Improving Opioid Prescribing: Sustainable Solutions

Opioid Prescription Management Toolkit for Chronic Pain

CLINIC WORKBOOK

Third Edition

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# Table of Contents

Acknowledgements .................................................................................................................. 1  
About the Toolkit ..................................................................................................................... 2  
Purpose ................................................................................................................................... 2  
Key Changes to Prescribing ..................................................................................................... 2  
Recommended Steps to Launch .............................................................................................. 3  
STEP 1: Self-Assess & Select Focus ......................................................................................... 4  
STEP 2: Prepare QI Team .......................................................................................................... 8  
STEP 3: Understand Process ..................................................................................................... 11  
STEP 4: Design New Process .................................................................................................... 14  
STEP 5: Implement ................................................................................................................... 16  
PDSA Cycle Check-In-Form ...................................................................................................... 17  
Opioid Prescription Management Strategies ........................................................................ 19  
STARTING POINT 0 – Self-assess Commitment ..................................................................... 20  
STRATEGY 1 - Assess and Re-assess ....................................................................................... 22  
STRATEGY 2 – Monitor before Prescribing ............................................................................ 29  
STRATEGY 3 - Prescribe .......................................................................................................... 33  
STRATEGY 4 - Document ......................................................................................................... 38  
STRATEGY 5 - Schedule ........................................................................................................... 39  
STRATEGY 6 – Engage Resources .......................................................................................... 41  
STRATEGY 7 – Manage the Population .................................................................................. 45  
Appendices .............................................................................................................................. 46  
References ............................................................................................................................... 88
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This Toolkit reflects knowledge based on the regulatory environment of the State of Vermont, 2012–2018. Please check indicated websites for updates and new information as you proceed with this project.

Design

Lucy Wolski, Arizona State University
ABOUT THE TOOLKIT

This Toolkit is for practice leaders, providers, and staff interested in improving management of opioid prescriptions for patients with non-palliative, chronic pain. It combines redesign of office practice workflow with proven strategies to manage opioid prescribing. This Toolkit was developed for ambulatory care clinics in Vermont and can be applied broadly to many settings.

PURPOSE

Provide a step-by-step process to plan and use strategies for managing opioid prescriptions to reduce diversions and misuse of prescriptions while helping patients manage chronic pain.

Assist providers and staff to create new office workflows for opioid prescribing that best work for their patients and practices, based on local and state policies and their professional expectations.

Decrease the inappropriate use of opioids and, thereby, prescription opioid misuse, opioid-related morbidity and mortality, and opioid-related health care costs.

Help practices make the opioid prescribing process easy for all to understand and to support a team-based approach to care, from the front desk staff, to the clinical staff, to the prescribers.

Engage clinic leadership in creating a practice-wide approach to opioid prescribing, evaluation, and improvement that seeks to provide the best long-term pain management therapy for each patient.

KEY CHANGES TO OPIOID PRESCRIBING

Each state experiences its own progression of opioid prescribing expectations, supported by national publications. One example of how these milestones can support each other is demonstrated by Vermont’s key milestones:

2006
Vermont Board of Medical Practice Policy

2007
Scott Fishman’s "Responsible Opioid Prescribing"

2012
Scott Fisherman’s "Responsible Opioid Prescribing" 2nd edition

2014
Vermont Board of Medical Practice Policy Update

2016
CDC Guidelines for Prescribing Opioids for Chronic Pain

2017
Vermont Opioid Prescribing Rules/Law Updated

2018
SPACE Trial1 and JAMA study: meta-analysis2


RECOMMENDED STEPS TO LAUNCH

The Toolkit is organized in five steps. For some practices, finding gaps in Legal Compliance in Step 1 may be sufficient to begin to make changes. All practices can benefit from strategies to manage initiation, maintenance, or adjustment of opioids by making detailed workflow changes for opioid prescription management:

**STEP 1: Self-Assess & Select Focus**
- Legal Compliance
- Initiate Opioids
- Maintain Opioids
- Adjust Opioids

**STEP 2: Prepare QI Team**

**STEP 3: Understand Process**

**STEP 4: Design Workflow Process**

**STEP 5: Implement**
STEP 1: Self-Assess & Select Focus

Number of Tasks = 6 | Estimated Time ~2 Hours

Assess if this Toolkit presents an approach that fits the practice. Meet with appropriate leadership members for your practice, complete and confirm.

1.1 ASSESS COMPLIANCE WITH THE LAW

- Make sure you know the legal requirements for your own state. Review the Vermont legal requirements listed on pages 7-8.
- Review each item and check the boxes that your practice does not perform for patients with chronic, non-palliative pain receiving opioid therapy. (You may need to complete a chart audit to determine this.)
- Give any checked items priority as you move through this Toolkit.

1.2 PRE-PROJECT SURVEY

Use the sample in the Appendix to set up pre-surveys for all providers and staff as baseline measures. Appendix B | Appendix C

☐ Pre-survey completed on: ________________________________

1.3 TIME COMMITMENT

Decide if your practice can support a quality improvement team for ~ eight hours over several months to use the Toolkit. The team should include a prescribing provider, a clinical staff member who assists with patient care, and a front desk staff member; others may be included as well.

☐ Practice commits to time on: ________________________________

1.4 TREATMENT COMMITMENT

Decide if all providers will commit to a consistent treatment approach across the practice for all patients prescribed opioids for non-palliative, chronic pain. Can providers agree on a consistent approach to treatment? See “Self-Assess Commitment” for treatment consistency.

☐ Practice commits to consistent approach on: ________________________________

1.5 TEAM COMMITMENT

Decide if the practice can use a team-based care approach, in which all practice members (clinical and non-clinical) work together to assist patients treated with opioids. See Self-Assess Commitment for Team-Based Care Approach.

☐ Practice commits to team approach on: ________________________________
1.6 WHICH KIT?

Select the collection of strategies (the “Kit”) with the greatest value for your practice at this time by focusing on the patient population that most needs your attention:

- Patients starting on a new course of opioid treatment: INITIATE KIT
- Patients with low to medium risk maintaining their opioid treatment: MAINTAIN KIT
- Patients with high risk or who need to reduce or discontinue opioid treatment: ADJUST KIT

☐ INITIATE OPIOID TREATMENT KIT
☐ MAINTAIN OPIOID TREATMENT KIT
☐ ADJUST OPIOID TREATMENT KIT
Legal Requirements (Step 1.1 above)

TRIAL NON-OPIOID & NON PHARMACOLOGICAL TREATMENT

Recommend Non-Opioid and Non-Pharmacological Treatment
- Nonsteroidal anti-inflammatory drugs (NSAIDs) and/or acetaminophen
- Acupuncture
- Chiropractic
- Physical therapy
- Yoga
  Only prescribe opioids if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, combine with non-opioid alternatives.

Query PDMP (Vermont: VPMS; check your state’s program)
First-time Prescriptions:
- Prior to writing a first opioid prescription for 10+ pills (e.g. opioids, tramadol)
- Prior to writing a first prescription for a benzodiazepine, buprenorphine, or methadone
- Prior to starting a patient on a chronic opioid (90+ days) for non-palliative therapy
Re-evaluation: At least annually (at least twice annually for buprenorphine)
  - Centers for Disease Control (CDC) recommendation: every prescription, or at least every 90 days
Replacement: Prior to writing a replacement (e.g. lost, stolen) of any scheduled II-IV controlled substance

Provide Patient Education and Obtain Informed Consent
- Discussion of risks, including side effects, risk of dependence and overdose, alternative treatments, appropriate tapering and safe storage and disposal
- Provide patient with the Vermont Department of Health (VDH) Patient Education handout
- Obtain signed informed consent, even for acute prescriptions
- CDC education resources: [https://www.cdc.gov/drugoverdose/](https://www.cdc.gov/drugoverdose/)
- CDC: Establish realistic treatment goals for pain and function and establish patient and clinician responsibilities for managing therapy, including when to discontinue therapy

Prescribe Nasal Naloxone when Indicated
- High Dose: 90+ Morphine Milligram Equivalent (MME) per day
- Concomitant benzodiazepine: Patients prescribed both an opioid and a benzodiazepine
  - CDC recommends avoiding co-prescribing of opioids and benzodiazepines
- CDC: History of overdose, history of substance use disorder, 50+ MME per day prescriptions

Arrange Evidence-based Treatment for Patients with Opioid Use Disorder
- CDC: Offer evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder

Complete Continuing Education Requirements
- Complete at least two hours of continuing education for each licensing period on the topic of Controlled Substances. Visit [vtad.org](http://vtad.org), [vtmd.org/cme-courses](http://vtmd.org/cme-courses), or check with your professional society for available courses.
Prescribe Lowest Effective Dose of Immediate-release Opioids

PEDIATRICS
Consider discussing the benefits and risks of prescribing an opioid to a pediatric patient with a colleague or specialist. Use extreme caution. Calculate dose for patient’s age and body weight. Consider the indication, pain severity, and alternative therapies. Limit prescriptions to 3 days or less with an average MME of 24 or less. Do not write additional prescriptions without evaluating the patient.

ADULTS
Minor Pain
(sprains, headaches, dental pain): no opioids

Moderate Pain
(non-compounded bone fractures, soft tissue surgery, most outpatient laparoscopic surgery):

<table>
<thead>
<tr>
<th></th>
<th>Average Daily</th>
<th>Total RX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone 5mg</td>
<td>MME: 24/0-4 tablets</td>
<td>0-5 days/0-20 tablets</td>
</tr>
<tr>
<td>Oxycodone 5mg</td>
<td>MME: 24/0-3 tablets</td>
<td>0-5 days/0-15 tablets</td>
</tr>
</tbody>
</table>

Severe Pain

<table>
<thead>
<tr>
<th></th>
<th>Average Daily</th>
<th>Total RX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone 5mg</td>
<td>MME: 32/0-6 tablets</td>
<td>0-5 days/0-30 tablets</td>
</tr>
<tr>
<td>Oxycodone 5mg</td>
<td>MME: 32/0-4 tablets</td>
<td>0-5 days/0-20 tablets</td>
</tr>
</tbody>
</table>

Extreme pain (beyond severe) in adults is limited to a 7 day max with a 350 MME max. This should be rare in primary care. Exceptions must be clearly documented. For the complete rules, visit the Rule Governing the Prescribing of Opioids for pain found at https://www.healthvermont.gov/sites/default/files/documents/pdf/REG_opioids-prescribing-for-pain.pdf

- Include the maximum daily dose or a “not to exceed” equivalent on the prescription.
- CDC: Prescribe immediate-release formulations when initiating opioids for chronic pain.

Evaluate Patients Regularly Using Best Practices

- Reevaluate patients (and document) at least every 90 days (both VT Rules and CDC)
- CDC: If benefits do not outweigh harms, taper opioids
- CDC: Use urine drug screening prior to initiating opioids. Rescreen at least annually
- Calculate MME. Consider 50-89 daily MME a “yellow light” and 90+ MME a “red light”
- Use evidence-based tools to reevaluate adherence to the pain management therapy plan, functional goals (e.g. RAPID3), and potential for abuse and diversion (e.g. 5As, SOAPP, COMM)

Document, Document, Document

- Medical evaluation, including physical and functional exams and assessment of comorbidities
- Diagnosis which supports the use of opioids for chronic pain and whether to continue opioids
- Individual benefits and risks, using evidence-based tools (e.g. RAPID3, 5As, SOAPP, COMM)
- Non-opioid and non-pharmacological treatments tried and trial use of the opioid
- PDMP query (Vermont Prescription Monitoring System or VPMS in Vermont)
- Department of Health Patient Education handout provided (as available)
- That the prescriber has asked the patient if he or she is currently, or has recently been, dispensed methadone or buprenorphine or prescribed and taken any other controlled substance
- Signed Controlled Substance Treatment Agreement and Informed Consent: update at least annually
- Acknowledgement that a violation of the agreement will result in a re-evaluation of the therapy plan
STEP 2: Prepare QI Team

Number of Tasks = 3 | Estimated Time ~1 Hour

Select and prepare your quality improvement (QI) team

2.1 SELECT TEAM MEMBERS – OPIOID PRESCRIPTION MANAGEMENT QI

Identify project champion, team leader, facilitator, and team members of Opioid Prescription Management (OPM), schedule team meetings, and identify other resources for the team’s work

- **OPM Practice leader champion**: decision-maker(s) or influencer(s) in the practice that decide whether to work on a particular project. Example: medical director, owner(s) of the practice
- **OPM Team leader**: one person with the responsibility to conduct the project by convening a team to work on it together. Examples: practice provider, clinical staff, manager/supervisor
- **OPM Team facilitator**: a person from the practice or from outside the practice who guides the team through this Toolkit, separate from the “team leader” role above
- **OPM Team members**: members of the practice who meet and work collaboratively on a team project

<table>
<thead>
<tr>
<th>OPM Practice Leader Champion</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPM Team Leader</td>
</tr>
<tr>
<td>OPM Team Facilitator</td>
</tr>
<tr>
<td>Other team members, including a prescriber, a clinical staff member, and a front desk staff member</td>
</tr>
</tbody>
</table>

Schedule of team meetings

- Weekly or Bi-Weekly? Yes No
- Minimum 1 hour? Yes No

Resources Needed

<table>
<thead>
<tr>
<th>Meeting room?</th>
<th>White board &amp; markers?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food &amp; beverage?</td>
<td>or Flip Chart/markers?</td>
</tr>
<tr>
<td>Community partner(s)?</td>
<td></td>
</tr>
</tbody>
</table>


2.2 SET TEAM CHARTER

A Team Charter is an explicit way to start an efficient and focused project team that understands its purpose and objectives.

**Purpose:** Create a statement that explains which Kit from Step 3 that the team will focus on, starting with the statement: “We will focus on…” and targeted areas relevant to the practice, such as:

- Medications that need practice management (opioids, benzodiazepines, stimulants…)
- Patients that need more structured management (chronic pain for three months or more)

Example: We will focus on the Maintenance Kit for opioid prescribing for non-palliative care patients on long term, stable opioid therapy for three months or more.

“We will focus on…”

“…”

**Objective:** Create a second statement that identifies what the project team is expected to do:

- Improve [the currently perceived problem of opioid prescription management]
- By selecting strategies from the Toolkit [excluding or including the following list…]
- In order to recommend specific changes to the practice leaders for approval
- By [date, allowing for at least eight hours of team meeting time as scheduled by the practice]

Example: The project team will create a common process for the practice to manage care for patients on long-term opioid therapy using any of the Toolkit strategies. The team will present its recommendations at a provider/staff meeting in three months for review before proceeding with implementation.

“The project team will create…”

“This charter becomes the starting point for the first team meeting.”
2.3 PICK IMPACT MEASURE

Identify a key indicator of the team’s objective that can be measured starting now. This indicator should reflect a current challenge in your practice, such as

- Number of patient requests for opioid prescription refills outside of office visits
- Provider interruptions about opioid prescription refills
- Pharmacy phone calls about opioid prescription refills

For more patient-centric measures, consider:

- Percent of qualifying patients on Narcan seen in a two-week period
- Percent patients above 90 Morphine Milligram Equivalents daily seen in a two-week period
- Percent of patients on problem list receiving opioid treatment without an adequate diagnosis seen in a two-week period

Use the simplest means possible, such as a log or list of the occurrences of the indicator as they occur or patients are seen in the daily workflow and patient care process. Select a two-week period that is “normal” for the practice (no holidays, vacations, large number of absences due to medical leave or outside events, etc.). The purpose of this log is to gather relevant data for the project team and to measure the success of the project later. An example graph of baseline data shows total number of medication refill phone calls by day (excluding weekends).

![Graph of Number of Medication Refill Phone Calls](image)

Name of Impact Measure: __________________________________________________________

How will data be collected? ______________________________________________________

Who will collect the data? ________________________________________________________

Date started? __________________________________________________________________

Date ended? _____________________________________________________________________
STEP 3: Understand Process

Number of Tasks = 3 | Estimated Time ~3 Hours

Learn about your clinical workflow process with your team

3.1 START UP TEAM & IDENTIFY KEY ISSUES

Checklist of team meeting prep tasks:

- Binder for each team member
- Legal Requirements checklist (if needed)
- Results of Pre-Survey baseline measure
- Kit strategies (Initiate, Maintain, or Adjust)
- Team members
- Team schedule
- Team Charter
- Results of Impact Measure

TIPS FOR SUCCESS

Invite a patient with long term opioid use experience, or a community member with contacts with similar patients, to talk about/answer questions regarding the perception of the practice’s management of opioid prescriptions. You may wish to include this patient in future QI team meetings but even a single meeting is valuable.

Start the team up with a binder for each member’s team notes and review at the first meeting:

1. The Team Charter: do any team members have questions about the charter or the Kit selected?
2. Results of the Baseline Practice Survey: do some practice members have concerns that should be addressed?
3. Results of the Baseline Impact Measure: how well is the current prescription management process working now?
4. Document the team’s answers to the following question on a white board or flip chart, with team members tracking in their binders: “What do we already know about issues related to prescribing opioids in our practice?”

Examples to consider:

- Characteristics of patients with chronic pain that the practice cares for
- Community factors that make care more challenging or easier in caring for patients
- Challenges that the practice has experienced in caring for patients with chronic pain

TIPS FOR SUCCESS

- It’s OK for team members to have strong feelings about these issues
- Capture the issue, not the feelings
- If a team member needs more discussion on an issue, follow up after the meeting and plan how to address either in the team or in the practice.

Document


3.2 ANALYZE THE FLOW OF WORK

Describe how opioid prescriptions are usually managed in the practice relative to the Kit identified in the Team Charter (Initiate, Maintain or Adjust). The example used in this Toolkit is: “We frequently have patients calling for an early refill.” The team can use this example or another of its choice.

Document the following steps on a white board or flip chart, while team members track in binders:

A. List the steps to respond to the challenge, one job function at a time. For example, patients calling for an early refill might result in the following steps:
   1. Patient calls for refill
   2. Nurse follows up with chart review and messages provider
   3. Patient calls again to ask about refill
   4. Nurse repeats message to provider
   5. Provider reviews message and chart, refills prescription, and messages front desk
   6. Front desk calls patient to pick up prescription
   7. Patient arrives to pick up prescription
   8. Pharmacy calls to notify that prior authorization is needed
   9. Provider arranges for prior authorization

B. Map the steps to illustrate the path taken by the patient and her/his information to present the process from the patient’s perspective. Example process map tracking patient experience:

C. Review the process map with the team, stopping at each process step to ask the team the following three questions, one at a time.
   - Roughly how often do patients, providers, or staff experience delays in this step that make them wait or make different choices:
     Never  Infrequently  About half the time  Most of the time  Always
   - Roughly how often do providers or staff lack information needed for this step:
     Never  Infrequently  About half the time  Most of the time  Always
   - Roughly how often do providers or staff lack resources (EHR access, clinical supplies, educational materials, etc.) needed for this step:
     Never  Infrequently  About half the time  Most of the time  Always

D. For each process step in which any of the above problems occur, draw a line down from the process step and make a note of the problem and how often it occurs:

   Infrequently: 25%  About half the time: 50%  Most of the time: 75%  Always: 100%
3.3 ANALYZE CHALLENGES & PICK STRATEGIES

Analyze the causes of challenges identified in the process map.

For each problem identified in the process map, ask: “what are the causes of the problems that make it hard to help the patient?” Often a cause has other root causes; ask “why does that happen” until no further causes can be identified. Capture these observations in lightening bursts near the process step. Example:

Review the Kit you selected in your Team Charter and the strategies it includes. Select the strategies from the Kit which best address the challenges identified above (especially those that occur 50% of the time or more) and any legal issues identified in Step 1. (Specific strategies are listed on Opioid Prescription Management Strategies.) The team may also add other strategies it identifies as valuable.

Check the Kit you selected in your Team Charter and identify the strategies selected:

☐ Initiate Opioid Treatment Kit
   Strategies selected:

☐ Maintain Opioid Treatment Kit
   Strategies selected:

☐ Adjust Opioid Treatment Kit
   Strategies selected:
**STEP 4: Design New Process**

**Number of Tasks = 3 | Estimated Time ~2 Hours**

Design a new workflow process with your team for practice

### 4.1 DESIGN NEW OPIOID RX PROCESS

Map out the workflow that includes your selected strategies to make the work flow clear and smooth for patients and practice members.

A. Create a new process map that incorporates the strategies selected from your Kit and your team’s ideas. Map the process from the patient’s perspective. Example:

![Process Diagram](image)

B. Every new workflow design can have hidden flaws; this is normal. Consider each of the following possible patient behaviors and check those that might upset the planned workflow. For those checked, plan a response that the whole practice can use for when:

- [ ] Patient can’t urinate for urine screen during visit
- [ ] Patient shows up unscheduled and says “I’ll wait for the doctor/NP/PA”
- [ ] Someone who is not the patient arrives to pick up the patient’s prescription
- [ ] Patient misses specialty appointment(s)
- [ ] Unexpected urine result (either positive or negative)
- [ ] Patient calls for early refill
- [ ] Patient doesn’t show up for random urine screen/pill count
- [ ] Patient is rude/loses control
- [ ] Established patient disagrees with the new plan for managing opioid prescriptions
- [ ] Patient asks for different provider than established primary
- [ ] Practice receives an anonymous tip about a patient
- [ ] Patient is very compliant with no “end point;” in other words, the behavior is so stable and predictable that it seems to be “too good to be true”

C. Using your practice’s method of developing procedures or protocols, develop a procedure or protocol for the practice to test out using the team’s new process map.
## 4.2 PLAN IMPLEMENTATION

Create an implementation plan, listing all tasks needed to carry out the implementation plan.

Instructions: Develop an implementation plan for each step in the new care process. Identify each task, along with who will take the lead and by what time the task should be finished or reviewed for an update.

Select measures to track to help make sure that the strategies are working. Example: Appendix I

<table>
<thead>
<tr>
<th>What</th>
<th>Who</th>
<th>By When</th>
<th>Measures of Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEW FLOW OF WORK</td>
<td>(list selected strategies)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
</tbody>
</table>

**TIPS FOR SUCCESS**

When putting your Implementation Plan into action, pick one or two strategies to try out at a time. This helps the team:

- Learn quickly about what’s working and what’s not
- Make adjustments that don’t disrupt other parts of the Implementation Plan

## 4.3 COMMUNICATE

Communicate thoroughly with every member of the practice, clinical & non-clinical. Use multiple methods:

How will info be shared?

Who will share the info?

Date Started:

Date Ended:
STEP 5: Implement

Number of Tasks = 4 | Estimated Time ~3 Meeting Hours

Carry out the implementation plan and measure the results

5.1 CHECK IN

Meet briefly and regularly to check on progress, using PLAN | DO | STUDY | ACT cycles (PDSA)

PDSA is similar to the methods used by scientific studies when applied to problem solving. It is used by many healthcare organizations for quality improvement projects. The four steps of PDSA are often presented as a repeating cycle of continuing steps:

**Plan:**
Team members plan a way to solve a problem by analyzing information, generating some ideas on how to improve it, predicting what will happen, & agreeing on actions to carry out the plan as an experiment.

*This is the same as your Implementation Plan.*

**Act:**
Team members decide whether the change is one to adopt (keeping it just as they tried it), adapt (improving the change to make it more effective), or abandon (finding something else to try next). They act on this decision to make lasting change and decide whether to repeat the PDSA cycle to find more improvements or to finalize their changes.

**Do:**
Team members do the experiment and record the results. The experiment is done in rapid cycles: a short period of a few days or a specific number of encounters.

*They collect data using performance measures identified for each tactic. Unless there is an important problem found at this time, no changes are made to the plan during this step.*

**Study/Check:**
Team members analyze the results so they can check them against their predictions (from Plan) and study the impact of their changes on the problem they are working on.

PDSA is a repetitive, four-step cycle of problem-solving, represented by arrows pointing in a clockwise direction. For a health care example, please watch this 6-minute video:

[http://www.ihi.org/education/IHIOpenSchool/resources/Pages/Activities/PDSACyclesFromCLABSIstoCucumbers.aspx](http://www.ihi.org/education/IHIOpenSchool/resources/Pages/Activities/PDSACyclesFromCLABSIstoCucumbers.aspx)

Use the PDSA Cycle Check-In-Form on the next page to track the team’s work over several meetings until the new process fits the practice workflow and is stable.
PDSA Cycle Check-In-Form

For each team meeting in this step, discuss and document the following:

**TIPS FOR SUCCESS**
Use this form for every cycle of improvement. When each cycle is completed, use this form to continue your communication plan started in Step 4.3

---

**Cycle # and Date**

**Our PLAN for this cycle:**

---

**We will DO this cycle and measure the results by:**

---

**We STUDIED the results and have the following conclusions:**

---

**We ACTED on our conclusions by deciding to adopt, adapt, or abandon the following parts of our plan and continue to a new PDSA cycle (on a new page) or to end our team’s work here:**

---
5.2 REPEAT IMPACT MEASURE FROM STEP 2

When the team’s work is nearly done, repeat measurement of the key indicator from Step 2.3. As before, select a two-week period that is “normal” for the practice (no holidays, vacations, large number of absences due to medical leave, etc.). Compare the baseline measures to current. Example graphs of baseline and post project data below show medication refill phone calls by day (without weekends).

Name of Impact Measure:

How will data be collected?

Who will collect the data?

Date Started:

Date Ended:

Example:

<table>
<thead>
<tr>
<th>Number of Medication Refill Phone Calls</th>
<th>Number of Medication Refill Phone Calls</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BEFORE</strong></td>
<td><strong>AFTER</strong></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
</tr>
<tr>
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5.3 POST-PROJECT SURVEY

Use the sample in the Appendix to set up post-surveys for all practice members as a current measure.

Appendix B | Appendix C

☐ Post-survey completed on:

5.4 CONCLUDE AND CELEBRATE

How and when will you celebrate completion of Toolkit?

TIPS FOR SUCCESS

Remember that teamwork is always something to celebrate. Even if the team didn’t accomplish everything it planned to, celebrate what it did accomplish. There can always be a “next time” to try some strategies again!
# Opioid Prescription Management Strategies

Experts agree that these strategies have high impact when prescribing opioids. Check your state laws & rules and start with the Kit (column) that matches the patient population of your focus.

<table>
<thead>
<tr>
<th>Starting Point 0 – Self-Assess Commitment to a Unified Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Treatment consistency across practice</td>
</tr>
<tr>
<td>b. Team-based care approach</td>
</tr>
</tbody>
</table>

## 1 – Assess and Re-assess

<table>
<thead>
<tr>
<th>Assess and Re-assess</th>
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</thead>
<tbody>
<tr>
<td>a. Initial Risk Assessment</td>
</tr>
<tr>
<td>b. Consider best practices in care: non-opioid &amp; non-pharmacological treatment</td>
</tr>
<tr>
<td>c. Ongoing risk assessment, such as COMM, and update plan regularly</td>
</tr>
<tr>
<td>d. Assess side effects (bowel habit, nausea, vomiting...)</td>
</tr>
<tr>
<td>e. Assess patient function</td>
</tr>
<tr>
<td>f. Assess patient pain</td>
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<tr>
<td>g. Recognize special issues presented by patients for therapeutic conversations</td>
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</tbody>
</table>

## 2 – Monitor before Prescribing

<table>
<thead>
<tr>
<th>Monitor before Prescribing</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Check Prescription Drug Monitoring Program (VPMS in Vermont) and repeat annually</td>
</tr>
<tr>
<td>b. Screen urine at least annually for presence/absence of substances (may be random)</td>
</tr>
<tr>
<td>c. Conduct pill count, depending on risk of individual (may be random)</td>
</tr>
<tr>
<td>d. Provide patient education on benefits and risks, initiate treatment agreement, &amp; obtain informed consent: update documents regularly and review with patients regularly</td>
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## 3 – Prescribe

<table>
<thead>
<tr>
<th>Prescribe</th>
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<tbody>
<tr>
<td>a. Best practices in prescribing for targeted patients; <em>e.g.</em>: offer naloxone when appropriate</td>
</tr>
<tr>
<td>b. Prescribe in multiples of 7 days in duration of dosage</td>
</tr>
<tr>
<td>c. Pre-write prescriptions for up to 84 days when management is stable</td>
</tr>
<tr>
<td>d. Prescribe bubble packs if risk level increasing, depending on availability</td>
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<tr>
<td>e. Tapering schedule – Schedule patients based on selected tapering schedule</td>
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</table>

## 4 – Document

<table>
<thead>
<tr>
<th>Document</th>
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<tbody>
<tr>
<td>a. Track dosage in MMEs, not quantity dispensed</td>
</tr>
<tr>
<td>b. Use a flowsheet to document repeating strategies for opioid management</td>
</tr>
</tbody>
</table>

## 5 – Schedule

<table>
<thead>
<tr>
<th>Schedule</th>
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<tbody>
<tr>
<td>a. Short interval follow up after initiating new Rx to review effect</td>
</tr>
<tr>
<td>b. Ongoing visits at least every 90 days (84 when using 7 day strategy above)</td>
</tr>
<tr>
<td>c. Update your practice’s Pain Management Council at next regular meeting</td>
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</table>

## 6 – Engage Resources

<table>
<thead>
<tr>
<th>Engage Resources</th>
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<tbody>
<tr>
<td>a. Identify resources that may be helpful and update periodically</td>
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<tr>
<td>b. Build a patient library with books, CDs, etc.</td>
</tr>
<tr>
<td>c. Build community support with other partners/agencies</td>
</tr>
<tr>
<td>d. Share skills that are widely useful, e.g. how to have “trigger” conversations</td>
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## 7 – Manage the Population

<table>
<thead>
<tr>
<th>Manage the Population</th>
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<tr>
<td>a. Roster: Include patient in registry for population management reports</td>
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0 - SELF-ASSESS COMMITMENT

a. Treatment consistency across practice

All the strategies in this Toolkit depend on a “Universal Precautions” approach to opioid prescribing, proposing that it is more effective to treat all patients receiving opioid therapy consistently with a single guideline agreed to by all prescribers in the practice. Providers should consider whether they differentiate among patients by age (“the patient is old enough for me not to worry about misuse or diversion”), employment (“has a good job”), income (“doesn’t need to worry about money”), or how long or well the provider has known the patient (“we go way back”). Although most patients present their pain-related needs accurately, those few who do not may have any of the above characteristics. Applying the selected strategies consistently across all patients receiving opioid therapy (Universal Precautions) by all prescribers improves their effectiveness.

Consistency of the use of the strategies across the practice also makes it easier for prescribers and staff to maintain. Furthermore, greater consistency leads to better patient ability to understand and make choices about adopting the behavior that the practice providers expect of them while using opioids to manage chronic pain.

This Toolkit assumes that providers use or are open to using a standard clinical approach for helping patients with chronic pain management. Chronic pain visits may include, for example:

- Pain and Functional Assessment
- Risk Evaluation
- Treatment Plan
- Follow-up and Monitoring
- Specialty Referral
- Urine Drug Testing
- Discussions around the possibility that Opioid Therapy will be terminated

Whatever strategies the practice chooses to support these patients, everyone benefits if all prescribers use them consistently. Before selecting any strategies, review and confirm the practice’s prescribing philosophy and the underlying expectations of some key questions:

- Are all providers willing to use opioids to care for patients with chronic, non-palliative care pain?
- Under what circumstances are unscheduled refills permitted; for example “at visits only” or “only enough until the next available appointment on the schedule?”
- What is the patient expected to do when calling for a refill; for example, “must call two business days before refill is needed?”
- How will providers respond to evidence that patients are using other substances, such as alcohol or marijuana?
- How will providers respond to concerning behavior by the patient? For example, does the practice take a “zero tolerance” perspective or does it allow concerning behavior under some circumstances?
- What is a covering provider expected to do in response to a refill request? For example, prescribe a sufficient dose until the next available appointment with the patient’s primary provider?
- How should the practice respond to anonymous phone calls about the patient or information from the Department of Corrections about parolees?
- What alternatives to opioid therapy will be offered to patients, such as mental health/behavioral health, physical therapy, complementary health services (acupuncture, chiropractic services)?
- Will these decisions be applied to ALL patients with chronic, non-palliative care pain (that is, will the providers agree to use a “Universal Precautions” approach)?

Confirm with your prescribing providers that a consistent treatment approach is a goal that all support.
b. **Team-based care approach**

All provider and staff roles in the practice can have an impact on patient education and reinforcement of practice protocols and policies regarding opioid prescription management. Because empathy and understanding are important skills to maintain in support of all patients, all providers and staff benefit from shared education on the practice’s policies and protocols regarding opioid prescription management. A “team approach” to implementing and maintaining these policies and protocols increases the likelihood of a sustained, consistent approach in the care of patients with chronic pain. See “Team Approach to Opioid Prescription Management” sample protocol in Appendix E.

Confirm with your prescribing providers that a team-based care approach is a goal that all support.
1 - ASSESS AND RE-ASSESS

a. Initial risk assessment

Prior to starting a course of opioid treatment for a patient, conduct an assessment to estimate the risk of misuse or abuse of controlled substances. These tools are brief and intended to be conducted by the provider, during the medical exam, or by the patient, prior to the exam. The risk factors for abuse include personal or family history of substance abuse, history of preadolescent sexual abuse, mental disease/pathology, social patterns of drug use, psychological stress, behavior associated with abuse or misuse, and uncontrolled or inadequately treated pain (the primary risk factor for misuse).

It is possible to reduce the risk of misuse and abuse by screening patients to address risk of misuse, abuse, and addiction and stratifying treatment for risk of misuse, abuse, and addiction. Tools currently available for initial assessment are found in Appendix G:

- ORT: Opioid Risk Tool (5 questions to be completed by provider, with patient)
- SOAPP-14: Screener and Opioid Assessment for Patients with Pain (14 questions, by patient)
- SOAPP-5: Screener and Opioid Assessment for Patients with Pain (5 questions, by patient)
- SOAPP-R: Screener and Opioid Assessment for Patients with Pain (revised assessment with 24 questions that can be completed by patient)
- Chronic Pain Assessment Algorithm and DIRE Score from the Institute for Clinical Systems Improvement (7 risk factors assessed by the provider)

Related tools that are available on the Internet or through professional organizations:
- Patient Self-Report Tool
- Mental Health Screening Tool
- Substance Abuse Risk Factors

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Review available assessment tools and select one for trial

Decide how the assessment will be conducted
- When will the patient receive the tool (in the waiting room or in the exam room)?
- Who will provide the tool (clinical staff or provider)?
- Who will assist the patient with the tool (clinical staff or provider)?
- Who will score the results for use during the clinical exam?
- Who will document the results in the chart?
- Where will the results be documented in the chart?

Trial the assessment with one provider and a sample of patients (approximately eight)

Decide if the trial will continue into implementation or if an alternate tool should be used; if continued, consider whether to put the assessment into the electronic record

Measure success
Example: Chart audit for an assessment prior to prescription of a new opioid treatment
b. Consider best practices in care

i. Non-opioid and non-pharmacological treatment

Research data suggest that opioids are no better than non-opioid alternatives in reducing pain and improving function for most patients with chronic pain. Non-opioid alternatives may include medications, such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), certain antidepressant medications, joint injections, and topical products. Non-opioid alternatives may also include non-pharmaceutical approaches, such as chiropractic or osteopathic manipulation, acupuncture, physical therapy, yoga, tai chi, cognitive behavioral therapy, or other modalities. Evaluate the individual risks and benefits of any treatment strategy.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

- Consider how non-opioid alternatives that have been shared with or attempted by the patient will be documented in your electronic health record. Documentation, at a minimum, should include the strategy and how long the non-opioid alternative was tried.
- Develop a list of non-opioid community resources that are available for pain management.
- Identify and try disease-specific treatments (e.g. triptans for migraines).
- Develop patient education supporting non-opioids as first-line treatment for chronic pain.

ii. Arrange for Medication Assisted Treatment (MAT) for patients with Opioid Use Disorder (OUD) or if patient develops and maintains high risk characteristics; engage patients and help get into treatment

Many patients with opioid use disorder suffer from chronic pain and from mental health disorders such as anxiety, depression, ADHD, or PTSD. Many have been subjected to psychosocial stressors or trauma. It is important that prescribers be alert to signs of substance abuse disorders (SUD) in patients with chronic pain and facilitate access to evidence-based treatment (such as medication assisted therapy) when indicated. Prescribers may have to balance the benefits and risks of dismissing a patient from the practice versus working with that patient to engage in treatment for SUD. This balancing may take into account perspectives of the patient, office staff, the prescriber, and the community—firing a patient abruptly may perpetuate a problem and have consequences for the next prescriber who may care for this patient and for the community at large.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

- Identify and address co-existing mental health conditions that may be contributing to the patient’s symptoms.
- Develop a list of community providers that can provide care for specific mental health conditions (anxiety, depression, ADHD, or PTSD), including information about limitations with respect to new patients and insurance carriers accepted. In Vermont, identify the “hub and spoke” organizations that are affiliated with your practice.
- Support referral and treatment uptake with mental health providers as needed.
- Chronic pain patients are at increased risk for suicide. Screen for suicidality when developing a plan for care.
- Follow up with providers and patient to track use of and progress with this service.
c. Ongoing risk assessment, risk and benefit review with patient & update plan regularly

At regular intervals, and at least annually, conduct an assessment to evaluate the success of opioid treatment. As with any chronic condition, the pathophysiology underlying the condition may change over time, as can the potential for harmful effects of the treatment. New treatments may become available, or new studies about known treatments may influence the optimal treatment plan. Chronic pain management is a very active area of research.

Regular assessment allows the provider to monitor patients consistently for changes in potential risk factors, encourage patients in self-management, and counsel patients on safe use.

Monitoring typically includes the 5As: analgesia, activity, adverse effects, aberrant/concerning behavior, and affect. A risk assessment tool is currently available for ongoing assessment and found in Appendix H:

- COMM: Current Opioid Misuse Measure (17 questions to be completed by patient)

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Review available ongoing assessment tools and select one for trial

Decide how the assessment will be conducted

- When will the patient receive the tool (in the waiting room or in the exam room)?
- Who will provide the tool (clinical staff or provider)?
- Who will assist the patient with the tool (clinical staff or provider)?
- Who will document the results in the chart?
- Where will the results be documented in the chart?

One provider trials the assessment with a sample of patients (~ 8 patients)

Decide if the trial will continue into implementation or if an alternate tool should be used

- If continued, consider whether the assessment should be built into the practice’s electronic health record

Measure success

- Chart audit to identify the presence of the assessment during the course of opioid treatment
- Chart audit to verify follow up of results in treatment plan
d. Assess side effects (bowel habit, nausea...)

The side effects most commonly encountered with opioids are: nausea, constipation, over-sedation, itching, and depressed mood. Less common side effects may include respiratory depression, delayed gastric emptying, hyperalgesia, immunologic and hormonal dysfunction, muscle rigidity, and myoclonus.

Routine questions about the common side effects can support early recognition and management.

**Steps to consider for the PLAN section of your PDSA Cycle for this Strategy**

Review symptoms and select those that the practice will track consistently.

Decide how to identify and document the symptoms:
- Who will assess the patient and when in the course of the visit?
- How will the symptoms be assessed?
- Who will document the results in the chart?
- Where will the results be documented in the chart?

Trial the assessment of symptoms with one provider and a sample of patients (~ 8 patients)

Decide if the trial will continue into implementation or if adjustment is needed

Measure success
Example: Chart audit for symptom tracking
e. Assess patient function

At regular intervals, conduct an assessment to evaluate the functional status. Consider functional improvements to be a primary goal of therapy, as function can improve even in the presence of pain. Functional improvements are important, as individual benefits of opioid therapy may vary, however the risks of opioid therapy are well established. There are several disease-specific tools that may be used to help establish and monitor realistic functional goals with patients. For example, the Pain, Enjoyment, and General Activity (PEG) Assessment Scale has a clinically meaningful improvement defined as a 30% improvement in score.

Tools currently available for ongoing functional assessment and found in Appendix H:

• PEG: Pain, Enjoyment, and General Activity (3 questions asked by the clinician)

• Rapid 3 Routine Assessment of Patient Index Data

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Review functional assessment tools and select one that the practice will use consistently.

Decide how to identify and document functional assessment:
• Who will assess the patient and when in the course of the visit?
• Who will document the results in the chart?
• Where will the results be documented in the chart?

Trial the assessment with one provider and a sample of patients (~ 8 patients)
• Establish realistic treatment goals when initiating therapy
• Evaluate within 1-4 weeks of initiating opioid therapy and at least every 3 months thereafter
• Evaluate with any increases in dosage, especially if patients are using methadone or fentanyl or are on 50+ MME doses per day
• If benefits do not outweigh risks, taper opioids

Decide if the trial will continue into implementation or if adjustment is needed

Measure success
Example: Chart audit for functional assessment
f. Assess patient pain

At regular intervals, conduct an assessment to evaluate pain. Routine assessments of pain are an important monitoring parameter of opioid therapy, although functional improvements should be a primary goal. Realistic improvement goals in pain should be decided on with patients early, as many patients with chronic pain may never be pain free. The Centers for Disease Control (CDC) recommends the three-item “Pain average, interference with Enjoyment of life, and interference with General activity” (PEG) Assessment Scale with a clinically meaningful improvement defined as a 30% improvement in score. The CDC guidelines also note that patients using opioids who do not have pain relief within 1 month are unlikely to benefit and should be tapered.

Tools currently available for ongoing pain assessment and found in Appendix H:

• PADT: Pain Assessment & Documentation Tool (over 24 questions to be completed by the provider with the patient)

• Cares Alliance Brief Pain Inventory (21 questions to be completed by patient)

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Review pain assessment tools and select one that the practice will use consistently

Decide how to identify and document pain assessment

• Who will assess the patient and when in the course of the visit?

• Who will document the results in the chart?

• Where will the results be documented in the chart?

Trial the assessment with one provider and a sample of patients (~ 8 patients)

• Establish realistic treatment goals when initiating therapy

• Evaluate within 1-4 weeks of initiating opioid therapy and at least every 3 months thereafter

• Evaluate with any increases in dosage, especially if patients are using methadone or fentanyl or are on 50+ MME doses per day

• If benefits do not outweigh risks, taper opioids

Decide if the trial will continue into implementation or if adjustment is needed

Measure success
Example: Chart audit for pain assessment
Recognize special issues presented by patients for therapeutic conversations

In addition to the validated tools used for the assessment of an individual’s risk for misuse, prescribers can be alert to other behaviors that may be associated with opioid misuse, such as: missing appointments, repeatedly misinterpreting instructions, rude behavior with staff, creating conflict between prescriber and staff (“splitting”), and others. Using a respectful and thoughtful team approach assures consistent messaging and helps keep prescribers and staff on the same page. Conversations with patients that share observations and ask open-ended questions to elicit new information can help in updating treatment plans appropriately.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Review commonly appearing special issues and select those that the practice will track consistently

Decide how to identify and document special issues that arise
  • Who is responsible for identifying special issues that arise?
  • What will be documented in the chart and what messages will alert providers?
  • Who will document the results in the chart?
  • Where will the results be documented in the chart?

Trial the assessment over time

Decide if the trial will continue into implementation or if adjustment is needed

Measure success
Example: Chart audit for functional assessment
2 – MONITOR BEFORE PRESCRIBING

a. Check Prescription Drug Monitoring Program (VPMS in Vermont)

The July 2017 Vermont Prescription Monitoring System (VPMS) rule requires a query for any new opioid Rx of 10+ pills, in addition to the previous query requirement for chronic Rx, or for “replacement” prescriptions. VPMS provides access to all dispensed medications by pharmacies in Vermont regardless of payer source, including cash. It does NOT include medications dispensed in Emergency Departments, hospitals, or clinics specializing in addiction management (i.e. Suboxone clinics). Access to VPMS is allowed to any prescriber and delegated staff working for the prescriber’s practice. Pre-registration and authorization are required. For more information: https://www.healthvermont.gov/alcohol-drugs/professionals/vermont-prescription-monitoring-system-vpms.

Prescribers must query VPMS in the following circumstances:
- Prior to writing a first opioid prescription for 10+ pills (e.g. opioids, tramadol)
- Prior to writing a first prescription for a benzodiazepine, buprenorphine, or methadone
- Prior to starting a patient on an opioid for a trial, or short term, treatment of chronic pain
- Prior to starting a patient on a chronic opioid (90+ days) for non-palliative therapy
- Prior to writing a replacement (e.g. lost, stolen) of any scheduled II-IV controlled substance

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Decide how often to review patients’ VPMS records: at every pain-related visit or at regular intervals

Decide who (such as the prescriber, delegated nurse, medical assistant, or other staff) will review VPMS records and when; for example:
- For pain-related visits: review as a part of pre-visit preparations (i.e. when printing the superbill, prepping the chart, or during the reminder phone call)
- At regular intervals: review patients’ records in batches to combine multiple requests in a single report
- Ensure all prescribers and delegated staff are trained and have active passwords
- Consider using the Bulk Patient Search and Report functions within VPMS
b. Screen urine at least annually

Periodically, and at least annually, collect a urine sample from all opioid therapy patients to test for the presence/absence of controlled substances. Note that there is no high-quality evidence that urine testing is an effective monitoring activity. However, urine screening is included in many national and state guidelines and is an expectation of good practice, even for low risk patients.

Depending on your practice’s experience with collecting urine samples, random collection may be appropriate at non-predictable intervals. There is a great deal of anecdotal evidence that most patients who comply with urine screening are not misusing or abusing their medications. However, those who do misuse often have strategies to conceal this fact from their providers. Random screening helps providers identify patients who are not honest about their medication usage.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Determine what form of urine screening to adopt

- Routine testing: regular screening of all patients at predictable intervals (for example, annually)
- Random testing: screening that occurs at unpredictable intervals

Prepare for key issues

- Interpretation of results will be affected by specific detection windows for substances screened
- Some practices report benefits of witnessed samples, in which the collection process is observed by clinical staff. Before deciding, consider cultural and gender barriers of staff/patients.
- Urine samples sometimes produce a result that the patient contests. Have a clear, easy to follow protocol for the chain of custody of samples while they are in practice.
- Develop a protocol for following up on positive results claimed to be false by the patient
- Consider the cost to the patient or practice or overall health care system
- If collecting urine samples randomly, decide if samples will be collected during regularly scheduled visits or in response to “on demand” visits required on the day-of-call. Day-of-call samples place a burden on patients and practices but may be appropriate in some communities.

Plan the logistics of collecting urine samples in the practice

- Physical space
- Make a part of rooming process
- Consider internal vs. external testing

Plan for how to make decision to obtain a random sample

- For scheduled visits, the decision can be dependent on special issues documented in the chart indicating unexpected behavior (calling in for medication refills). Or the decision may be based on a plan to screen at least once/quarter. Or it may be determined randomly, such as by a coin toss.
- For on-demand visits, patients may be randomly assigned to a “day of the week” based on the primary provider’s schedule in the practice. A random subset of “Monday’s” patients are called on Monday morning and are required to come to the practice for a urine screen. Or use a roster of patients with chronic pain to randomly select a subset of patients to call.

Determine who makes the decision and when the decision gets made.

- For on-demand visits, develop a phone call script to assist callers

Plan a documentation process for results, including

- For on-demand visits, non-responders or no-shows
- Inability to produce a sample at the time of the visit

Measure success

- For on-demand visits, log of phone calls made and responses
- Chart audits to confirm the presence of lab results
- Chart audits to confirm follow up in treatment plan for positive results
**c. Conduct a random pill count, depending on risk of individual**

Randomly review pill containers or bubble packs to confirm the number of doses remaining in the prescription period. This strategy can be conducted in tandem with Urine Screens (see above). Patients are called (for scheduled or unscheduled visits) with a reminder to bring their prescription medications in their original containers to their visits.

**Action Steps**

**Issue to consider:** is the benefit of doing a pill count greater than the risk of asking patients to carry controlled, unsecured substances with them over the course of the day?

**Develop a plan for how to make a decision to conduct a random pill count**
- For scheduled visits, the decision can be dependent on any special issues documented in the chart indicating unexpected behavior (calling in for medication refills). Or the decision may be based on a plan to screen at least once/quarter. Or it may be determined randomly, such as by a coin toss.
- For on-demand visits, patients may be randomly assigned to a “day of the week” based on the primary provider’s schedule in the practice. A random subset of “Monday’s” patients are called on Monday morning and are required to come to the practice for a pill count. Or use a roster of patients with chronic pain to randomly select a subset of patients to call.

**Determine who makes the decision and when the decision gets made**
- For on-demand visits, develop a phone call script to assist callers

**Plan a documentation process for results,** including
- For on-demand visits: non-responders or no-shows
- Unable to produce medications (for example, forgot to bring them)

**Measure success**
- For on-demand visits: log of phone calls made and responses
- Chart audits to confirm pill-count documentation
- Chart audits to confirm follow up in treatment plan for unexpected results.
d. **Provide patient education on benefits and risks, initiate treatment agreement, & obtain informed consent**

i. **Update the practice’s standard education, agreement, and consent documents regularly**

The patient informed consent and treatment agreement (contract) includes the expected standard of care of the practice (e.g., the procedure for obtaining a refill prescription) and the expected behavior of the patient (e.g., receiving pain medications from only one prescriber and one pharmacy). Patient education and a written consent form are required for patients receiving any opioid prescription, acute or chronic.

**Action Steps**

**Determine the expectations** of the practice for its patients who use opioid therapy for chronic pain

**Create or update the patient agreement template** for use with all patients with chronic pain. Note that:
- Practices that are part of a larger health care system may need to obtain further review
- Expectations related to this topic are subject to change; anticipate future updates.
- Some patients may have low levels of literacy. Write for a broad audience and avoid jargon.

**Plan how to replace the old agreement** with a new one, to be reviewed and signed by the patient. Document the date of agreement review in the medical record (such as on a flowsheet) for easy identification of patients who have not received updated agreements and date of next review with patient.

**Plan how to provide a copy for the patient** and to retain a signed copy for the patient’s medical record

**Consider sharing completed agreements with other providers**, e.g., Emergency Departments

**Measure success**
- Presence of an updated patient agreement template for practice use
- Chart review identification of completed agreements in patient charts
- Recency of last date of update

ii. **Update the patient’s knowledge, understanding, and use of their signed documents regularly**

At regular intervals, and at least annually, review the patient agreement with the patient and confirm patient/provider compliance with the expectations set forth. The risk of opioid misuse remains high throughout the entire period of treatment. Periodic review of the expectations accepted by the patient, along with the reminder that opioid therapy is not necessarily a permanent treatment for pain, reinforces continued awareness by the patient that the ultimate goal is to maintain or improve health and function.

**Action Steps**

**Plan a documentation process** for identifying the date of last agreement review
**Decide how to make a copy of the original patient agreement** available for provider and patient review, or provide access to blank agreements for review and re-signature
**Determine the process for review** and who reviews the chart to determine when the next review is needed

**Measure success**
- Presence of the agreement in the patient chart; Recency of last date of update
a. **Best practices in prescribing:**

**Start with immediate release opioids; avoid doses greater than 50 or 90 MME/day; avoid concurrent benzodiazepines; offer naloxone**

When initiating opioids, the CDC has emphasized the importance of starting with the lowest effective dose and increasing gradually, typically using immediate release medication formulations. Particular caution, and a reassessment of the risk and benefits, should be undertaken when the dose exceeds 50 morphine milligram equivalents (MME) per day as these dosages are associated with higher risk of overdose and death. Daily doses beyond 90 MME/day are in the highest risk category and should be justified with appropriate documentation.

Naloxone is a non-addictive opioid reversal medication used to immediately decrease the life-threatening side effects of opioids, such as impaired breathing, sedation, and loss of consciousness. Patients prescribed higher doses (higher MME per day), those who are prescribed both an opioid and a benzodiazepine, patients with a history of overdose, and patients with a history of substance use disorder are at increased risk for overdose death, although they may not see themselves as at risk. However any patient, family member, or bystander interested in carrying naloxone should be encouraged to do so.

**Steps to consider for the PLAN section of your PDSA Cycle for this Strategy**

- Engage prescribers in discussion/agreement to calculate morphine milligram equivalents (MME) and document in chart.
- Consider how your electronic health record can support MME documentation
- Understand where patients can access naloxone. Vermont pharmacists may sell naloxone to any person who wants it, without a prescription, per the Standing Order for Distribution of Naloxone Prescription for Overdose Prevention. The Vermont Department of Health offers free naloxone in locations around the state. Please check the Vermont Department of Health website and advise patients to call before arriving to receive a naloxone rescue kit. Recommend patients update their clinic medication list and pharmacy medication profile to reflect receipt of naloxone.
- Calculate MME. Consider 50-89 daily MME a “yellow light” and 90+ MME a “flashing red light.”
- Offer naloxone to all patients on chronic opioids, even in the absence of obvious risk factors
- Create patient education materials that lower the stigma for accepting naloxone. Emphasize naloxone is for preventing bad outcomes (e.g. similar to carrying epinephrine for preventing life-threatening allergic reactions)
- Educate patients on the use of naloxone and encourage patients to educate family members or significant others who may likely be present during an overdose
- Maintain a supply of naloxone in the clinic, in case a patient overdoses while in the building. Train staff to know how to access and use naloxone in this situation

**Measure success**

- Presence of MME documentation in chart
- Presence of patient education and adjusted treatment plan for doses above 50 MME/day
- Presence of offering of naloxone to patients for doses above 50 MME/day or concurrent dosing of benzodiazepine
b. Prescribe in multiples of 7 days in duration of dosage

Prescribe medication dosages for periods that are multiples of 7 days (28 days, 56 days, 84 days...). This strategy only applies to medications not packaged by the manufacturer in fixed amounts. Prescriptions for 28 days instead of 30 days will not be due on weekends and are likely to be due on days when the prescribing provider is routinely in the office.

- Note: when possible, medications should be planned to start on Tuesdays, Wednesdays, Thursdays, or Fridays so that an early “refill medication” message is received on a day that the practice is open.

- Patients may take up to three days to fill a prescription and may therefore call again later than expected. Adjust the quantity of doses given so that the next prescription is likely to run out on the day of the week that the primary provider is usually available to follow up on refill requests.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Post monthly calendars in locations where providers write prescriptions (for example, in exam rooms) to make prescription counts easy to calculate.

Prescribers write opioid prescriptions in 7 day multiples, using a single system to produce scripts (e.g. electronic OR handwritten, but not both)

- 30 days -> 28 days
- 60 days -> 56 days
- 90 days -> 84 days

Measure success

- Monitor prescription date cycles
- Survey provider and staff satisfaction
c. Pre-write prescriptions for up to 84 days when management is stable

For a patient on a stable course of treatment with predictable refill intervals, pre-print multiple prescriptions for up to three months (preferably, in periods of 28 days, up to 84 days as explained in the previous strategy). Prescriptions can be given a “do not fill before” date that matches the treatment plan for the patient. Prescriptions for future periods can be:

• Held at the front desk for future pick-up

• Given to the patient for self-management, with clear explanations that they will not be replaced if accidentally destroyed, lost, stolen, or misplaced (note: pharmacies will NOT fill these before the “fill date” determined by the provider)

• Given to the patient to give to the pharmacy for future dispensing

• If technically available, send prescriptions electronically

Mailing scripts through the postal service is NOT recommended, either to patients or to pharmacies.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Determine whether the front desk will hold the prescriptions to be filled in the future or if they will be given to the patient

• If given to the patient, determine whether the provider hands the scripts directly to the patient or takes it to the front desk, thereby requiring the patients to “check out” for completion of any additional steps (such as scheduling the next visit).

• If given to the patient to leave at the pharmacy, identify available pharmacies willing to hold unfilled prescriptions for opioids. Some retail pharmacies will NOT accept this responsibility.

• If held by the front desk, create log in/sign out protocol for office staff

Consider whether “prior authorization” will be needed for some scripts some of the time. If so, consider keeping the information about the next renewal date for these authorizations where staff can initiate the renewal process in advance.

Measure success

• Log of prescription pick-up

• Patient phone volume for prescription requests.
d. **Prescribe using bubble packs if risk level is increasing, depending on availability in local pharmacies**

If risk level is increasing and local pharmacies can provide support, prescribe medications with dispensing instructions that require secure packaging: bubble packs, bingo cards, tear off strips, etc. These forms of packaging are uniquely stamped, connecting each dispensed package to a specific patient. As a result, medication checks can confirm that the patient has the appropriate package and the appropriate amount of medications, forestalling any inclination of patients to borrow (or rent) pills to meet the expectations of the provider.

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**Steps to consider for the PLAN section of your PDSA Cycle for this Strategy**

**Identify available pharmacies**, by geographic location, that are able to dispense medications in these forms. Find out if this form of packaging will be costly to the patient or covered by insurance plans.

**Determine if the provider will require patients to change pharmacies** in order to use this strategy.

**Place lists of cooperating pharmacies** in exam rooms or embedded in documentation system for easy access by prescribers.

**Measure success**
- List of available pharmacies
- Prescription records in patient charts
All chronic opioid regimens should come with a periodic evaluation of risks and benefits of continuing treatment. If the benefits no longer outweigh the risks, opioids should be tapered. The decision to taper opioids ideally is between a patient and their provider. Consider tapering to a reduced dosage or tapering and discontinuing opioid therapy when your patient:

- requests a dosage reduction
- does not have clinically meaningful improvement in pain and function (e.g., 30% improvement on the 3-item PEG scale or other assessment tool)
- is on dosages 50+ MME per day without benefit
- is prescribed both an opioid and a benzodiazepine
- shows signs of substance use disorder (e.g. work or family problems related to opioid use, difficulty controlling use) or other “red flags” (positive COMM score, issue with PDMP)
- experiences overdose or other serious adverse event
- shows early warning signs for overdose risk such as confusion, sedation, or slurred speech

**Steps to consider for the PLAN section of your PDSA Cycle for this Strategy**

Engage prescribers in the practice about their agreement to

- Ask and/or screen patients for pregnancy prior to tapering. If a patient is pregnant, engage specialists (e.g. high-risk obstetrics). Do not attempt to taper on your own, unless you have specific experience and training in this area.
- If tapering or discontinuing due to newly identified opioid use disorder (OUD), arrange for evidence-based treatment for OUD
- Initiate behavioral and other non-opioid pain management strategies while tapering
- Calculate total MME for patient’s opioid regimen
- If patient is on multiple opioids, prioritize which one to taper first
- If patient is on an opioid and a benzodiazepine, prioritize which one to taper first
- Work with the available strengths to reduce the dose
- Make sure the patient understands and can follow the plan
- Consider use of bubble-packing to help patients follow the plan
- Check in with the patient often (more frequently if on a faster tapering approach)
- Slow down the taper if patient is experiencing withdrawal effects
- Monitor pain and function with evidence-based tools (e.g. PEG)
- Consider a tool such as the Clinical Opiate Withdrawal Scale (COWS) to monitor for withdrawal symptoms ([https://www.mdcalc.com/cows-score-opiate-withdrawal](https://www.mdcalc.com/cows-score-opiate-withdrawal))

Consider how your electronic health record can support tapering documentation

**Measure success**

- Review charts for tapering protocol and consider case review for complex situations

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37
a. Track dosage in MME

Clinicians should be familiar with the conversion of opioids into milligram morphine equivalents (MME). The Centers for Disease Control maintains internet- and phone-based applications for this purpose. Of note is that methadone dosing is particularly complex as the conversion rate varies with the daily dose.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

- Discuss/agree on calculating morphine milligram equivalents (MME) and document in chart. To use the CDC MME Calculator, go to: https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
- Consider how your electronic health record can support MME documentation
- Calculate MME. Consider 50-89 daily MME a “yellow light” and 90+ MME a “flashing red light.”

Measure success
• Presence MME documentation in chart

b. Use a flowsheet to document strategies selected above from “Assess & re-assess” and “Before prescribing” actions

Documentation of visits related to chronic pain is consistently charted on a flowsheet or other template that prompts providers to gather specific kinds of data. The documentation process should be integrated into the practice’s health record system. A standard flowsheet or template should include specific data elements that providers want to include in their decision-making process with patients. It should follow the standard flow of questions asked during the medical exam. Example fields include:

- Current medications
- Treatment goal
- PDMP result and date (VPMS in Vermont)
- Urine drug screen result and date
- Pill count result and date
- Risk assessment score and date
- Pain score and date
- Functional status score and date
- Bowel habit and date
- Cognitive function and date
- Patient agreement present and date
- Special issues (e.g. alcohol use, illicit substance use, prescription mishandling, cancelled appointment)
- Drug and alcohol counseling completed: result and date
- Quantity dispensed
- Visit required for next prescription.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Design flowsheet or template based on the philosophy, protocols, and selected strategies from Toolkit
Plan data entry roles: for example, who enters lab data or updates the PDMP (VPMS) fields
Trial usability of flowsheet, including arrangement of fields for data entry, drop down choices for responses, and appearance when reviewing at a later visit
Measure success
• Review charts for adherence to documentation standard
• Collect feedback from providers, in their roles as primary provider and covering provider
a. Short interval follow up

Most patients on chronic opioid therapy were initiated on acute therapy and it is not uncommon for the transition from acute to chronic to be somewhat vague. Extra caution is warranted in the early phase of opioid therapy, with frequent follow up and reassessment of risk and benefits. Many clinicians recommend establishing a clear “exit plan” at the time initiation—this is an explicit discussion of the expected duration of therapy or a contingency plan for discontinuation of treatment if it is not effective. This language is often included in patient consent and treatment agreement forms.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Establish an expectation with patients that the early stages of opioid treatment, or periods of adjustment, require regular assessment for its effects in not more than 4 weeks of initiation

Link opioid treatment start up or change with the scheduling process for the practice

Measure success
For patients receiving new or changed opioid therapy, review their visit patterns.

Monitor patient phone calls for unexpected requests: (i.e. adjustments in medications, early refills)

b. Pain Management visits every 84 days

Regular, scheduled patient visits specifically for “chronic pain management” ensure that assessment, treatment, and monitoring of patients undergoing opioid treatment are planned for and addressed, rather than incidental to other medical needs that arise. For patients on opioid treatment for chronic pain, a visit every 90 days is now required under the July 2017 Vermont rules. The definition of opioid under these rules includes tramadol. With the focus of the visit on pain management, provider and patient can be assured of having the time needed for a conversation about the current effectiveness of treatment and the need for any changes. A benefit of this strategy can be fewer unexpected calls or provider interruptions because there will always be a “next scheduled visit” for this purpose.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Create a unique type of visit for “Chronic Pain Management” within the scheduling system

Establish a practice expectation for how often Chronic Pain Management visits should occur

Establish an expectation with patients that the end of the Chronic Pain Management visit includes creating an appointment for the next one

Initiate the first set of Chronic Pain Management visits with patients, introducing the plan through a letter from the practice or through a discussion with their primary providers

Measure success
For patients receiving opioid therapy, review their visit patterns.

Monitor patient phone calls for unexpected requests: (i.e. adjustments in medications, early refills)
The Chronic Pain Management Council gives practice providers meeting time to review specific patient treatment history and plans. It may be used to share a common approach across the practice, when a new provider joins the practice, or when a past provider leaves the practice and turns over care for current pain management patients to other providers. This strategy shares responsibility for opioid prescribing across the practice and provides an alternate opinion regarding the suitability of a patient for chronic opioid therapy. Some practices use this approach only when responding to special patient issues and decisions about stopping therapy.

Providers meet to conduct a chart review of long term chronic pain patients on opioid treatment at regular meetings or on an “as needed basis.” Decisions about changes in pain medications or to discontinue medications take place separately from the patient visit. The primary provider collects information from the patient in order to represent the patient’s condition accurately and express the need for pain control. The providers who agree to meet as the “Pain Management Council” provide an objective perspective on the best practice of care for an individual patient. The primary provider meets with the patient again to review the recommendation of the Council and to help the patient plan follow up actions.

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**Steps to consider for the PLAN section of your PDSA Cycle for this Strategy**

**Plan regular meeting times for group discussion** to support decisions around changes in treatment for complex patients.

**Providers take turns bringing selected patients’ case histories** to the Pain Management Council for case review.

**Measure success**

Provider satisfaction
a. Identify community resources that may be helpful and update periodically

Every community has unique resources that can help patients find alternative ways to respond to chronic pain or its causes. Create a one page overview, complete with website addresses, for patients to engage with these resources, including:

- Chiropractic care
- Acupuncture
- Traditional Chinese Medicine
- Training in Mind/Body approaches, including stretching, medication management, relaxation, and stress management techniques, and mindfulness
- Chi Kung or Qi Gong (also known as Chinese yoga) or Tai Chi
- Behavioral health providers to assist with health behavior self-management plans

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

- Develop a list of non-opioid community resources that are available for pain management
- Confirm availability to work with patients with chronic pain
- Update list periodically
b. Build a patient library with books, CDs, etc.

Develop a library of resources that are available to loan to patients or that patients may buy from practice, including books, audio programs, and websites. Examples that have helped many patients:

**Books**
- **Managing Pain before it Manages You**
  Workbook format
  Margaret A Caudill
  ISBN 978-1-59385-982-4

- **Natural Pain Relief – Shinzen Young**
  Short book with CD of exercises. Well-known, local author who specialize in mindfulness and its application to pain and suffering
  ISBN 978-1-60407-088-0

**Audio Files**
- **Mindfulness Meditation for Pain Relief**. By the founder of the Center for Mindfulness. Jon Kabat-Zinn. Available on CD from any major retailer.

**APPS for Smart Phones**
- **Autogenic Training and Progressive Muscle Relaxation** by 01 Digitales Design. This includes both progressive muscle relaxation and autogenic relaxation, both helpful for people with chronic pain. There is a small fee associated with this app.

- **Stop, Breathe, and Think** – An award winning app from Tools for Peace. This nonprofit has made this app available for free.

- **Mindfulness Training App** – Sounds True. A well-known publisher has gotten participation from many experts in mindfulness for this app.

- **Headspace** – An excellent app, which has a free basic section, followed by a subscription with hours of meditation instruction. This includes 30 sessions on pain management.

**Steps to consider for the PLAN section of your PDSA Cycle for this Strategy**

Engage prescribers in a conversation about resources they would recommend to their patients. Determine which of these the practice would like to make available on a loan/purchase basis to its patients

Create a list of resources and arrange a process to procure, store, and loan these resources to patients
c. Build community support with other partners/agencies

Every community has resources – schools, churches, hospitals, recovery centers, housing programs, and shelters – that can support a community response for assisting its members in responsible opioid use and effective responses to opioid misuse. Leaders from such organizations in your community can learn about local opioid use and join forces to create community goals in response to reports on community-based statistics. They can assist directly in sharing information, raising community awareness, and working through existing community programs to provide support.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Identify community organizations and leaders interested in learning about opioid use in the community and supporting program responses regarding opioid responsibility and responsiveness:

- Health care providers (medical and behavioral, preventative and acute care/emergency care)
- Recovery centers
- Public health providers
- Educators
- Community program coordinators
- Funders (e.g. for training)
- Community businesses with a commitment to health/wellness, prevention, or education
- Legislators when legislature is not in session
- Community agencies or organizations (churches, town government)

Determine what community-based information exists about opioid use, including reports from the state Department of Health, summary statistics from the practice’s registry on opioid prescribing, and information from other local initiatives. Make sure data shared includes no personal information but is aggregated at the population level, e.g. to describe groups of people by age category, not individuals.

Develop broad goals and specific objectives of community engagement – this may involve requesting time on agendas at regular meetings of these organizations or creating a community event.

Prepare for predictable issues that might arise, using the above forums to discuss such issues as

- Needle exchange programs
- Distribution of and training for naloxone
- Updates from Medication Assisted Treatment (MAT) teams, such as trends in care, new standards, primary care treatment in the use of prescription and non-prescription opioids

Plan logistics of community work based on identified needs, for example, new programs in education may require funding support or conference space; current community needs without supportive programs to support them may require start up support.

Create tools and methods to support community work such as communication networks, grant applications to access funding, and educational resources.

Measure success

- Attendance/participation
- Degree to which participants find the work meaningful
- Participation in specific projects
- Completion of tangible projects (e.g. summits)
- Development of network/inclusion in network/diversity of inclusion in network
- Consistency of activities

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d. Share skills that are widely useful, e.g. how to have “trigger” conversations

Given the scope of the opioid crisis in the US, there has been a strong focus on developing educational materials for prescribers and for office staff. The CDC guidelines have served as the most widely disseminated general overview of responsible opioid prescribing. In 2018 the FDA updated the “Risk Evaluation and Mitigation Strategy” (REMS) which requires pharmaceutical companies to provide education for health care providers prescribing opioids, and information for healthcare providers to use when counseling patients about the risks and benefits of opioids. Such counseling can be triggered by evidence of high-risk behavior, serious adverse events, opioid-related side effects, and patient preference, resulting in conversations that support alternative therapies and/or opioid tapering.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Participate in an educational program regarding opioid prescribing

These programs typically offer continuing education credits and also satisfy state-level educational requirements. Examples include:

- The Boston University SCOPE of Pain program (Safer/Competent Opioid Prescribing Education) offers online core content and supplemental training for opioid prescribers. This includes a module on a patient-centered approach to opioid tapering.
- American Society of Addiction Medicine CO*RE/ASAM Pain Management and Opioids: Balancing Risks and Benefits curriculum
- The Veterans Administration has developed print materials entitled “Opioid Taper Decision Tool” which is focused on tapering opioids, when appropriate.
- The Defense and Veterans Center for Integrative Pain Management offers a 35 minute video entitled “Initiating Collaborative Tapering” which includes examples of difficult conversations around opioid tapering. [http://www.dvcipm.org/clinical-resources/joint-pain-education-project-jpep/pain-educational-videos/#tapering](http://www.dvcipm.org/clinical-resources/joint-pain-education-project-jpep/pain-educational-videos/#tapering)

Identify local experts who may be available to educate office staff and prescribers regarding approaches to managing chronic pain, for example academic detailing programs

Engage the practice in a discussion of lessons learned and how these may be implemented into local practice
7 – MANAGE THE POPULATION

a. Roster: Use your health record system’s registry to create population management reports

Patients using opioids or other controlled substances for chronic pain are placed on a registry or uniquely flagged for easy identification. The registry can be used as a prompt for identifying patients whose care is governed by practice protocols and other strategies used for opioid prescription management. This registry may be useful in confirming adherence with regulations that require that patients be looked up in the PDMP (Vermont Prescription Monitoring System or VPMS in Vermont) at least annually.

Reports from this registry may also be helpful to identify patients who may be overdue for other surveillance strategies such as urine testing or pill counts, or other follow up as desired by the practice.

Steps to consider for the PLAN section of your PDSA Cycle for this Strategy

Create or update a roster of patients using opioids for long term pain management
• The roster may be developed by providers as they see patients over several months—this is relatively easy as patients must have their prescriptions renewed at short intervals. Another strategy to develop a registry is by downloading from the PDMP (VPMS in Vermont) using a three or six month lookback for all prescriptions by a specific prescriber—this is currently called the MyRx feature in VPMS. Alternatively if working with an electronic medical record it may be possible to define a roster of patients based on billing or pharmacy codes.

• Consider using tools associated with the practice’s Electronic Medical Record system, if available. For example, some practices agree to add a specific problem such as Chronic Pain Syndrome (ICD9 - 338.4) or Other Chronic Pain (ICD10 – R52.2).

Print out the roster of patients organized by the practice as a whole and by prescriber. Do this early in the project in order to
• Review for patients who are missing and should be on the roster
• Review for patients who are present who should be removed
• Consider whether cross-covering providers should be included in the team’s work or asked for input as the team progresses

Use the roster to track patients who need follow up due to
• The practice’s protocols with respect to chronic pain management (e.g. as a way to identify patients who need to have a discussion about their treatment)
• Strategies implemented from this Toolkit, such as regular Chronic Pain Management visits, identification for random urine screens, etc.
• Contact for care management
• Chart review for chronic pain protocol

Measure success
• Cross reference the roster with patient visit history
• Cross reference the roster with medications prescribed
APPENDICES

A  Guidelines for Use of Opioids in Chronic Pain

B  Prescriber Survey - Readiness for Change and Evaluation of Current Practice

C  Staff Survey - Readiness for Change and Evaluation of Current Practice

D  Template for Team Meeting Agendas

E  Sample Protocol for Team Approach to Opioid Prescription Management

F  Vermont Board of Medical Practice Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain

G  Validated Initial Risk Assessment Tools

H  Ongoing Risk Assessment Tools

I  Implementation Plan Template
Appendix A
Guidelines for Use of Opioids in Chronic Pain

Initial Evaluation

Evaluate the cause of pain
PCP to treat underlying cause

Evaluate psychological conditions using
PCP or MH Behaviorist to evaluate underlying psychiatric conditions using standardized screening tools and risk for opioid abuse

Screen for risk of opioid abuse

significant psychological cause?
YES
Follow-up with psychology

High risk for opioids?
YES
Referral to pain specialist recommended to evaluate for treatment options and surveillance – go to Decision to Use Opioids

NO
PCP to treat

Documentation/reference material: Chronic Pain Guidelines, R. Pinckney, V:2012/04/17

Decision to Use Opioids

PCP to treat underlying cause

Pain relief treatments that increase functionality

Referral Specialist

YES

Include cognitive behavioral therapy and/or other mind body

Include: reason for referral, interventions that have been tried already, and results of psychiatric and opioid risk screening

Referral options: mind-body clinic, pain clinic for procedures, other modalities, psychiatric evaluation

Patient should be offered evidence-based, multifaceted program
Appendix A
Starting a Patient with Chronic Pain on Opioids

When taken together, the guidelines and latest research have a sobering message: that there are very few patients who get improved pain and function by using opioids for chronic pain. Most patients who feel that they are getting improvement from opioids are likely experiencing reduced pain-related anxiety as opposed to reduction in pain and an improvement in function. Therefore, the vast majority of patients with chronic pain should not be on opioids for their pain management.

This begs the question: Who should be on opioids for chronic pain? What characteristics define the patients that will truly benefit from opioids? There is no direct research that answers this question. However, we can assemble available research and guidelines to come up with some ideas. The following guide is meant to provide a structured approach to evaluating patients who may benefit from opioids for chronic pain. It is meant to enhance but not replace a clinician's own assessment along with other information available for specific patients that may influence medical decision making.

There are two ways to prescribe opioids for chronic pain: daily scheduled use and opioids for breakthrough only. Less information is available to identify candidates for breakthrough only.

Daily use of opioids (steps refer to boxes in diagram, next page)

Step 1. Assess likelihood of benefit
   a. Does the patient have severe, debilitating pain? Mild to moderate pain without major impact on function is usually well controlled by other lower risk measures. Quantifying the functional impact of chronic pain is ideally done by using a validated tool.
   b. Has the patient tried all disease specific and general chronic pain treatments? Due to advances in research, there is a very long list of evidence-based therapies for most specific causes of chronic pain and for chronic pain in general. Though barriers to some of these therapies may exist for some patients, a patient reporting a lack of access to an evidence-based therapy should not immediately rule in the use of opioids as an alternative. It is common for patients in chronic pain to lack self-efficacy both in their health and finances. Patient empowerment is not only preferable, but can be very therapeutic and part of the recovery process.
   c. Does the patient have a health condition likely to respond to opioids? Many conditions are felt to be unresponsive to long term use of opioids either due to the nature of the condition or possibly the effects of tolerance. In some cases opioids are felt to worsen the underlying condition. This list comes from consensus and/or research. Patients who have one of the following conditions should refrain from taking opioids long-term, on a daily basis: migraines, fibromyalgia, osteoarthritis of the hips, osteoarthritis of the knee, irritable bowel and functional bowel syndromes, non-specific low back pain. By extension myofascial pain of any type arguably should not be treated with opioids.

Step 2. Assess the risk of opioid therapy
   a. Risk of addiction – The research suggests that most patients on opioids for chronic pain are much more likely to develop addiction than they are to have a meaningful improvement in pain and function. Selecting patients with low risk for addiction is an important step in increasing a favorable risk-benefit ratio. There are three methods of determining risk of addiction; the use of validated tools, epidemiological predictors, and urine drug screens.
   b. Risk of overdose – patients on benzodiazepines are the largest risk factor for overdose. In addition, the use of other sedating medication, alcohol use, and sleep apnea are other potential risks to consider
   c. Risk of other complications – chronic constipation, presence of a second cause of pain that could get worse on opioids (such as migraines), potential for medication interaction
   d. Safe environment for medication storage and delivery – A concerning phenomenon has been the abuse of prescription drugs by family members and other caregivers including overdose. When patients are unable to store and administer their own medication extra caution should be exercised and precautions be put in place.
Appendix A

Step 3. Assess response to opioids – Patients who are started on scheduled opioid therapy should have their response to therapy closely monitored. Specifically, function should be measured by a validated tool and whenever possible confirmed another way. According to the CDC, improving one’s function is not enough. At least a moderate improvement in function (30% or more) is required to validate the ongoing use of opioids and balance the potential risks of therapy.

Use of opioids for breakthrough pain only
For some patients, their daily pain is successfully managed by other methods but they experience intermittent, severe, debilitating exacerbations in their pain. Many pain treatments are not easily administered for acute pain or require time to work, making opioids an attractive option. The challenge in determining ideal candidates for breakthrough-only opioid treatment is that there are no long-term data about the success of this approach as there is for daily opioid therapy. Also, functional tools are not validated for breakthrough pain treatments.

The steps from the prior algorithm for daily opioids that are most useful to consider are:
Step 1a and 1c – assess the potential benefit
Step 2 a,b,c,d – assess the risks of therapy

![Flowchart](chart.png)

1Potential for benefit is high when
a. The patient has severe debilitating pain
   And
b. The patient has tried all disease specific treatments and general chronic pain treatments
   And
c. The patient does not have one of the following causes of chronic pain: Fibromyalgia, Migraines, osteoarthritis of the knee or hip, functional bowel syndrome, non-specific low back pain

2Opioid risk is low when:
   a. Addiction risk is low
      i. No addiction risk factors
         - age >30
         - No incarceration
         - Non smoker
         - No substance abuse history
         - No family hx substance abuse
         - No current THC use
      ii. ORT or SOAP-PR is negative
      iii. Negative urine drug screen
   b. Overdose risk low
      i. No use of benzodiazepines
      ii. see other risks above
      c. No medical contraindications
   d. Safe environment for storage and administration

3Opioid trial
A patient should have a 30% or greater improvement in a standardized measure of function
Appendix A
Opioid Monitoring

Source material: Opioid Monitoring Algorithm: Monitor and Document for Four A’s, B. Erickson, V.2012/04/18

Example of “5A’s”: see Appendix J

Tapering Opioid
Categories of Patients

Voluntary

Patient: “I don’t want to take this anymore.”

Involuntary

Patient: “Nothing else works for me.”

Concerning (unclear)

Provider: “I don’t know what’s going on, but opioids don’t feel like a good choice for this

Concerning (diversion or addiction)

Multiple lost prescriptions, early refill requests, “red flag” in urine screen, etc.

Concerning (diversion or addiction)

Do not prescribe opioids. If patient has a substance use disorder, arrange for treatment

Concerning behaviors: screen and review for concerning behaviors (abuse and misuse of meds)
• Urine opioid confirmations
• Urine tox screens
• COMM questionnaire
• Document in VPMS

Document and address concerning behaviors:
• Track this under pain medication treatment problem overview
• Consider behaviorist when abuse addiction, diversion and maladaptive coping suspected
• Firing of patients is not recommended as a routine practice

Taper opioids. Everything is negotiated, including taper speed.

At each visit monitor and document for the “5 A’s”

Analgesia Improvement in pain

Activity level: Assess functional response to treatment using standardized measures

Affect: mood

Adverse effects: constipation, sedation, cognitive effects, endocrine effects

Concerning behaviors: screen and review for concerning behaviors (abuse and misuse of meds)
Concerning behavior: dose escalations, early refills, lost prescriptions, etc.

Document concerning behaviors: include “Prescription Agreement” for controlled substances on Problem List

PCP or Medical Home Behaviorist to evaluate using standardized tools

Results of evaluations

Indeterminant
Increase intensity of surveillance system

Diversion suspected: when patient fraudulently attempts to obtain opioids
Discontinue opioids: go to Tapering Diagram – diversion is strongly suspected
Consider notifying law enforcement: 802-989-9566

Addiction
If addiction only: go to Tapering Diagram – addiction is strongly suspected
Refer patient with opioid addiction and coexistent pain to specialist

Pseudo addiction
Alter pain plan and/or further mental health consultation

Maladaptive coping, a.k.a. chemical coping, or personality conflict or disorder

Benign explanation
Routine surveillance

Psychological evaluation

Documentation by K. McKnight: Narcotics Prescribing_2012_08
Appendix B
Prescriber Survey - Readiness for Change and Evaluation of Current Practice

Instructions: Think about how your practice helps patients with chronic pain needs. Does it need to change? Is it ready to change? Please provide your opinions by rating each statement below according to how it applies to your practice now.

Circle one answer in response to each statement below:

1. My practice has clear and well-organized policies and approaches to opioid prescribing for chronic pain.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

2. My practice has updated our patient contract/agreement to reflect current state law.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

3. The opioid prescribers in my practice have agreed to manage patients with chronic pain consistently as a practice.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

4. The whole practice (staff and prescribers) has a team approach to opioid prescribing for chronic pain patients.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

5. Our providers and staff are willing to use a structured process to plan and make changes to the way we prescribe opioids.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

6. Our practice is able to give at least one provider and two staff time off from regular duties for about 8 hours of team meetings to work on a quality improvement project.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

7. We have a provider leader who can share information with other providers and champion the results of a team that works on opioid prescribing.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

8. We are able to avoid being distracted or overwhelmed by competing demands (such as other big projects) or financial concerns.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

9. The people I work for can handle the challenges that might arise in implementing changes in opioid prescribing.  
   1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

10. I believe that improving opioid prescribing is good for patients with chronic pain.  
    1 Strongly Disagree  2 Disagree  3 Agree  4 Strongly Agree

Please circle your response:

11. Are you registered to use the prescription drug monitoring program (VPMS in Vermont)?  
    Yes  No  Don't know
    2  1  0

12. Do you have a “delegate” (someone else in your office) who can use the Vermont Prescription Monitoring System for you?  
    Yes  No  Don't know
    2  1  0
### Appendix B

For the following questions, we will ask you about care for patients who have chronic pain that is treated with opioids. How often do you use the following strategies with these patients?

<table>
<thead>
<tr>
<th>Question</th>
<th>Never (0)</th>
<th>A few patients (1)</th>
<th>Complex patients (2)</th>
<th>Some patients (3)</th>
<th>Most patients (4)</th>
<th>All patients (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. A special patient visit type (such as Chronic Pain Management) to see patients with chronic pain specifically for opioid management.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14. A roster of patients on chronic pain medication to identify and track them easily.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15. A template, check list, or flow sheet to display data for patients with chronic pain medication.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16. An initial assessment tool to evaluate pain, ability to function, or risk of diversion (examples: SOAPP, SF12, Oswestry, Rapid 3).</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. Ongoing assessments for pain, function, and risk of diversion or abuse for patients on opioids for chronic pain (examples: COMM, OAT, 5 As).</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. Prescriptions for chronic pain management planned in 7 day increments (for example, every 14, 28, 56, or 84 days).</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19. Issuing multiple prescriptions on the same day to be filled at staggered intervals by patients.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20. Review of patients and care plans at provider meetings (example: &quot;Pain Management Council&quot;) to evaluate opioid usage and changes in the patient’s plan.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>21. Urine screens to monitor patients.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>22. RANDOM urine screens to monitor patients.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>23. RANDOM pill counts to monitor patients.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>24. Tamper resistant prescription packaging for accurate pill counts (such as bubble packs or punch packs).</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>25. Prescription drug monitoring program (VPMS in Vermont) at least once/year and at initiation of treatment of opioids for chronic pain.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>26. Patient agreement/contract for patients on long term opioid therapy for chronic pain.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**Satisfaction: Please rate**

27. Your satisfaction with the system for prescribing opioids in your office. | Very unsatisfied (1) | 2 | 3 | Very satisfied (4) |
28. Your patients’ satisfaction with the system for prescribing opioids in your office | 1 | 2 | 3 | 4 |
29. Overall I would rate my knowledge, skill, and comfort with prescribing opioids safely and effectively | Fair (1) | Good (2) | Very good (3) | Outstanding (4) |
## Appendix C

### Staff Survey - Readiness for Change and Evaluation of Current Practice

**Instructions:** Circle one answer in response to each statement below. Rating scales below range from strongly disagree to strongly agree. You do not need to put your name on this survey.

Please choose the best single answer to describe your office practice:

<table>
<thead>
<tr>
<th></th>
<th><strong>Statement</strong></th>
<th><strong>Strongly Disagree</strong></th>
<th><strong>Disagree</strong></th>
<th><strong>Agree</strong></th>
<th><strong>Strongly Agree</strong></th>
<th><strong>Don't Know</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>My practice has clear and well-organized policies and approaches to opioid prescribing for chronic pain.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>My practice has updated our patient contract/agreement to reflect current state law.</td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>The opioid prescribers in my practice have agreed to manage patients with chronic pain consistently as a practice.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>The whole practice (Staff and prescribers) has a team approach to opioid prescribing for chronic pain patients.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>Our providers and staff are willing to use a structured process to plan and make changes to the way we prescribe opioids.</td>
<td>1</td>
<td>2</td>
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<td>6</td>
<td>Our practice is able to give at least one provider and two staff time off from regular duties for about 8 hours of team meetings to work on a quality improvement project.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>0</td>
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<tr>
<td>7</td>
<td>We have a provider leader who can share information with other providers and champion the results of a team that works on opioid prescribing.</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>8</td>
<td>We are able to avoid being distracted or overwhelmed by competing demands (such as other big projects) or financial concerns.</td>
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<td>4</td>
<td>0</td>
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<tr>
<td>10</td>
<td>I believe that improving opioid prescribing is good for our patients with chronic pain.</td>
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<td>2</td>
<td>3</td>
<td>4</td>
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For the following questions, we will ask you about care for patients who have chronic pain that is treated with opioids. You may skip those you are uncertain about. How often does your practice use the following strategies with these patients:

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<tr>
<th></th>
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<td>5</td>
</tr>
</tbody>
</table>

**Satisfaction:** Please rate

<table>
<thead>
<tr>
<th></th>
<th>Very unsatisfied</th>
<th>Very satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. Your satisfaction with the system for prescribing opioids in your office.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>26. The patients’ satisfaction with the system for getting opioids for chronic pain (whether by phone or in person).</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>27. The patients’ overall attitude regarding visiting the office for chronic pain management (i.e. patient frustration, anger or confusion).</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

**Registration**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>28. Are there one or more staff members (other than prescribers) who are able to act as a delegate on the prescription drug monitoring program (VPMS in Vermont)?</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Appendix D

Template for Team Meetings Agenda

Use the following template and list of agenda items to develop team meeting agendas as needed for your team. These agenda items in total usually take about 8 one-hour meetings to complete. Each agenda item is paired with the Meeting Number your team will likely work on this item; sometimes items are covered in more than one meeting. These items and their timing are not requirements, just guidelines. Use the template as it works best for your team.

**Opioid Prescription Management QI Team Agenda**

<table>
<thead>
<tr>
<th>NAME OF PRACTICE:</th>
<th>DATE:</th>
<th>TIME:</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARTICIPANTS NAMES:</td>
<td>MEETING #:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agenda Items</th>
<th>Meeting Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introductions (as needed)</td>
<td>#1</td>
</tr>
<tr>
<td>2. Purpose of this Quality Improvement (QI) Project</td>
<td>#1</td>
</tr>
<tr>
<td>• Generally: opioid management to prevent diversion and misuse</td>
<td></td>
</tr>
<tr>
<td>• Specifically: (example from practice: improve monitoring for patients with high dose opioids)</td>
<td></td>
</tr>
<tr>
<td>3. What to Expect:</td>
<td>#1</td>
</tr>
<tr>
<td>• About 8 team meetings (1 hour each, at a minimum) with practice members and Non-practice members</td>
<td></td>
</tr>
<tr>
<td>• Use of chart or EMR data to measure performance</td>
<td></td>
</tr>
<tr>
<td>• Surveys for all providers and staff to complete before and after the project</td>
<td></td>
</tr>
<tr>
<td>4. Background</td>
<td>#1</td>
</tr>
<tr>
<td>5. Current State</td>
<td>#1, revisit in #2</td>
</tr>
<tr>
<td>6. Conversation with patient from practice</td>
<td>#2 or 3</td>
</tr>
<tr>
<td>Conversation with one or two patients from the practice who use or who have used opioids for chronic pain management. This is a listening and learning exercise, not a time for team talking. Questions to prompt the conversation:</td>
<td></td>
</tr>
<tr>
<td>1. How long have you been coming to the practice (ice-breaker question)</td>
<td></td>
</tr>
<tr>
<td>2. We are trying to improve the way we manage opioid prescriptions. Is there anything we could do (could have done) to make the process easier for you?</td>
<td></td>
</tr>
<tr>
<td>3. We are worried that some of our prescriptions are misused by other patients in our practice. Do you have any advice for us?</td>
<td></td>
</tr>
<tr>
<td>7. Measures of Performance – Pre-Project, including provider/staff surveys</td>
<td>#2, results in 4, 5</td>
</tr>
<tr>
<td>8. Problem Identification</td>
<td>#3, revisit in #4</td>
</tr>
<tr>
<td>9. Best Practice Strategies</td>
<td>#4</td>
</tr>
<tr>
<td>10. Opportunities &amp; Future State</td>
<td>#5</td>
</tr>
<tr>
<td>11. Implementation Plan</td>
<td>#6, update #7, #8</td>
</tr>
<tr>
<td>12. Measures of Performance – Post-Project, including provider/staff surveys</td>
<td>#8</td>
</tr>
<tr>
<td>13. Plan next steps, communication with practice members, and next meeting</td>
<td>All Meetings</td>
</tr>
</tbody>
</table>
Appendix E
Sample Protocol for Team Approach to Opioid Prescription Management

OUR GOAL
Develop consensus among providers to control the prescribing of controlled medications in a way that is consistent across the practice and reduces stress on providers and staff to serve the patients of our community.

OUR CHRONIC PAIN PATIENTS ARE:
• Patients whose treatment is with an opioid for four weeks or more (such as Vicodin, T#3, Percocet, Dilaudid, Fentanyl)
• Patients who are on a stable dose of opioids
• Patient who are seen on fixed interval visits, not more than 84 days apart
• In the electronic record, patients who are listed on the Registry with “R” beside their name

OUR VPMS LOOK UP PROCESS
Nurse A will:
• Look up patients on the PDMP (Vermont: VPMS) the day prior to visit
• Leave report or notes on the provider’s desk the day prior
• Check for updated agreement/contract and enter in the pink sticky note stating when it was last signed
• Give each nurse a list of patients who need a new contract

PATIENT ARRIVES
a. Patient arrives on time
b. Nurse will room the patient
c. Patient provides a urine sample
d. Patient is given the updated narcotic contract (if it needs to be updated and the visit is specifically for Chronic Pain)

e. Provider reviews:
   • PDMP (Vermont: VPMS)
   • Labs
   • Telephone encounters
   • Current signed agreement
   • Specialty notes

PATIENT ENCOUNTER
a. Patient Care
b. Provider will go over the agreement/contract with patient and answer any questions regarding the contract. Point out Rx will only be filled at Chronic Pain visits
c. Agreement signed with patient
d. Three prescriptions printed, signed, stapled, and placed in the wall file/basket
e. Future prescriptions will have a DO NOT FILL DATE
f. DO NOT GIVE TO PATIENT until he/she is at check out
g. Attach the updated contract with the prescriptions for check out staff to scan and give to patient
h. Counseling on prior authorization

CHECKOUT/PHARMACY
a. Schedule the next CPM visit
b. Give prescription to patient and instruct to bring it to their pharmacy
c. Scan the new agreement/contract
d. Give copy of contract to patient
e. Patient gives all three prescriptions to their designated pharmacy to be filled and to keep future prescriptions
f. Nurses have a prior authorization binder. This is kept in the nurses’ station and updated monthly by the Referral Nurse

Provider will review the PDMP patient list and determine who will need a urine sample.
Appendix F (footnotes are found at the end of Appendix F)

Vermont Board of Medical Practice

Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain

Background and Introduction

The Vermont Board of Medical Practice (the Board) is committed to protecting the public and to assisting its licensees to meet their professional obligations by providing quality health care. To those ends, in January 2006 the Board published its first Policy for the Use of Controlled Substances for the Treatment of Pain. That policy was largely based on a model policy published by the Federation of State Medical Boards (FSMB) in 2004. In 2013, FSMB published a revised model policy that incorporates the latest best practices and new developments in the healthcare profession regarding the safe and effective use of controlled substances to treat chronic pain. The Board has carefully reviewed that new policy and adapted it to reflect Vermont laws, regulations, and Board expectations.

The Board acknowledges the hard work performed by FSMB and the great value to the Board and the profession of having a set of common core expectations in place as so many physicians across the nation strive to provide quality pain treatment. The usefulness of the past and current model policies is confirmed through the many endorsements they have received.

The FSMB model policies have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities, and along with Vermont many other states have adopted all or part of the Model Policies.

In its introduction to the 2013 Model Policy, FSMB included an overview of the issues addressed in the policy. While the Board acknowledges that the practice environment in Vermont may not be identical to the national environment considered by FSMB, the issues addressed in the Model Policy are all relevant to Vermont practice and were considered by the Board when promulgating this Vermont policy. Accordingly, the Board incorporates the following discussion directly from the introduction to the FSMB as a useful statement of the context and the problem set targeted by this Policy.

FSMB Statement of Issues Addressed in the New Model Policy

There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated. Since the 2004 revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffers from pain so intense as to interfere with the activities of daily living. Pain arises from multiple causes and often is categorized as either acute pain (such as that from...
Appendix F

traumatic injury and surgery) or chronic pain (such as the pain associated with terminal conditions such as cancer or severe vascular disease or with non-terminal conditions such as arthritis or neuropathy). This model policy applies most directly to the treatment of chronic pain and the use of opioid analgesics but many of the strategies to improve appropriate prescribing and mitigate risks can be applied to the use of other controlled medications and to the treatment of acute pain.

Undertreatment of pain is recognized as a serious public health problem that compromises patients’ functional status and quality of life. A myriad of psychological, social, economic, political, legal and educational factors—including inconsistencies and restrictions in state pain policies—can either facilitate or impede the ability and willingness of physicians to manage patients with pain.

While acknowledging that undertreatment of pain exists, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment.

Indeed, some cases of intractable pain actually result from overtreatment in terms of procedures and medications.

Complicating the picture, adverse outcomes associated with the misuse, abuse and diversion of prescription opioids have increased dramatically since the FSMB’s last review. Physicians and other health care professionals have contributed—often inadvertently—to these increases.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioids by physicians may include: 1. physician uncertainty or lack of knowledge as to prevailing best clinical practices; 2. inadequate research into the sources of and treatments for pain; 3. sometimes conflicting clinical guidelines for appropriate treatment of pain; 4. physician concerns that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; 5. physician misunderstanding of causes and manifestations of opioid dependence and addiction; 6. fear on the part of physicians of causing addiction or being deceived by a patient who seeks drugs for purposes of misuse; 7. physicians practicing outside the bounds of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and 8. inadequate physician education about regulatory policies and processes. Inappropriate treatment also can result from a mistaken belief on the part of patients and their physicians that complete eradication of pain is an attainable goal, and one that can be achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

Patients share with physicians a responsibility for appropriate use of opioid analgesics. This responsibility encompasses providing the physician with complete and accurate information and adhering to the treatment plan. While many patients take their medication safely as prescribed and do not use opioids problematically, some patients—intentionally or unintentionally—are less than forthcoming or have unrealistic expectations regarding the need for opioid therapy or the amount of medication required. Other patients may begin to use medications as prescribed, then slowly deviate from the therapeutic regimen. Still others may not comply with the treatment plan because they misunderstood the physician’s instructions. Some patients share their drugs with others without intending harm (a pattern of misuse that is seen quite often among older adults). Then there are patients who deliberately misuse or are addicted to opioids, and who mislead, deceive or fail to disclose information to their physicians in order to obtain opioids to sustain their addiction and avoid withdrawal.

Patients often leave medications unsecured where they can be stolen by visitors, workers and family members, which is another important source of diversion. Thus a prescription that is quite appropriate for an elderly patient may ultimately contribute to the death of a young person who visits or lives in the patient’s home. Therefore, the physician’s duty includes not only appropriate prescribing of opioid analgesics, but also appropriate education of patients.
Appendix F

regarding the secure storage of medications and their appropriate disposal once the course of treatment is completed\(^{18,23}\).

A more problematic individual is the criminal patient, whose primary purpose is to obtain drugs for resale. Whereas many addicted patients seek a long-term relationship with a prescriber, criminal patients sometimes move rapidly from one prescriber (or dispenser) to another. Such individuals often visit multiple practitioners (a practice sometimes characterized as "doctor shopping") and travel from one geographic area to another not for the purposes of relief of legitimate pain but in search of unsuspecting targets\(^{19-21}\). Physicians' attention to patient assessment and the routine use of state prescription drug monitoring programs (PDMPs), where available, have been cited as effective ways to identify individuals who engage in such criminal activities\(^{20-23,45}\).

Conclusion

The goal of this Model Policy is to provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:

- Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain: not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.

- Inadequate monitoring during the use of potentially abusable medications: Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.

- Inadequate attention to patient education and informed consent: The decision to begin opioid therapy for chronic pain should be a shared decision of the physician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances or certain conditions (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.

- Unjustified dose escalation without adequate attention to risks or alternative treatments: Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.

- Excessive reliance on opioids, particularly high dose opioids for chronic pain management: Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic non-cancer pain only when safer and reasonably effective options have failed. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.

- Not making use of available tools for risk mitigations: When available, the state prescription drug monitoring program should be checked in advance of prescribing opioids and should be available for ongoing monitoring. In addition, the Model Policy is designed to communicate to licensees that the state medical board views pain management as an important area of patient care that is integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that physicians will not be sanctioned solely for prescribing opioid analgesics or the dose (mg./mcg.) prescribed for legitimate medical purposes. However, prescribers must be held to a safe and best clinical practice. The federal Controlled Substances Act 25 defines a "lawful
Appendix F

prescription” as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on physicians a responsibility to minimize the potential for misuse, abuse and diversion of opioids and all other controlled substances.

Finally, the Board stresses three points about this policy.

1. This is a policy that provides guidelines. On its own, the policy will not be the basis for an allegation of unprofessional conduct. It is offered to assist providers. However, parts of the policy reflect Vermont and federal laws and regulations that must be followed. Failure to follow those requirements may result in action by another regulatory or law enforcement agency, such as the D.E.A., or an allegation from the Board of unprofessional conduct under 26 V.S.A. § 1254(a)(27) (failure to comply with provisions of federal or state statutes or rules governing the practice of medicine or surgery). In addition, the policy reflects the Board’s understanding of the standard of care at the time the policy is adopted. Thus, failure to follow the guidance may put a provider at risk of failing to meet the standard of care, which could lead to an allegation of unprofessional conduct under 26 V.S.A. § 1354(a)22 or 26 V.S.A. § 1354(b).

2. By its terms, this policy pertains only to treatment of chronic pain. Many of the expectations that apply to treatment for chronic pain do not apply strictly to treatment of acute pain, or to use of controlled substances other than opioids. Also, as a policy targeting use of opioids for chronic pain, it is not directed at palliative, end-of-life care. However, some of the statutory and regulatory requirements noted in the guidelines do apply more broadly and physicians need to be mindful of that. For instance, any provider who writes a prescription for any DEA Schedule II, III, or IV substance must be registered for VPMS. Furthermore, all controlled substances carry some risk of misuse, abuse, and diversion. Thus, you are encouraged to consider whether some of the practices set forth here may be of benefit in prescribing situations that are not specifically covered by this policy.

3. Statutes and regulations change, and the standard of care evolves. The Board will endeavor to update this policy as needed, but the existence of this policy does not reduce the obligation of all prescribers to keep up with changes to law, regulations, or the standard of care.

In closing, we hope that you find this Policy of help in this challenging area of practice and encourage your comments and suggestions as to how it could be improved.

Adopted by Board motion on April 2, 2014.
Appendix F
SECTION I: PREAMBLE

The Vermont Board of Medical Practice is obligated under the laws of the State of Vermont to protect the public health and safety. The Board recognizes that principles of high-quality medical practice dictate that the people of the State of Vermont have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain.

This policy has been developed to articulate the Board’s position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain.

A. Responsibility for Appropriate Pain Management:

All physicians and other providers of healthcare should be knowledgeable about assessing patients’ pain and function, and familiar with methods of managing pain. Unless indicated otherwise expressly or by context, all references in this document to “physician” should be read to include other licensees of the Board who may prescribe DEA scheduled controlled substances, which includes podiatrists, physician assistants, and residents who hold a limited training license. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics. Whenever federal laws and regulations differ from those of Vermont, the more stringent rule is the one that should be followed.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met.

The Board considers the use of opioids for pain management to be for a legitimate medical purpose when based on sound clinical judgment and current best clinical practices, appropriately documented, and of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient’s response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed. There should be documentation of appropriate referrals as necessary.

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below).

Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient’s response to treatment, and the
Appendix F
patient’s risk level relative to the use of medications with abuse potential.8,10,12,14,26-38.

B. Preventing Opioid Diversion and Abuse:

The Board also recognizes that individuals’ use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health.3 The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes.5,19,44 Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances.19-23,38,45-46.

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the Vermont Prescription Monitoring System (VPMS).1 The Board will judge the validity of the physician’s treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is safe management of the patient’s pain while effectively addressing other aspects of the patient’s functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose.4,29.

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient’s level of risk.

SECTION II: GUIDELINES

The Board has adopted the following criteria for use in evaluating a physician’s management of a patient with pain, including the physician’s prescribing of opioid analgesics:

A. Understanding Pain:
The diagnosis and treatment of pain is integral to the practice of medicine.4,34-37. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy.4,8.

B. Patient Evaluation and Risk Stratification:
The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic7 and reflect an appropriately detailed patient evaluation. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient’s pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient’s physical and psychological functioning.31.

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated.33,36,48-53. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient’s sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.
Appendix F

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? 

Assessment of the patient’s personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation, and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient’s level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose. Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse. Therefore, patients with a history of substance use disorders should have a thorough evaluation of their risk for relapse and opiate misuse. Patients considered to be at a higher risk should not be prescribed opioids or should receive consultation from an addiction specialist, if possible, before starting opioids. Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be aware of addiction treatment options, including the role of replacement agonists such as methadone and buprenorphine. Physicians who are interested in treating addiction in the office need to be aware that they must have a special DEA license, known as an x-license, to do so.

Information provided by the patient is necessary for the evaluation process, but often is not adequate on its own to allow for proper evaluation of a patient. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients occasionally provide fraudulent records, so if there is any reason to question the truthfulness of a patient’s report, it is best to request records directly from the other providers.

If possible, the patient evaluation should include information from family members and/or significant others. VPMS should be consulted to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from VPMS should be documented in the patient record.

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance. With all patients, the physician’s decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician’s own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community.

C. Development of a Treatment Plan and Goals:

The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications. Effective means of achieving these goals vary widely, depending on the type and causes of the patient’s pain, other concurrent issues, and the
Appendix F
preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function. Ongoing documentation of treatment should reference the treatment plan, as appropriate.

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered.

D. Informed Consent and Treatment Agreement:

The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient’s surrogate or guardian if the patient is without medical decision-making capacity. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications.

Use of a written informed consent and treatment agreement (sometimes referred to as a “treatment contract”) is highly recommended. The failure to use a treatment contract in a given case does not per se constitute unprofessional conduct, but in the absence of a treatment agreement contract, documentation in the patient’s chart should meet the same goals and support a conclusion that the standard of care was met.

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy
- Potential side effects (both short- and long-term)
- The likelihood that tolerance to and physical dependence on the medication will develop
- The risk of drug interactions and over-sedation
- The risk of impaired motor skills (affecting driving and other tasks)
- The risk of opioid misuse, dependence, addiction, and overdose
- The limited evidence as to the benefit of long-term opioid therapy
- The physician’s prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician’s policy on early refills and replacement of lost or stolen medications
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement)

Treatment agreements outline the joint responsibilities of physician and patient and are indicated for opioid or other medications that may be abused. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety
- The patient’s responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication)
- The patient’s responsibility to obtain his or her prescribed opioids from only one physician or practice
- The patient’s agreement to periodic drug testing (as of blood, urine, hair, or saliva)
- The physician’s responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills

E. Initiating an Opioid Trial:

Safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a
Appendix F

defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient’s level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety\(^5\). When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrated to effect. It is generally suggested to begin opioid therapy with a short acting opioid and consider rotating to a long-acting/extended release opioid only if indicated. Vermont law now requires checking VPMS in certain circumstances before a prescription for controlled substances is written, including when initiating treatment of chronic pain with opioids, as further discussed in the following section.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events\(^2\) and/or potential risks.

F. Monitoring and Adapting the Treatment Plan:

The physician should regularly review the patient’s progress, including any new information about the etiology of the pain or the patient’s overall health and level of function\(^35,49-50\). When possible, collateral information about the patient’s response to opioid therapy should be obtained from family members or other close contacts.

In addition to the need to consider information from the patient and close contacts, physicians must make use of the state prescription monitoring system. Vermont law now requires all providers who prescribe or dispense any Schedule II, III, or IV drugs to register to use VPMS. It also requires consultation of VPMS in specified circumstances\(^2\):

- At least annually for ongoing opioid chronic pain treatment;
- When first prescribing opioids for long-term, chronic pain treatment expected to last for 90 days or more;
- The first time prescribing a Schedule II, III, or IV opioid for chronic pain; and
- Before writing a replacement prescription for any Schedule II, III, or IV controlled substance. Replacement refers to the issuance of a prescription to replace medication reported by the patient as lost or stolen. (The Board notes that Vermont law also requires that a replacement prescription be marked “REPLACEMENT” and documented in the chart as a replacement prescription.)

The law also tasks the Commissioner of Health with creating rules relating to those requirements, including consideration of additional situations that trigger a required check of VPMS; the rules are not published as of the date of this policy, but will be posted on the Board webpage. If a provider fails to follow the requirements of the statute and any applicable rules, there may be both a violation of Vermont law relating to the practice of medicine, which is one form of unprofessional conduct, and such failure may be a factor in evaluating whether the standard of care was met.

The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted\(^44-51\). As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the “5As” of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect)\(^38,52\).

Validated brief assessment tools that measure pain and function, such as the three-question “Pain, Enjoyment and General Activity” (PEG) scale\(^47\) or other validated assessment tools, may be helpful and time effective.

Continuation, modification or termination of opioid therapy for pain should be contingent on the
Appendix F

physician’s evaluation of: 1. evidence of the patient’s progress toward treatment objectives and 2. the absence of substantial risks or adverse events, such as overdose or diversion\textsuperscript{21-23,45}. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life\textsuperscript{29}. Information from family members or other caregivers should be considered in evaluating the patient’s response to treatment\textsuperscript{14,35-36}. Use of measurement tools to assess the patient’s level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes\textsuperscript{14,49}.

G. Periodic Drug Testing and Response to Evidence of Aberrant Behavior:

Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs\textsuperscript{53-54}. Drug testing is an important monitoring tool because self-reports of medication use are not always reliable and behavioral observations may detect some problems but not others\textsuperscript{55-59}. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence. Use of testing should not be limited to instances in which the provider perceives a problem; the regular use of testing as a universal precaution will avoid having the request for a test become a confrontation that affects the physician-patient relationship.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing\textsuperscript{53}. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, but physicians should use their judgment as to steps needed to ensure reliability of results for individual patients. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites\textsuperscript{53}. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately\textsuperscript{54}. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed\textsuperscript{53}. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist\textsuperscript{59-60}.

While immunoassay, point of care (POC) testing has its utility in the making of temporary and “on the spot” changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings found very high rates of “false negatives and positives”\textsuperscript{53,81}.

Test results that suggest opioid misuse should be discussed with the patient. It may be helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record\textsuperscript{53}.

Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize
Appendix F

diversion (e.g., selling, sharing or giving away medications). The Board acknowledges the limitations of pill counts, but believes that there may be benefit and notes that there are means to limit the ability of patients to find “work arounds” to pill counts, such as serialized blister pack packaging.

As noted earlier, consulting VPMS before prescribing opioids for chronic pain and during ongoing use is highly recommended and required in some circumstances by Vermont law, as discussed above at Section F, Monitoring and Adapting the Treatment Plan. VPMS is useful for monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers21-23,55,62. If the patient’s progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed35-37,62-63. Prescriptions of shorter duration and more frequent appointments are additional steps that may be taken by a physician who is concerned about the risk of misuse, abuse, or diversion presented by a patient. Evidence of misuse of prescribed opioids demands prompt intervention by the physician19,21-23,32,35. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician’s knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors23.

The presence of illicit drugs or drugs not legitimately prescribed in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others62-63. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan64.

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response31,22-23,38,46. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death23,65-67. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

H. Consultation and Referral:

The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed37-38. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available31,66. Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT], so as to make appropriate referrals when needed23,31,37,39.

I. Discontinuing Opioid Therapy:

Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate46. If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient’s changing physical status and needs, as well as to support safe and appropriate medication
Appendix F

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient’s quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use\textsuperscript{38, 45}. If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering and withdrawal regimen. Withdrawal can be managed either by the prescribing physician (who may want to consult with an addiction specialist) or by referring the patient to an addiction specialist\textsuperscript{63}. The termination of opioid therapy should not mark the end of treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate\textsuperscript{21-23}. Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

J. Medical Records:

Every physician who treats patients for chronic pain must maintain accurate, complete, and legible medical records. Information that should appear in the medical record includes the following\textsuperscript{22-23,38,43-44}:

- Copies of the signed informed consent and treatment agreement
- The patient’s medical history
- Results of the physical examination and all laboratory tests
- Results of the risk assessment, including results of any screening instruments used
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity)
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement
- Notes on evaluations by and consultations with specialists or other providers, and notation by the receiving provider of response to the information and recommendations
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors\textsuperscript{21-23,30,38,45,68}. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record\textsuperscript{25}. The name, telephone number, and address of the patient’s pharmacy also should be recorded to facilitate contact as needed\textsuperscript{23}. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review\textsuperscript{25}.

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient\textsuperscript{23,38,45,68}.

K. Compliance with Controlled Substance Laws and Regulations:

To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by Vermont, and comply with applicable federal and Vermont laws and regulations\textsuperscript{25}. Physicians licensed by the Board who
Appendix F

have a DEA registration number must include at least 1 hour AMA PRA Category 1 CreditTM CME on safe prescribing in every two-year licensing period, as required by Vermont law and the Board’s Rules for CME.

Physicians are referred to the Physicians' Manual of the U.S. Drug Enforcement Administration for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA’s website at www.deadiversion.usdoj.gov. This policy, other Board of Medical Practice communications regarding prescribing, and any other relevant Vermont policies or regulations are made available on the Board’s website:
http://healthvermont.gov/hc/med_board/bmp.aspx

L. Practice Systems:

The Board recommends that physicians ensure that their practices establish systems and processes to help practice effectively, safely, and in accordance with this policy. Consistent processes and training of staff will allow for better care, deter misuse and diversion, and protect the patient and the physician. Examples of systems follow:

- The law and regulations surrounding VPMS allow for use of delegates to perform checks. It is not necessary for the physician to check the system, so the Board encourages establishment of a process that provides for office staff to get the needed information from VPMS for the provider.
- Another recommendation is to issue prescriptions for controlled substances for a duration that is a multiple of 7, up to 28 days (and adjusted for holidays) to reduce the incidents of prescriptions running out on weekends, and thereby reduce the need for a physician who does not know the patient as well, but who is on call, to write a prescription.

SECTION III:

DEFINITIONS

For the purposes of this Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors22-23. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician’s knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm29. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state (“high”) or to sustain opioid dependence that is opioid addiction, or use that is for any purpose other than that for which the medication was prescribed28.

Addiction: A longstanding definition of addiction is: “a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors”28. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm28.

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as “a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one’s behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can
Appendix F

result in disability or premature death.40

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

**Controlled Substance**: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA)25, which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government’s control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA. The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

The CSA does not limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in Schedules II or III under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

**Dependence**: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist.28 It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the International Classification of Mental and Behavioural Disorders, 10th Edition (ICD-10) of the World Health Organization70, and the Diagnostic and Statistical Manual (DSM) of the American Psychiatric Association71. In the DSM-IV-TR, a diagnosis of “substance dependence” meant addiction. In the upcoming DSM V, the term dependence is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings69.

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid”70. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction71,72.

**Diversion**: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution73-74. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to
Appendix F

the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA.25,75.

Pharmaceuticals that make their way outside this closed distribution system are said to have been “diverted”25, and the individuals responsible for the diversion (including patients) are in violation of federal and Vermont law. Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system17,19,74.

Misuse: The term misuse (also called nonmedical use) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice.28

Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS). The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides.35

Most physicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most commonly currently used and misused prescription opioids—may be present in the sample that was analyzed.53,59-260.

Pain: An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less.4,76

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic non-cancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life.4,76

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. Primary hyperalgesia is pain sensitivity that occurs directly in the damaged tissues, while secondary hyperalgesia occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment.77

Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug’s effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction.28

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual’s pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected.36

Universal Precautions: The concept of universal precautions is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level
Appendix F

of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient’s pain score and level of function.
8. Regularly evaluate the patient in terms of the “5 A’s”: Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder, the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk.

Adopted by Board motion passed at the meeting held on April 2, 2014

References


64. Schnoll SH & Finch J. Medical education for pain and addiction: Making progress toward answering a need. *Journal of Law, Medicine &


80. National Summit for Opioid Safety: Project ROAM and Physicians for Responsible Opioid Prescribing; October 31 and November 1, 2012; Seattle, WA.

Appendix G
Validated Initial Risk Assessment Tools

Opioid Risk Tool

<table>
<thead>
<tr>
<th>Patient</th>
<th>Date</th>
</tr>
</thead>
</table>

**Instructions:** *Mark each box that applies*

<table>
<thead>
<tr>
<th></th>
<th>Female Score</th>
<th>Male Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Family History of Substance Abuse</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alcohol ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Illegal Drugs ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs ☐</td>
<td>☐</td>
</tr>
<tr>
<td>2. Personal History of Substance Abuse</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alcohol ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Illegal Drugs ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Prescription Drugs ☐</td>
<td>☐</td>
</tr>
<tr>
<td>3. Age (Mark box if 16-45)</td>
<td>☐</td>
<td>1</td>
</tr>
<tr>
<td>4. History of Preadolescent Sexual Abuse</td>
<td>☐</td>
<td>3</td>
</tr>
<tr>
<td>5. Psychological Disease (Any one of)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attention Deficit Disorder ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Obsessive Compulsive Disorder ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Bipolar ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Schizophrenia ☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td>Depression ☐</td>
<td>☐</td>
</tr>
<tr>
<td><strong>Total Score risk Category</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Risk</td>
<td>0-3</td>
<td></td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>4-7</td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>≥8</td>
<td></td>
</tr>
</tbody>
</table>

Appendix G
Validated Initial Risk Assessment Tools
Assessment Algorithm

1. Patient has pain

2. Critical First Step: Assessment
   - History and physical
   - Key questions
   - Pain and functional assessment tools

3. Determine biological mechanisms of pain

4. Neuropathic pain
   - Peripheral (e.g., complex regional pain syndrome, HIV sensory neuropathy, metabolic disorders, phantom limb pain)
   - Central (e.g., Parkinson’s disease, MS, myelopathies, poststroke pain)

5. Muscle pain
   - Fibromyalgia syndrome
   - Myofascial pain syndrome

6. Inflammatory pain
   - Inflammatory arthropathies (rheumatoid arthritis)
   - Infection
   - Postoperative pain
   - Tissue injury

7. Mechanical/Compressive pain
   - Low back pain
   - Neck pain
   - Musculoskeletal pain (shoulders/elbow, etc.)
   - Visceral pain

4–7a Pain types and contributing factors are not mutually exclusive. Patients frequently do have more than one type of pain, as well as overlapping contributing factors.

8. Is pain chronic?
   - NO → See ICSI Acute Pain Guideline
   - YES

9. Is there a correctable cause of pain?
   - YES → Specialty involvement
   - NO

10. Other assessment
    - Work and disability issues
    - Psychological and spiritual assessment
    - Contributing factors and barriers

11. To Management Algorithm
    See next page

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Appendix G

Validated Initial Risk Assessment Tools

Principles

Chronic pain is defined as persistent pain, which can be either continuous or recurrent and of sufficient duration and intensity to adversely affect a patient’s well-being, level of function, and quality of life (Wisconsin Medical Society, 2004 [R]). If the patient has not been previously evaluated, attempt to differentiate between untreated acute pain and ongoing chronic pain. If a patient’s pain has persisted for six weeks (or longer than the anticipated healing time), a thorough evaluation for the cause of the chronic pain is warranted.

The goals of treatment are an emphasis on improving function through the development of long-term, self-management skills including fitness and a healthy lifestyle.

ASSESSMENT

Chronic pain assessment should include determining the mechanisms of pain through documentation of pain location, intensity, quality and onset/duration; functional ability and goals; and psychological/social factors such as depression or substance abuse.

The goal of treatment is an emphasis on improving function through the development of long-term, self-management skills including fitness and a healthy lifestyle.

MANAGEMENT

A patient-centered, multifactorial, comprehensive care plan is necessary, one that includes addressing biopsychosocial factors. Addressing spiritual and cultural issues is also important. It is important to have a multidisciplinary team approach coordinated by the primary care physician to lead a team including specialty areas of psychology and physical rehabilitation.

- Empathetic listening is critical.
- Recognize that the term “chronic pain” may elicit a highly emotional resonance with some patients.
- Use diagnostic and anatomical terms.
- Focus on improving function.

Level I treatment approaches should be implemented as first steps toward rehabilitation before Level II treatments are considered.

Medications are not the sole focus of treatment in managing pain and should be used when needed to meet overall goals of therapy in conjunction with other treatment modalities.

Careful patient selection and close monitoring of all non-malignant pain patients on chronic opioids is necessary to assess the effectiveness and watch for signs of misuse or concerning behavior.

- Physicians should not feel compelled to prescribe opioids or any drug if it is against their honest judgment or if they feel uncomfortable prescribing the drug.

Review care plan and goals at every visit.
Appendix G

FOLLOW-UP CONSIDERATIONS

Involvement of a pain specialist in the care of a patient with chronic pain occurs optimally when the specialist assumes a role of consultation, with the primary care provider continuing to facilitate the overall management of the patient’s pain program. It is recommended that the primary care provider receive regular communications from the pain specialist and continue visits with the patient on a regular schedule, even if the patient is involved in a comprehensive management program at a center for chronic pain. The primary care provider should not expect that a consulting pain specialist will assume primary care of a patient unless there has been an explicit conversation in that regard between the consultants and the primary care provider. This is particularly true in regard to the prescribing of opioids: the primary care provider should expect to continue as the prescribing provider, and ensure the responsible use of the opioids through contracts, urine toxicology screens, etc. (the exception to this may occur with the admission of the patient into an opioid tracking program). Conversely, the consulting pain specialist should not initiate opioids without the knowledge and consent of the primary care provider.

PATIENT FOCUS GROUP: KEY LEARNINGS FOR PROVIDERS

- Be aware that the term chronic pain may elicit a highly emotional response. Patients may feel discouraged that the pain will never go away despite their hope a cure will be found.
- Although patients would like a quick fix to their pain, frustration occurs when interventions that only provide temporary relief are found or utilized.
- Patients want to be included in the treatment plan. They are often proactive in seeking ways to alleviate or eliminate their pain. They may see several types of physicians and may have also tried to find relief from their pain in additional varieties of ways. Teamwork and empathetic listening in the development of a treatment plan are critical.
- When the physician acknowledges that chronic pain affects the whole person and really listens, patients are more likely to be open to learning how to live by managing their pain versus curing their pain.
- Most patients want to return to a normal routine of completing activities of daily living, (e.g., playing with children/grandchildren, going for a walk, and working within their limitations). The focus should be on improving function.
- Many patients have utilized a variety of interventions including medications and complementary therapies.

COGNITIVE-BEHAVIORAL STRATEGIES FOR PRIMARY CARE PHYSICIANS

There are a number of cognitive-behavioral strategies that primary care providers can utilize to help their patients manage chronic pain.

- Tell the patient that chronic pain is a complicated problem and for successful rehabilitation, a team of health care providers is needed. Chronic pain can affect sleep, mood, levels of strength and fitness, ability to work, family members, and many other aspects of a person’s life. Treatment often includes components of stress management, physical exercise, relaxation therapy and more to help them regain function and improve the quality of their lives.
Appendix G

- Let the patient know you believe that the pain is real and is not in his/her head. Let the patient know that the focus of your work together will be the management of his/her pain. ICSI Patient Focus Group feedback included patient concerns that their providers did not believe them/their child when they reported pain.
- Ask the patient to take an active role in the management of his/her pain. Research shows that patients who take an active role in their treatment experience less pain-related disability.

OPIOIDS: IMPORTANT CONSIDERATIONS

Before prescribing an opioid, the work group recommends using the DIRE tool to determine a patient’s appropriateness for long-term opioid management.

When there is non-compliance, escalation of opioid use, or increasing pain not responding to increasing opioids, consider whether this represents a response to inadequate pain control (pseudoaddiction, tolerance, or opioid-induced hyperalgesia) or a behavioral problem indicating the patient is not a candidate for opioid therapy.

Physicians must bear in mind that opioids are not required for everyone with chronic pain. The decision to use or continue opioids depends on many factors including type of pain, patient response and social factors. Physicians must have the fortitude to say no to opioids when they are not indicated, and to discontinue them when they are not working.

Discontinuation of opioids is recommended when it is felt that they are not contributing significantly to improving pain control or functionality, despite adequate dose titration. It is recommended that the primary care physician discontinue when there is evidence of substance abuse or diversion. In these cases, consider referral to substance abuse counseling. It is recommended to not abruptly discontinue but to titrate off by decreasing dose approximately 10%-25% per week. When a patient is unable to taper as an outpatient, a clonidine patch or tablets, or referral to a detox facility are potential options.
Appendix G
Validated Initial Risk Assessment Tools

Personal Care Plan for Chronic Pain

This tool has not been validated for research; however, work group consensus was to include it as an example of a patient tool for establishing a plan of care.

1. **Set Personal Goals**
   - ☐ Improve Functional Ability Score by points: ______________; by date __________
   - ☐ Return to specific activities, tasks, hobbies, sports, etc., by date: __________
     1. ________________________________________________
     2.__________________________________________________
   - Return to ☐ limited work or ☐ normal work by date: ________________________________

2. **Improve Sleep**
   - Hours of sleep per night: goal ______________ current __________
   - Follow basic sleep plan
   - ☐ Eliminate caffeine and naps, relaxation before bed, go to bed at target bedtime: ______
   - ☐ Take night time medications
     1. ________________________________________________
     2. ________________________________________________

3. **Increase Physical Activity**
   - ☐ Attend physical therapy ______________ days per week
   - ☐ Complete daily stretching ______ times per day, for ______ minutes
   - ☐ Complete aerobic exercise/endurance exercise
     - ☐ Walking ______________ times per day, for ___ minutes or pedometer ______ steps per day
     - ☐ Treadmill, bike, rower, elliptical trainer ______ times per week, for ___ minutes
     - ☐ Target heart rate goal with exercise ___________ bpm
   - ☐ Strengthening: elastic, hand weights, weight machines ______________ minutes per day, ___ days per week

4. **Manage Stress**
   - List main stressors: ________________________________
   - ☐ Formal interventions (counseling or classes, support group or therapy group):
     ______________________________________________________
   - ☐ Daily practice of relaxation techniques, meditation, yoga, creative/service activity, etc.:
     ______________________________________________________
   - Medications: __________________________________________

5. **Decrease Pain**
   - Best pain level in past week: _____ / 10, worst pain level in past week: _____ / 10
   - ☐ Non-medication treatments: ☐ Ice/heat
   - ☐ Medications: _________________________________________
   - ☐ Other treatments: _____________________________________

Physician Signature ___________________________ Date ___________________________
## DIRE Score: Patient Selection for Chronic Opioid Analgesia

The DIRE Score is a clinician rating used to predict patient suitability for long-term opioid analgesic treatment for chronic non-cancer pain. It consists of four factors that are rated separately and then added up to form the DIRE score: Diagnosis, Intractability, Risk and Efficacy. The Risk factor is further broken down into four subcategories that are individually rated and added together to arrive at the Risk score. The Risk subcategories are: Psychological Health, Chemical Health, Reliability, and Social Support. Each factor is rated on a numerical scale from 1 to 3, with 1 corresponding to the least compelling or least favorable case for opioid prescribing, and 3 denoting the most compelling or favorable case for opioid prescribing. The total score is used to determine whether or not a patient is a suitable candidate for opioid maintenance analgesia. Scores may range from 7 at the lowest (patient receives all 1s) to 21 at the highest (patient receives all 3s).

For each factor, rate the patient’s score from 1 to 3 based on the explanations in the right-hand column.

<table>
<thead>
<tr>
<th>Score</th>
<th>Factor</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>DIAGNOSIS</strong></td>
<td>1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, non-specific back pain.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Slowly progressive condition concordant with moderate pain, or fixed condition with moderate objective findings. Examples: failed back surgery syndrome, back pain with moderate degenerative changes, neuropathic pain.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis.</td>
</tr>
<tr>
<td></td>
<td><strong>INTRACTABILITY</strong></td>
<td>1 = Few therapies have been tried and the patient takes a passive role in his/her pain management process.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Most customary treatments have been tried but the patient is not fully engaged in the pain management process, or barriers prevent (insurance, transportation, medical illness).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate response.</td>
</tr>
<tr>
<td></td>
<td><strong>RISK</strong> (R= Total of P+C+R+S below)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Psychological</td>
<td>1 = Serious personality dysfunction or mental illness interfering with care. Example: personality disorder, severe affective disorder, significant personality issues.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Personality or mental health interferes moderately. Example: depression or anxiety disorder.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = Good communication with clinic. No significant personality dysfunction or mental illness.</td>
</tr>
<tr>
<td></td>
<td>Chemical Health</td>
<td>1 = Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Chemical coper (uses medications to cope with stress) or history of CD in remission.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = No CD history. Not drug focused or chemically reliant.</td>
</tr>
<tr>
<td></td>
<td>Reliability</td>
<td>1 = History of numerous problems: medication misuse, missed appointments, rarely follows through.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Occasional difficulties with compliance, but generally reliable.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = Highly reliable patient with meds, appointments &amp; treatment.</td>
</tr>
<tr>
<td></td>
<td>Social Support</td>
<td>1 = Life in chaos. Little family support and few close relationships. Loss of most normal life roles.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Reduction in some relationships and life roles.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = Supportive family/close relationships. Involved in work or school and no social isolation.</td>
</tr>
<tr>
<td></td>
<td><strong>EFFICACY SCORE</strong></td>
<td>1 = Poor function or minimal pain relief despite moderate to high doses.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 = Moderate benefit with function improved in a number of ways (or insufficient info – hasn't tried opioid yet or very low doses or too short of a trial).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 = Good improvement in pain and function and quality of life with stable doses over time.</td>
</tr>
</tbody>
</table>

Score 7-13: Not a suitable candidate for long-term opioid analgesia
Score 14-21: May be a good candidate for long-term opioid analgesia
# Appendix H

## Ongoing Risk Assessment Tools

**PEG (Pain, Enjoyment, General Activity): A Three-Item Scale Assessing Pain Intensity and Interference**

1. What number best describes your **Pain on average** in the past week?

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>no pain</td>
</tr>
<tr>
<td>2</td>
<td>pain as bad as you can imagine</td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

2. What number best describes how, during the past week, pain has interfered with your **Enjoyment of life**?

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>no pain</td>
</tr>
<tr>
<td>2</td>
<td>pain as bad as you can imagine</td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

3. What number best describes how, during the past week, pain has interfered with your **General activity**?

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>no pain</td>
</tr>
<tr>
<td>2</td>
<td>pain as bad as you can imagine</td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

*From Krebs et al., 2009*
Appendix H

Ongoing Risk Assessment Tools

Routine Assessment of Patient Index Data (RAPID)

The RAPID3 includes a subset of core variables found in the Multi-dimension HAQ (MD-HAQ). Page 1 of the MD-HAQ, shown here, includes an assessment of physical function (section 1), a patient global assessment (PGA) for pain (section 2), and a PGA for global health (section 3). RAPID3 scores are quickly tallied by adding subsets of the MD-HAQ as follows:

1. **OVER THE LAST WEEK, were you able to:**
   - **without ANY difficulty**
   - **with SOME difficulty**
   - **with MUCH difficulty**
   - **UNABLE to do**

<table>
<thead>
<tr>
<th></th>
<th>a. Dress yourself, including tying shoelaces and doing buttons?</th>
<th>b. Get in and out of bed?</th>
<th>c. Lift a full cup or glass to your mouth?</th>
<th>d. Walk outdoors on flat ground?</th>
<th>e. Wash and dry your entire body?</th>
<th>f. Bend down to pick up clothing from the floor?</th>
<th>g. Turn regular faucets on and off?</th>
<th>h. Get in and out of a car, bus, train, or airplane?</th>
<th>i. Walk two miles or three kilometers, if you wish?</th>
<th>j. Participate in recreational activities and sports as you would like, if you wish?</th>
<th>k. Get a good night’s sleep?</th>
<th>l. Deal with feelings of anxiety or being nervous?</th>
<th>m. Deal with feelings of depression or feeling blue?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>__ 0</td>
<td>__ 1</td>
<td>__ 2</td>
<td>__ 3</td>
<td>__ 1</td>
<td>__ 2</td>
<td>__ 3</td>
<td>__ 1</td>
<td>__ 2</td>
<td>__ 3</td>
<td>__ 1</td>
<td>__ 2</td>
<td>__ 3</td>
</tr>
</tbody>
</table>

2. **how much pain have you had because of your condition OVER THE PAST WEEK?**
   Please indicate below how severe your pain has been:

   - **NO PAIN**
   - **PAIN AS BAD AS IT COULD BE**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>0.5</th>
<th>1.0</th>
<th>1.5</th>
<th>2.0</th>
<th>2.5</th>
<th>3.0</th>
<th>3.5</th>
<th>4.0</th>
<th>4.5</th>
<th>5.0</th>
<th>5.5</th>
<th>6.0</th>
<th>6.5</th>
<th>7.0</th>
<th>7.5</th>
<th>8.0</th>
<th>8.5</th>
<th>9.0</th>
<th>9.5</th>
<th>10</th>
</tr>
</thead>
</table>

3. **considering all the ways in which illness and health conditions may affect you at this time, please indicate below how you are doing:**

   - **VERY WELL**
   - **VERY POORLY**

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>0.5</th>
<th>1.0</th>
<th>1.5</th>
<th>2.0</th>
<th>2.5</th>
<th>3.0</th>
<th>3.5</th>
<th>4.0</th>
<th>4.5</th>
<th>5.0</th>
<th>5.5</th>
<th>6.0</th>
<th>6.5</th>
<th>7.0</th>
<th>7.5</th>
<th>8.0</th>
<th>8.5</th>
<th>9.0</th>
<th>9.5</th>
<th>10</th>
</tr>
</thead>
</table>

**conversion table**

- **Near Remission (NR):** 1=0.3; 2=0.7; 3=1.0
- **Low Severity (LS):** 4=1.3; 5=1.7; 6=2.0
- **Moderate Severity (MS):** 7=2.3; 8=2.7; 9=3.0; 10=3.3; 11=3.7; 12=4.0

1. Ask the patient to complete questions 1, 2, and 3 while in the waiting room prior to his/her visit.
2. For question 1, add up the scores in questions A-J only (questions K-M have been found to be informative, but are not scored formally). Use the formula in the box on the right to calculate the formula score (0-10). For example, a patient whose answers total 19 would score 6.3. Enter this score as an evaluation of the patient’s functional status (FN).
3. For question 2, enter the raw score (0-10) in the box on the right as an evaluation of the patient’s pain tolerance (PN).
4. For question 3, enter the raw score (0-10) in the box on the right as an evaluation of the patient’s global estimate (PTGE).
5. Add the total score (0-30) from questions 1, 2, and 3 and enter them as the patient’s RAPID3 cumulative score. Use the final conversion table to simplify the patient’s weighed RAPID3 score. For example, a patient who scores 11 on the cumulative RAPID3 scale would score a weighted 3.7. A patient who scores between 0–1.0 is defined as near remission (NR); 1.3–2.0 as low severity (LS); 2.3–4.0 as moderate severity (MS); and 4.3–10.0 as high severity (HS).
Appendix I
Implementation Plan Template

Instructions: Develop an implementation plan for each step in the new care process. Identify each task, along with who will take the lead and by what time the task should be finished or reviewed for an update.

Select measures to track to help make sure that the strategies are working. See suggestions at the bottom of each “strategy” page in the Toolkit. Example Implementation Plan:

<table>
<thead>
<tr>
<th>What</th>
<th>Who</th>
<th>By When</th>
<th>Outcome &amp; Next Step</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CURRENT PLAN</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintain Registry of Patients on Opioid</td>
<td>All Providers</td>
<td>Ongoing</td>
<td>Staff A will run a new report. Providers will recheck and remove patients who are occasionally users.</td>
</tr>
<tr>
<td>Treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Develop Front Desk Protocol</td>
<td>Staff B, Staff C, and Practice Manager</td>
<td>DONE</td>
<td>Check with staff at next meeting for fine tuning and adjustments.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patients who will not be scheduled for Chronic Pain Management visits will not be on the registry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patients who are on the registry and call for an early refill will be told “No” by everyone they talk to</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patients not on the registry who call for a refill or an early refill will be transferred via message to the PCP. If the PCP is not available, the covering provider will refill to next PCP visit.</td>
</tr>
<tr>
<td>PDMP (VPMS) Review prior to Chronic Pain</td>
<td>Nurse A</td>
<td>Soon</td>
<td>Waiting for password from Health Department. Will trial and share with nursing staff.</td>
</tr>
<tr>
<td>Management visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Update agreement to include “refills at</td>
<td>Practice Manager and</td>
<td>9/13/13</td>
<td>Finalize draft, remove all old copies, and replace Nurses to include with VPMS reports</td>
</tr>
<tr>
<td>appointments only”</td>
<td>Providers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wall sleeve for Rx mounted near printer</td>
<td>Practice Manager</td>
<td>9/23/13</td>
<td>To be ordered</td>
</tr>
<tr>
<td>(Front Desk basket for now); stapler</td>
<td></td>
<td>9/9/13</td>
<td></td>
</tr>
<tr>
<td>nearby</td>
<td></td>
<td>DONE</td>
<td></td>
</tr>
<tr>
<td>Prior authorization notebook with</td>
<td>Nurse B</td>
<td>9/16/13</td>
<td>Set up and share with all nursing staff</td>
</tr>
<tr>
<td>monthly tabs for tickler</td>
<td></td>
<td>DONE</td>
<td></td>
</tr>
<tr>
<td>Add updated Patient Agreement to rooming</td>
<td>Nurse A</td>
<td>Soon</td>
<td></td>
</tr>
<tr>
<td>process</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MEASUREMENT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Track phone call volume for opioid refills</td>
<td>Nurse A, Nurse B, and</td>
<td>Completed</td>
<td>Repeat for 1st half of October by Triage Nurses from 9/30/13-10/11/13. Practice Manager will post data sheet on wall.</td>
</tr>
<tr>
<td></td>
<td>Practice Manager</td>
<td>for 1st</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 weeks of</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>September</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note practice deviations from protocol</td>
<td>Everyone</td>
<td>Ongoing</td>
<td>Bring to next meeting – 10/4/13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey to be repeated in early December</td>
<td>Staff D</td>
<td>12/2-6/13</td>
<td></td>
</tr>
</tbody>
</table>
REFERENCES


2. CARES Alliance Pain Assessment and Documentation Tool. 2010 [cited 2014 June 12]; Available from: www.caresalliance.org/ResourceList.aspx?userType=6&itemType=11


