic Pain Learning Collaborative:** QC and project staff will conduct a 9-month Chronic Pain Learning Collaborative modeled after the successful "Breakthrough Series" model of the Institute for Health Improvement (IHI), using a structured program of collaborative learning with the leadership teams from the participating PCMH sites. Leadership teams from the sites will be brought together at a series of Learning Sessions, and will receive direct QI training and support on the best practices identified through the learning community of participating practices. Likely activities include three learning sessions and monthly team conference calls/webinars in which site teams will

be asked to share challenges and successes of their QI efforts to implement the key changes for improving chronic pain management.

- c) ***Project ECHO for Chronic Pain Management:*** Providers and other members of the leadership team from the participating PCMH sites will also receive support and education from a group of multi-disciplinary chronic pain specialist experts by participating in weekly case presentations through a telehealth video connection to the Community Health Center's (CHC) Project ECHO for Chronic Pain Management.

CHC's Project ECHO for Chronic Pain Management is a highly successful weekly videoconference that joins up to 20 primary care practices with a multidisciplinary team of pain specialists to improve the management of patients with chronic pain. The ECHO team includes specialists with wide expertise in pain management including anesthesiology, physical medicine and rehabilitation, behavioral health and pharmacy. Unlike the traditional pain consult model or traditional telemedicine interventions, Project ECHO uses case-based learning to provide support and education to the PCP, enabling them to more effectively manage complex pain cases. The specialist team provides advice and guidance for each case presented by the participating provider, and in addition delivers a brief weekly didactic on a pain-related topic. Cases are discussed in an interactive format led by the ECHO team with input from specialists in pharmacy, behavioral health, internal medicine and pain management as well as participants. Questions are posted by participants on Twitter and answered "live" by the faculty team. Members keep a live blog where they note key points and other reflections on each week's presentation. Project ECHO creates "knowledge networks" that build expertise in primary care providers and PCMH practices, and creates a collaborative learning environment between the specialty team and the primary care participants.

c. Evaluation Design

Evaluation for the initiative will be conducted in partnership with an experienced research team from the CHCs Weitzman Quality Institute (WQI), with support from PCHC and other participating sites. To evaluate the effectiveness of this interventional strategy to achieve improvements in patient outcomes, we will utilize an evaluation model that incorporates conventional outcomes specific to providers such as participation, satisfaction, and knowledge, and additionally includes and prioritizes outcomes relevant to patients including patient functional status and quality of life. In planning and assessing this project as a provider and primary care site-directed performance improvement activity, we will seek to directly address the needs at the patient health and community health levels. Given that these are also the most challenging areas to improve, the intervention is designed to be intensive and comprehensive enough to address the multiple levels often required for improvement.

We will use a controlled, quasi-experimental design employing quantitative and qualitative data collection and analysis and a composite of metrics to provide greater validity and enhanced understanding of the results of this multifaceted intervention. For control purposes, we will utilize a comparison group to gather information on provider knowledge and attitude using provider surveys. Data will be collected in a cross-sectional manner at baseline and at the end

of the intervention. The time interval between the pre- and post- data collection will be 9 months. An important aspect of this evaluation design will be the use of the same data collection tools and procedures that provide data on the same metrics we specify in our needs/baseline assessment. This will allow us to collect, analyze and report on data with the same metrics pre- and post-intervention, making it easier to compare data and results. Data on intervention activities will be collected on a regular basis throughout the intervention period (weekly for all ECHO sessions and monthly/quarterly for the Collaborative activities).

The first level of outcomes will be designed to measure the extent to which the intervention has been adopted using a series of surveys and phone interviews that will be administered both pre- and post-intervention. The provider surveys will measure knowledge, self-efficacy, adherence to pain management standards of care, and attendance and satisfaction with the interventional activities, while patient measures will include the impact of pain on function and quality of life.

The evaluation will be guided by questions about the implementation and the scope and impact of the project. We propose to *test* the following evaluation questions and hypotheses:

Question 1: Will a quality improvement (QI) intervention improve quality of care as measured by patient, provider, and process outcomes?

Hypothesis 1: Implementing the QI intervention will result in improved quality of pain management by participating providers through:

- Increased adherence to evidence-based protocols and guidelines for chronic pain management and safe prescribing/monitoring of opioids
- Increased utilization of guideline-recommended multidisciplinary treatment options, including behavioral health co-management for pain
- Improved assessment of chronic pain and safe opiate prescribing
- Improved documentation of pain management
- Decreased inappropriate use of chronic opioid medications for chronic pain

Hypothesis 2: Implementing the QI intervention will result in improvement in patient functional status and quality of life for patients with chronic pain receiving care from the intervention providers.

Question 2. How satisfied are participating primary care providers with the overall quality improvement initiative and specifically with the learning collaborative and Project ECHO?

Hypothesis 3: Providers taking part in the QI intervention will express greater knowledge, confidence and satisfaction with their ability to manage pain by the end of the intervention, as compared to providers in the control group.

2. Selection Criteria

Providers and Practice Teams: Each participating practice site will identify an interested primary care provider and behavioral health provider to serve as members of the Chronic Pain Improvement Collaborative and Project ECHO team. Selection will be based on level of interest and ability to attend Project ECHO sessions and Collaborative learning sessions. The selected providers will be invited to participate in the intervention and research study and will review and

sign an informed consent document. Each participating practice will also be asked to identify two additional members of their improvement team, including an administrative leader and support staff, to participate in the Learning Collaborative. Each member of the team will be asked to commit to attending learning sessions, as well as weekly performance improvement team meetings during the action phases. In addition, the primary care provider and behavioral health provider will be expected to attend weekly telehealth Project ECHO sessions.

Provider Control Group: Since randomization is not possible, we will utilize the next suitable evaluation approach for estimating intervention effect on provider's pain knowledge and self-efficacy - the quasi-experimental, pre-post with a comparison group design, adjusting for known differences. QC will identify a control group of clinicians from non-participating PCMH practices in Maine to complete knowledge and self-efficacy surveys. QC will assist with identifying a suitable cohort of clinicians to comprise the control group, matching control and intervention group on the basis of size, technical capacity, and populations served.

Patients: All adult patients (age ≥ 18) with chronic pain of any cause, cared for at sites participating in the study will be eligible to be reviewed as part of the evaluation. We will use a validated algorithm that uses a combination of visit codes, medication data, and pain scores to identify patients with chronic pain; from previous studies, this algorithm has been shown to be 95% accurate in correctly identifying patients with chronic pain using large data sets.

3) Data Sources and Collection Methods:

Pre- and post-intervention data will originate from multiple sources: EHR systems, using queries and chart reviews; online survey instruments; phone interviews; and progress reports. Study data will be collected at baseline and post-intervention and will include operational measures, knowledge and attitudes surveys, provider treatment choices and patient outcomes. All data on patient outcomes and provider practice decisions will be retrieved from the **EHR** systems, de-identified, and analyzed by the study team. All data retrieval queries will be validated by random chart reviews of at least 25 records. Data elements will include the patient's PCP name and specialty, their demographics, patient pain scores, medication prescribing records, laboratory results, opioid agreement use, and behavioral health and medical referrals. Random manual chart reviews will be conducted to validate electronic queries and to capture data not available through electronic queries. **Operational data** on ECHO Pain sessions and Collaborative sessions will be collected prospectively and reviewed regularly with the Principal Investigators, with ongoing evaluation and process improvement during the intervention period. **Interview** data will be obtained from individual members of all improvement teams participating in the improvement collaborative. Measures will focus on primary care team satisfaction and team effectiveness. The actual number and depth of changes made to improve chronic pain care will be assessed using monthly reports from teams to project staff. Other measures will include spread of changes, reported barriers and facilitators to change, and practice and healthcare center characteristics.

The following primary outcomes will be assessed:

I. Primary care provider outcomes

- *Pain care knowledge survey (Appendix A):* The KnowPain-50 (KP50) Survey is a 50-item, validated tool for assessing physician pain management knowledge. To assess primary care providers' knowledge about pain and pain management, we will administer the KP50 Survey to all providers in the intervention and control group at baseline and 9 months after the start of the intervention.
- *Pain management attitudes and beliefs (Appendix B):* Pain care beliefs survey is an 11-item measure assessing PCP's attitudes and beliefs regarding pain care survey.
- *Pain management self-efficacy survey (Appendix C):* Project ECHO self-efficacy survey is a 21-item measure (*University of New Mexico Project ECHO*)

II. Opioid prescribing safety and monitoring

- % of PCP adult panel receiving opioid prescriptions
- % of high-dose opioid prescriptions (> 100 mg morphine equivalent)
- % of patients receiving chronic opioids with a documented opioid agreement
- % of patients receiving chronic opioids with a urine toxicology screen within past 6 mos

III. Multimodal care

- % patients with chronic pain co-managed by integrated behavioral health
- % patients with chronic pain referred for complementary and alternative medical (CAM) modality

IV. Patient outcomes

- *Pain functional status scores (SF-8) (Appendix D):* Providers often focus on diagnosing and treating conditions, while patients are more concerned about quality of life (QOL); thus we include QOL as an important outcome in the evaluation. We will evaluate the QOL in patients with chronic pain by means of the SF-8 Health Survey. This is an 8-item version of the SF-36 that yields a comparable 8-dimension health profile and comparable estimates of summary scores for the physical and mental components of health and can be answered in a shorter time compared with other questionnaires including SF-36.
- % patients with documentation of a pain assessment through discussion with the patient, including the use of a standardized tool(s) on each visit
- % patients with documentation of a follow-up plan when pain is present
- % patients with documentation of a pain assessment
- % patients with documentation of a pain care plan
- % of patients with documentation that the patient received pain education.

4. Analysis

Clinical, operational and demographic data will be analyzed using descriptive statistics. Appropriate statistical analyses will be undertaken to test for statistically significant differences pre- and post-intervention as well as between the two groups of providers in the study (intervention and control). Primary study hypotheses regarding between-group differences on provider measures (e.g. pain management knowledge, attitudes and beliefs about pain care scores, and self-efficacy scores) will be examined. The impact of the intervention on different

providers' measures will be tested statistically using a 2x2 mixed factorial analyses with an inter factor (intervention group versus control group) and an intra-factor (pre- versus post-intervention). We will examine correlations between provider measures, team effectiveness and changes that the teams rated a success to different patient measures. Before and after scores on a continuous scale for the cohort of chronic pain patients (e.g. pain severity) will be analyzed for statistically significant difference using paired t-tests. Analyses, where appropriate, will be performed for each site separately as well as for all intervention sites combined. An alpha level of 0.05 will be adopted as the criterion for significance. Lastly, qualitative data from the team reports and surveys will be analyzed in accord with established procedures. We will use standard qualitative content analysis with clustering techniques to identify the repetitive themes regarding providers' experiences participating in the different components of the initiative.

The amount of change expected from this intervention is a 10-20% increase in overall knowledge and self-efficacy scores for providers in the intervention group. For patients, we expect to see a 20-30% decrease in primary care utilization (average number of visits per year).

5. Methods to control for other factors outside this intervention

We will take the following steps to filter out confounding variables: we will identify primary care providers willing to serve in a control group from PCMH practices that are not participating in the intervention. These controls, along with the participants, will be asked to complete pre- and post-intervention survey questionnaires evaluating their pain management knowledge and self-efficacy. Subjects who decline to participate in the intervention will not be included in the control group. The intervention/control groups and outcome measures will be chosen before the intervention is delivered. Evaluation of the quality of chronic pain care delivered, as well as the participating providers' chronic pain management knowledge and self-efficacy will be made before and after the intervention. We will closely match the study's intervention and control groups prior to the intervention; the control group will not receive the intervention. If we find differences in the characteristics of participants in the intervention and control groups that might influence how they respond to the intervention, we will apply more sophisticated techniques that allow a correction of these differences.

Among quasi-experimental study designs, the pre/post control design is the most sound in terms of establishing causality. This design is an improvement on pre-experimental designs in that we can determine whether there is a change in provider knowledge and self-efficacy after the intervention and thus decrease the chances of confounding due to other factors. Therefore, there will be considerable confidence that any differences between intervention group and control group will be due to the intervention. The design allows for many comparisons (i.e. between groups, pre- to post-intervention in one group). Using pre/post control design is also a useful way of ensuring that the study has a strong level of internal validity because the pre-intervention ensures that the groups are equivalent, thus filtering out confounding variables.

6. Dissemination of Project Outcomes

This project brings together a powerful partnership of primary care leaders in Maine. We will disseminate best practices from this initiative through the leadership and wide array of existing

education and communication channels available from QC, the MMA, the Maine Primary Care Association, and the Maine Association of Family Physicians, leveraging our collective roles as trusted quality leaders in the state.

3. Detailed Workplan and Deliverables Schedule

On notification of grant award, Maine Quality Counts and its partners will immediately identify key stakeholders to participate in the guidance and oversight of this 14-month initiative. By January 31, 2014, the multi-stakeholder steering group will identify specific components of best practice guidelines as a set of key practice changes; they will also develop criteria for selection and issue an application for participation to all PCMH primary practices in Maine (155+).

The three Provider Leaders will attend the Atlanta Chronic Pain Collaboratory in January, and will bring the learnings from this session into the development of the practice application and change package to be developed. Five to 10 practices will be selected as sites by March 31, 2014.

Beginning in April, and throughout the project, the project team will provide written materials, conduct site visits and regular webinars and conference calls that reflect adherence to best practice guidelines for the 5-10 practice sites. Sites will develop team-based workflow and systems using specific decision-support tools such as SOAPP; ORT, and dose and taper calculators. The project team will help the sites develop plans to collect real-time data that will provide feedback to providers.

Also beginning in April 2014, the project team will conduct the first of three learning sessions and launch monthly webinars based on the IHI Breakthrough Series collaborative model. In addition, participating sites will be asked to identify a provider team to participate in the very successful “Project ECHO for Chronic Pain Management”. Sites will participate monthly in case presentations through a telehealth video connection to the Community Health Center (CHC) in Connecticut.

Experienced researchers from CHC will lead the evaluation component of the project. In January CHC will identify a control group at non-participating PCMH practices in Maine. CHC will be responsible for creating or adapting data collection tools including chart review, EHR data retrieval queries, survey instruments, and interview scripts. As soon as the 5-10 sites are identified, CHC will collect baseline data by reviewing charts and EHR data. Throughout the project CHC will collect data on ECHO Pain Sessions (weekly) and Learning Collaborative data (quarterly). From 10/1/14 through 10/31/14 CHC will collect post intervention data. Results will be analyzed and summarized in a report on project outcomes to be delivered 3/2015.

Organizational Detail

1. Leadership and Organizational Capability: Maine Quality Counts will serve as the lead organization for this initiative, working with the Weitzman Quality Institute as our evaluation partner. Recognizing the value of building a strong statewide alliance to promote this initiative, we will also partner with the Maine Primary Care Association, Penobscot Community Health Center, the Maine Medical Association, and the Maine Academy of Family Physicians.

Maine Quality Counts

Maine Quality Counts (QC) is a regional, non-profit health improvement collaborative that brings together consumers, providers, payers, and government to transform health and healthcare in Maine by leading, collaborating, and aligning improvement efforts. QC has strong relationships with providers, and has led several key statewide improvement initiatives in Maine, including the multi-payer Maine Patient Centered Medical Home Pilot, and the Robert Wood Johnson Foundation's "Aligning Forces for Quality" initiative, an effort aimed at driving improvements in quality of care statewide by aligning efforts to improve quality through performance measurement and public reporting, providing quality improvement assistance to providers, and engaging consumers in improving health care.

QC is an IRS-approved 501(c) 3 organization, incorporated in the state of Maine since 2006 and governed by a Board of Directors whose members include physical and behavioral health providers, commercial and government payers, state government and community based agencies; and consumers and consumer advocacy agencies. QC has over 80 supporting Members, representing a wide set of stakeholders statewide. QC has the proven and deep leadership, project management, and financial capacity to serve as the lead agency for this initiative. As both the direct and indirect recipient of foundation and government grants, QC has financial management expertise and technology to manage complex funding streams, and to comply with all grant management and auditing requirements.

Weitzman Quality Institute, Community Health Centers (Evaluation Partner)

The Weitzman Quality Institute (WQI) in Middletown, CT was established in 2012 by the Center for Health Care, Inc. (CHCI), a leading health-care provider in Connecticut providing comprehensive primary care services in medicine, dentistry, and behavioral health and committed to caring special populations and building healthy communities. WQI has served since its inception as the institutional home of CHCI's research, quality improvement, and knowledge dissemination work. The Institute is dynamic, interdisciplinary, and cross-institutional and welcomes the input and participation of interested clinical and non-clinical leaders from around the world. WQI promotes critical investigation, training, and innovation in areas that have direct implications to the day to day practice of primary care.

WQI is committed to a research agenda focused on answering questions that arise in the daily practice of primary care. Adopting patient-centered strategies and promoting the implementation of evidence based care are among the Institute's top priorities. Research is cross disciplinary, involving medicine, dentistry, behavioral health, pharmacy, and nursing. Currently WQI has over \$2.5 million dollars in funding to support research in a wide variety of areas a number of federal and private philanthropic sources.

One of the principal elements of WQI's research agenda is the study and evaluation of quality improvement (QI) and system redesign strategies for healthcare delivery. Critical to achieving the goals of WQI is the development of organizational change strategies that promote sustained quality improvement. CHCI's quality improvement team, operated through WQI, is developing and studying a unique quality improvement infrastructure using the latest tools and techniques from both healthcare, and non-healthcare industry.

Project Partners

- **Maine Primary Care Association**

The Maine Primary Care Association (MPCA) is a membership organization representing the collective voices of Maine's community, tribal, migrant and homeless health centers – sometimes referred to as Maine's health care safety net. MPCA has over 65 member sites spread across the state. For over 30 years, MPCA has provided technical assistance and training, housed relevant programs and services and advocated on behalf of Maine's safety net and the hundreds of thousands of patients it serves.

MPCA is a leader in improving chronic pain management efforts in Maine, and in 2011, led a statewide effort to develop and document formal guidelines for chronic non-cancer pain management and safe opiate prescribing. MPCA staff worked with FQHC medical directors, clinicians, and allied professional groups to develop a white paper outlining the challenges and opportunities in Maine; the paper, "Opiate Use for Chronic, Non-Cancer Pain", identifies high leverage points to improve the treatment of chronic, non-cancer pain and improve safe prescribing practices for opiates. The elements identified within the paper support Maine's patient-centered, primary care providers in shifting the focus of chronic pain treatment from analgesia to function, with a goal towards developing treatment goals that are objective and verifiable and improve the quality of life and care experienced by Maine's patient population.

- **Penobscot Community Health Care**

Penobscot Community Health Care (PCHC), is the largest Federally Qualified Health Center (FQHC) in Maine, and is among the four largest and most comprehensive of 100 FQHCs in New England, serving 60,000 patients annually in 17 sites. PCHC provides fully integrated medical, mental health and dental care and embraces innovative approaches to transforming lives while transforming the health care system. PCHC is accredited by the Joint Commission and only the 11th FQHC in the country to be certified by the Joint Commission as a Primary Care Medical Home. PCHC participates in the CMS ACO program, and is among the first few FQHCs in the country to earn Certification by the NCQA as a Patient-Centered Medical Home (PCMH); PCHC practices have earned NCQA certifications for evidence-based medicine.

PCHC has a strong commitment to integration of behavioral health services, and behavioral health professionals are integrated into every PCHC medical practice. Beginning in 2013 PCHC established a "Controlled Substance Intervention" (CSI) program designed to help improve the management of controlled substance prescriptions, and to help ensure patient safety. CSI group reviews all charts of patients receiving high dose opioids for chronic non-cancer pain, all

cases of premature deaths of patients on controlled substances, and charts sent for review (on an ad hoc basis) by providers with specific questions or seeking specific guidance.

- **Maine Medical Association**

The Maine Medical Association (MMA) brings physicians together to support Maine physicians, advance the quality of medicine in Maine, and promote the health of all Maine citizens. MMA's membership includes over 3,700 physicians, with over 2,300 active members. The MMA is a knowledge-based organization, operating two non-profit foundations, managing a dozen medical specialty organizations and a fully staffed Medical Professional Health Program that serves physicians, dentists, nurses, pharmacists, physician assistants and other health professionals. The MMA has been committed to improving chronic pain management and safe prescribing of opioids, and offers a wide range of programs, educational resources, products and services to its members.

- **Maine Academy of Family Physicians**

The Maine Academy of Family Physicians (MAFP), a constituent chapter of the American Academy of Family Physicians (AAFP), is the largest specialty physician organization in Maine, currently representing over 700 family physicians, family medicine residents, and medical students. The MAFP's priorities include: advocating for the specialty of Family Medicine in Maine, and for patients and Maine citizens; enhancing communication to and among family physician members and primary care physicians statewide; and providing clinical and policy information to family physicians in Maine.