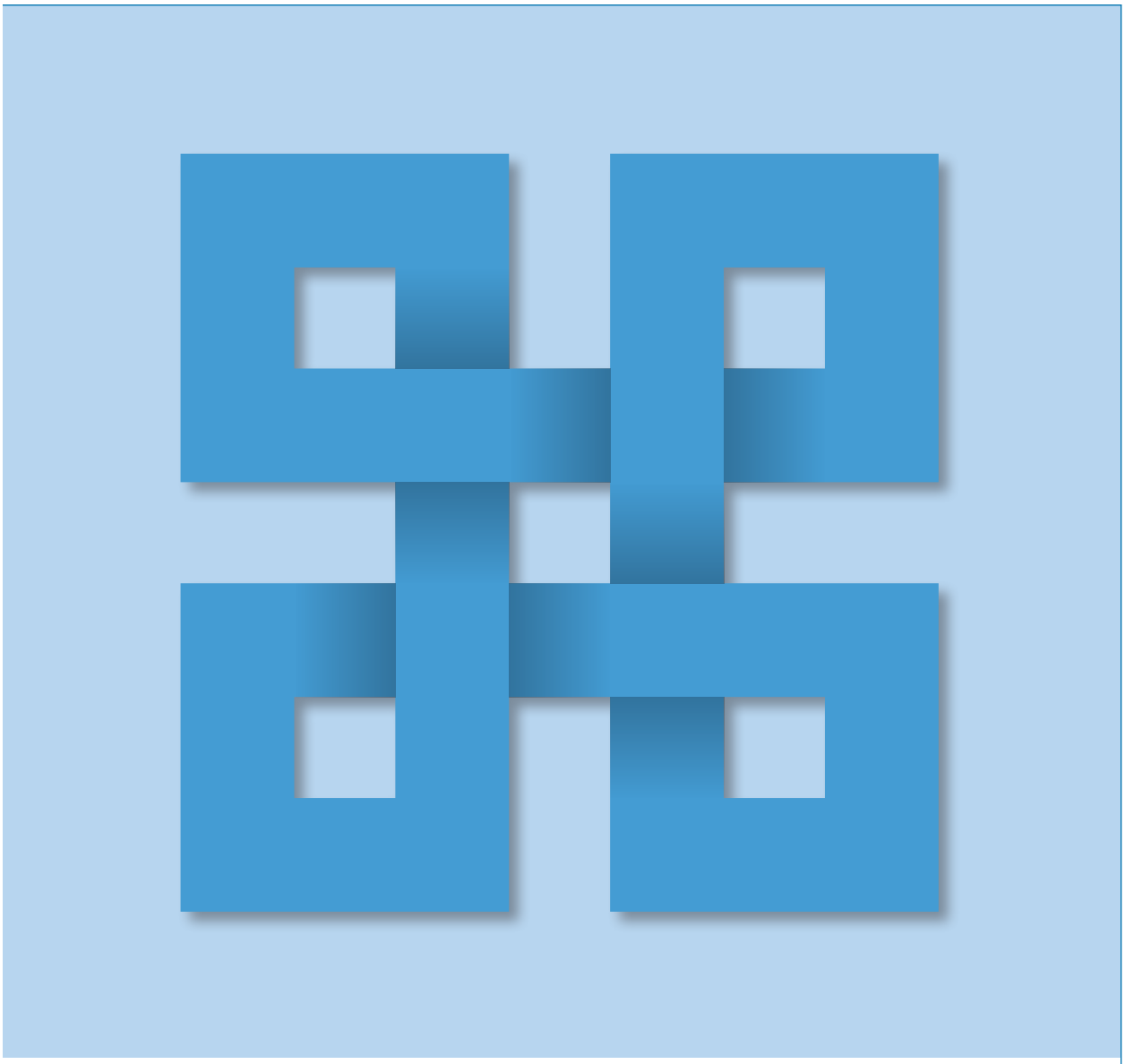


Improving Opioid Prescribing: Sustainable Solutions for Vermont

OPIOID PRESCRIPTION MANAGEMENT TOOLKIT FOR CHRONIC PAIN **FACILITATOR MANUAL**

SECOND EDITION

Connie van Eeghen, DrPH
Charles D. MacLean, MD
Amanda G. Kennedy, PharmD, BCP

Prepared By
Connie van Eeghen, DrPH
Research Assistant Professor
University of Vermont Larner College of Medicine

Charles D. MacLean, MD
Associate Dean for Primary Care
University of Vermont Larner College of Medicine
Office of Primary Care

Amanda G. Kennedy, PharmD, BCPS
Director
The Vermont Academic Detailing Program
University of Vermont Larner College of Medicine
Office of Primary Care

Contact Information
University of Vermont Office of Primary Care
Arnold 5
1 South Prospect Street
Burlington, VT 05401
(802) 656-2179
www.vtad.org

Acknowledgements
We thank the many providers and practice staff members who trialed portions of the toolkit in its development process and gave us feedback along with endless patience and support. Although it is not possible to acknowledge everyone in this publication, we appreciate the following Vermont practices and their willingness to contribute their valuable time and efforts to this project:

- Barre Internal Medicine
- Cold Hollow Family Practice
- Danville Health Center
- Dr. Michael Corrigan's Practice
- Georgia Health Center
- GoodHEALTH
- Grace Cottage Family Practice
- Green Mountain Family Practice
- Mad River Family Practice
- Northwestern Orthopaedics
- Richford Health Center
- Waterbury Medical Associates

Thanks To
The Office of Primary Care and staff team for its support throughout this project.

Funding
This toolkit was funded by Grant #03420-6120P from the Vermont Department of Health, 2012-2014, to the University of Vermont Office of Primary Care

This Toolkit reflects knowledge based on the regulatory environment of the State of Vermont, 2012–2014. Please check indicated websites for updates and new information as you proceed with this project.

Design
Lisa Cadieux, Liquid Studio
www.liquidstudiodesign.com

The University of Vermont
LARNER COLLEGE OF MEDICINE
OFFICE OF PRIMARY CARE

Opioid Prescription Management Toolkit for Chronic Pain

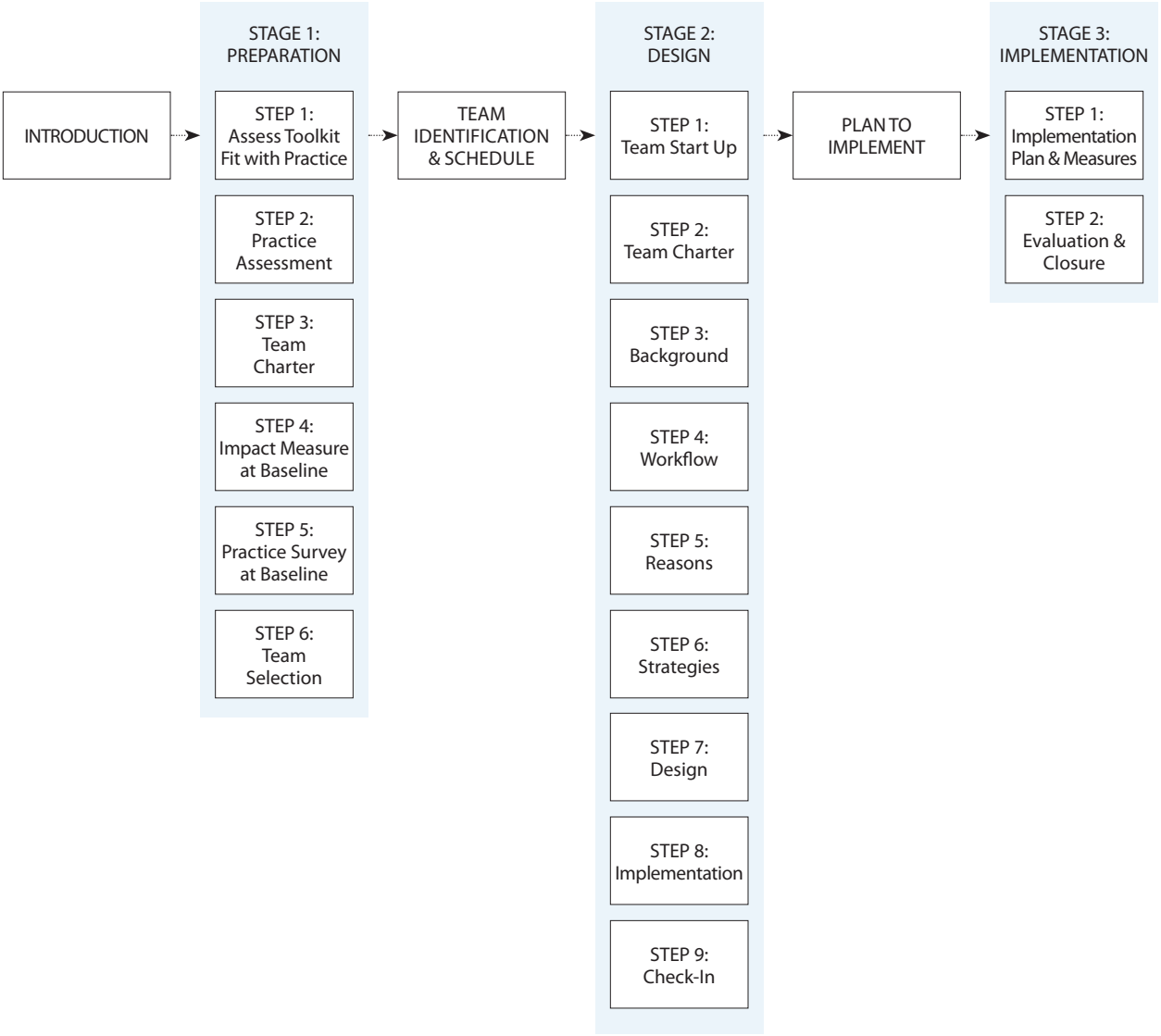
This toolkit is intended for ambulatory care practices whose leaders, providers, and staff want to improve the process of managing opioid prescriptions for their chronic pain, non-palliative care patients. It provides a detailed description of each step to facilitate a project on this specific topic and is targeted for use by project facilitators and anyone interested in project facilitation.

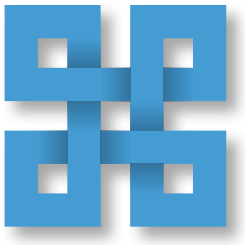
A streamlined version of this toolkit, *The Practice Fast Track*, is available to highlight the 17 strategies that can be used to improve opioid prescription management (also included here). That version may be of interest to those who have already conducted the initial steps of creating a project team and are interested in experimenting with a few strategies relatively quickly. Please refer to the Office of Primary Care website, www.med.uvm.edu/opc, to access *The Practice Fast Track*.

The Facilitator Toolkit is made up of modules in three stages that can be used sequentially or in the order that is most effective for the practice. The diagram below identifies the modules in each stage to help you navigate to the starting point you wish to explore first.

You may wish to read the following introduction to find out more about this toolkit and what can be found in its stages and modules.

OPIOID PRESCRIPTION MANAGEMENT STRATEGIES FOR CHRONIC PAIN: TOOLKIT STRATEGIES AND MODULES





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Introduction

PURPOSE

The purpose of the toolkit is to provide a step-by-step process to plan and use strategies for managing opioid prescriptions to reduce diversion and misuse of prescriptions while helping patients manage chronic, non-palliative care-related pain.

The focus of this toolkit is on in-practice solutions, which providers and staff have direct control over. This toolkit presents choices that practice members can make, based on their knowledge of local and state policies and their own professional expectations.

To accomplish this, the toolkit outlines three separate stages of this process:

Stage 1: Preparation: practice leaders decide whether this is a good process for the practice and, if so, prepare a practice-based project team to carry it out.

Stage 2: Design: the project team reviews the current issues facing the practice regarding opioid prescriptions and selects specific strategies that can be used by individual providers or the practice as a whole.

NOTE: the workflow redesign steps identified in this toolkit are based on a specific quality improvement method known as "Lean" or "Toyota Production System." This toolkit does not provide specific instruction on workflow design; resources for such instruction can be found in the reference section[1-4]. The toolkit uses the Lean "A3" model[5]. Other workflow methods can be used, such as Clinical Microsystems; the facilitator should select a method that matches the needs of its team.

Stage 3: Implementation: the project team and other practice members review the team's work and the team's plan to get started. The project team and other practice members collaborate in putting some or all of the selected strategies in place following the practice's preferred quality improvement process, such as "Plan, Do, Study, Act" (PDSA cycle).

On July 1, 2017, two new rules regarding controlled substance prescribing went into effect in Vermont (see Vermont Department of Health website). The Opioid Prescribing rule requires that prescribers follow many of the strategies described in this toolkit, and also specifies quantity limits on opioid prescriptions that are among the strictest in the country. The other new requirement is for the prescription of naloxone to patients on high dose opioids (>90 MME/day) or patients on concomitant opioids and a benzodiazepine.

The Vermont Prescription Monitoring System (VPMS) rule specifies when a query of the prescription drug monitoring program is required, the biggest change being a requirement to query for a first time prescription of more than 10 pills.

We have updated this toolkit to reflect these new rules.

REASON FOR THIS TOOLKIT

Opioid use has increased dramatically in the last decade; this has been accompanied by a parallel increase in prescription opioid misuse, opioid-related morbidity and mortality, and opioid-related health care costs[6]. There are increasing concerns about the possibility of opioid diversion from legitimate prescriptions.

A sizeable proportion of opioids are prescribed in primary care settings, for both short and long-term treatment. Most primary care physicians have fewer than 50 patients on chronic opioid therapy[7].

Prescribing opioids is becoming more complex, due in part to an increasingly strict standard of care and more documentation requirements. Many states are adopting regulations that require the use of consent forms and treatment agreements for patients on chronic opioid therapy; the use of the state prescription drug monitoring program (in Vermont: VPMS); and even specialist consultation for patients on high dose opioid therapy.

Opioid prescribing can be very confusing and disruptive to the office workflow, from the front desk staff, to the nursing staff, to the prescribers. This can result in less than optimal care for patients.

The use of a toolkit that combines the redesign of office practice workflow with the use of new strategies of care is a proven approach to helping practices make changes[8].

The suggested approaches to improving opioid prescribing in this toolkit are based on the most recent guidelines, textbooks, expert opinion, and field work with practices that have adopted various strategies.

This toolkit provides new strategies for managing opioid prescriptions for patients with chronic pain.

These strategies may require changes in office work flow.

TOOLKIT AND LEADERSHIP

This toolkit includes tools for assessing and changing practice workflow related to opioid prescription management or other medications requiring a structured approach. It calls for the participation of people in several key roles:

- **Practice leader or leaders:** decision-makers in the practice that decide whether to work on a particular project. Example: medical director, owner(s) of the practice.
- **Team leader**: an individual given the responsibility to conduct a project by convening a team to work on it together. Example: practice provider, practice clinical staff, practice supervisor.
- **Team facilitator**: a person from the practice or from outside the practice who guides the team through its work. Although "team leader" and "team facilitator" are sometimes the same person, separating these roles and assigning them to different people often speeds the work of the team and may result in a more successful outcome.
- **Team members**: members of the practice who meet and work collaboratively on a team project.

This toolkit strongly recommends the involvement of practice leaders from the start of a project on opioid prescription management:

Identify at least one practice leader to plan this project by leading the preparation tasks in Stage 1 (pages 9-11) and following up on later stages of work, as described in Stages 2 and 3.

Practice leaders action steps:

- Review the toolkit
- Conduct the steps in "Stage 1: Preparation" or delegate to another member of the practice
- Communicate the work of the project to all members of the practice during "Stage 2: Design"
- Follow up on steps to make decisions and provide support as needed during "Stage 3: Implementation"
- Bring the project to a close

The work involved in using the toolkit will be completed by a Team Leader and a Project Team, which may include one or more practice leaders.

What if: the practice can't commit to the resources needed to conduct these steps?

Recommendation: Take a mental step back from this project. Is this the right problem? Skip to Stage 1, Step 2 and assess whether the practice is ready to tackle opioid prescription management. These answers may help diagnose whether there are specific obstacles that practice leaders can address. If the practice is assessed as "ready," but commitment is not certain, consider the Quick Start option (Introduction, page 7) to test one strategy and confirm whether there is buy-in.

CHRONIC PAIN MANAGEMENT GUIDELINES

If you are seeking a toolkit for clinical guidance in chronic pain management, STOP! This toolkit provides guidance on strategies for managing opioids prescribed for chronic pain.

Resources for clinical guidance can be found in many places, and it is always advisable to check for updates in the literature. Those that have been helpful in the past include:

- Scott M. Fishman, MD: Responsible Opioid Prescribing: A Clinician's Guide, Second Edition (2013)
- Boston University School of Medicine Continuing Medical Education: www.opioidprescribing.com/overview
- CARES Alliance resources: www.caresalliance.org/ResourceList.aspx?userType=6&itemType=11
- Institute for Clinical Systems Improvement Assessment & Management Algorithm: www.icsi.org/_asset/bw798b/ChronicPain.pdf
- Roger Chou, Use of Chronic Opioid Therapy, *Journal of Pain*, 2009 (with appendix of assessment tools)

A diagrammatic protocol for opioid management with chronic pain (source: University of Vermont Medical Center, 2014) as a general guide is found in Appendix A. Per the Vermont Board of Medical Practice, the protocol should be preceded by provider education in order to understand the relevant pharmacologic and clinical issues in the use of such analgesics and to be able to structure a treatment plan that carefully reflects the particular benefits and risks of opioid use for each individual patient. Prior to starting treatment, providers should assist patients with an understanding of informed consent, a treatment agreement, and a presentation of treatment as a trial, with defined evaluation points that are more frequent during the initial and dose-adjustment periods. The protocol for opioid management will be made easier with a practice policy of "universal precaution" monitoring that can include drug testing (urine screens) and also pill counts. Based on this preparation, the protocol in Appendix A includes:

- Initial Evaluation and Risk Stratification (may include information from previous providers, family, significant others, and the Vermont Prescription Monitoring System – VPMS)
- Treatment (general)
- Decision to use opiates (opioids)
- Opioid Monitoring
- Diversion is strongly suspected
- Addiction is strongly suspected
- Opiates (opioids) are not working
- Opiates (opioids) working; joint decision to stop use
- Narcotics Prescribing: aberrant behaviors

Quick Start Guide

Sometimes a practice needs to make an immediate change quickly. Although this approach may miss some opportunities for making opioid prescription management more effective for patients and easier for providers and staff, it may be a practical alternative for getting started. (Note: the "Fast Track Toolkit" is a streamlined toolkit that supports this approach.)

After completing the actions in the Recommended Steps (see right), assess the effectiveness of the strategy selected after a month. Because patients on opioid treatment often receive prescriptions with enough doses for about a month, it can take a few weeks before providers and patients feel the results of the change. Adding several strategies at the same time can also be helpful, but each strategy requires a team member to carry out the implementation steps needed for the change to be tried out and assessed. A diagram of the Quick Start modules in each stage will help you navigate across stages and steps in the Toolkit and put a quick trial of an opioid prescription management strategy to the test.

If the team decides to continue to add strategies, consider using the Facilitator's Toolkit in full. Many changes call for more time to understand and modify work flow so that strategies interact across providers, staff, and patients successfully.

RECOMMENDED STEPS:

Stage 1: Preparation

Team Charter (Step 3)

Team Selection and Scheduling (Step 6)

Stage 2: Design

Team: Start Up and confirm Team Charter (Steps 1 and 2)

Team: Describe the background (Step 3)

Team: Analyze the flow of work (Step 4)

Team: Select one strategy for one provider to trial for one month (Strategies 8–17 from Step 6). Frequently used strategies (in order of "more often used" to "less often"):

- VPMS regular reporting (Strategy 16)
- Urine screens (Strategy 13)
- Ongoing risk assessment (Strategy 12)
- Prescribing in multiples of 7 days (Strategy 9)
- Pre-print prescriptions for future use (Strategy 10)

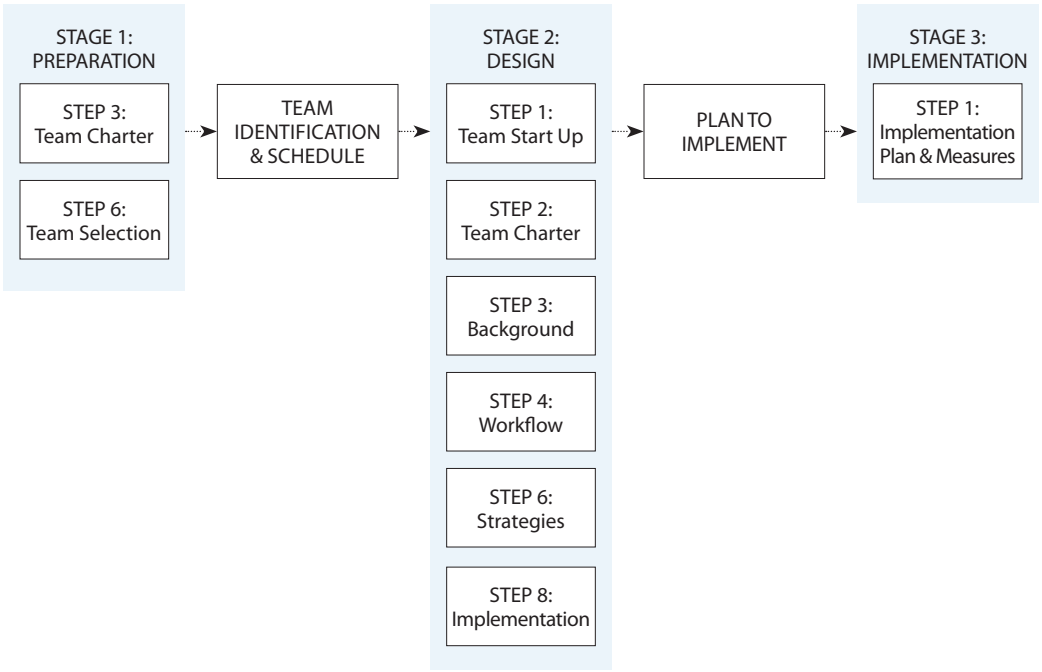
Team: Draft implementation plan (Step 8)

Stage 3: Implementation

Implementation plan updates (Step 1)

Informal assessment with provider and staff: Continue or change plan?

QUICK START GUIDE



1 Preparation

Stage 1: Preparation

Practice leaders decide whether this toolkit is a good choice for the practice. If it is, they prepare a practice team to carry it out. This stage is estimated to take about six hours of practice leaders' time, but some of this work may be shared with other practice members. The six steps in this stage are listed below, with more detail on following pages.

1. Determine if this toolkit is a good match
2. Practice readiness assessment
3. Team charter
4. Impact measure at baseline
5. Practice survey at baseline
6. Completion of Stage 1

STEP 1: DETERMINE IF THE TOOLKIT IS A GOOD MATCH FOR THE OFFICE PRACTICE

This toolkit uses a "Universal Precautions" approach, proposing that it is more effective to treat all patients consistently with a single guideline for all long term, non-palliative care-related, opioid prescription patients 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"), how long or well the provider has known the patient ("we go way back"), or other patient characteristics. 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 opioid prescription patients (Universal Precautions) improves their effectiveness.

This toolkit was created based on the experiences of many providers who found that the more consistent the use of the strategies, the more easily they and their staff could maintain their use. 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 the goal of chronic pain management is not the elimination of pain but patient self-management of chronic pain using a variety of interventions in order to maintain health function. Opioid therapy is one of those interventions and is the specific focus of this toolkit.

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

For assistance with the development of a standard clinical approach, please see any of the resources in Introduction: Chronic Pain Management guidelines (page 6).

1

STEP 2: CONDUCT A PRACTICE READINESS ASSESSMENT

Giving providers and staff new tasks for opioid prescription management can be very helpful to patients but runs the risk of making work more challenging to providers and staff. Before starting such a project, practice leaders should evaluate whether this project is a good fit for their practice. The Opioid Prescription Management Readiness for Change Assessment survey (see Appendix B) can be used to collect anonymous feedback from a sample of practice members to guide the decision on whether to use this toolkit to improve opioid prescription management in the practice.

1. Identify about eight practice providers and staff from different roles across clinical and non-clinical staff to complete the survey in Appendix B (if the practice has eight or fewer members, distribute to everyone).
2. Distribute the survey, with instructions about the date it should be returned by and where it should be sent.
3. Average the responses by statement. For example, if the statement "Our practice's community has a drug abuse/mismanagement problem" received ratings of 1, 2, 5, 3, 4, 5, 5, and 5, (5 being most indicative of readiness for change) then the average response for this statement is 3.75.
4. If the average response for any statement is less than 3.0 or has more than two responses as a "1" or a "2," then consider, as practice leaders, whether this is an indication that the project should be done at this time or needs additional preparation before starting.
5. Review all comments for additional indications of whether the practice is ready to conduct this project at this time.

When ready to proceed, continue with the remaining steps in "Stage 1: Preparation."

STEP 3: CREATE A "TEAM CHARTER" WITH A SPECIFIC PURPOSE AND OBJECTIVE

A Team Charter is an explicit way to start an efficient and focused project team that understands its purpose, boundaries, and objective(s).

Purpose: Create a statement that explains what the team will focus on, starting with the statement: "The project team will address…" and adding the targeted areas related to:

- Medications that need practice management (opioids, benzodiazepines, stimulants…)
- Patients that need more structured management (chronic pain for three months or more)
- Any other patient population or substance relevant to the practice

Example: The practice will address opioid prescription management for non-palliative care patients who have been on long term, stable opioid therapy for three months and who need monitoring and follow up.

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.

This charter becomes the starting point for the first team meeting.

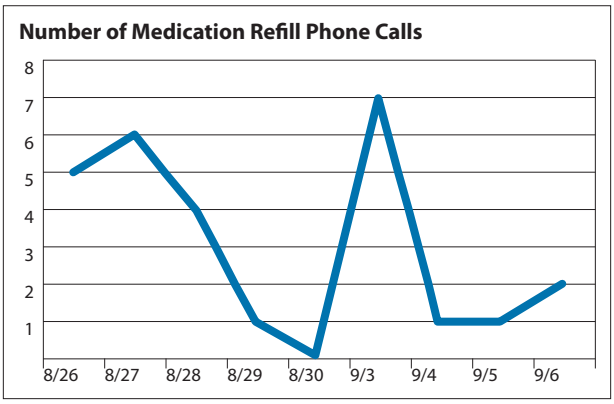
STEP 4: MEASURE IMPACT AT BASELINE

Quality improvement project teams are responsible for measuring change from a baseline (pre-project) state in order to adjust their interventions based on these early results. Before the project gets started, and using the simplest means possible, keep a log or list of the occurrence of at least one of the following kinds of events. Select the events to log as fits the current concerns of the practice. Select a two week period that is "normal" for the practice (no holidays, vacations, large number of absences due to medical leave, etc.). Keep a separate log for each kind of event tracked. The purpose of this log is to gather useful information for the project team and to measure the success of the project later.

Example events to consider tracking via event logs:

- Front desk or prescription line phone calls received about opioid refills
- Provider interruptions due to questions about an opioid prescription
- Pharmacy phone calls or faxes about an opioid prescription

Add up the daily totals for each of the measures and plot the daily numbers on a graph (see example below). Calculate the average daily count of each measure. Share this information with the team and save for use at project completion.



STEP 5: SURVEY ALL PRACTICE MEMBERS AT BASELINE

Survey the entire practice before the project gets started, using paper or electronic surveys (e.g. SurveyMonkey or REDCap) for the degree of perceived provider and staff satisfaction with opioid prescription management. The purpose of this survey is to gather helpful data for the project team and to measure project success later by repeating part of the survey after project completion. The survey also helps identify key issues the project team may need to address in implementing its recommendations. The opioid prescription management practice survey (see Appendix C) can be used to collect anonymous feedback from all practice members. Steps to follow:

1. Identify all practice providers and staff who will receive the survey in Appendix C.
2. Distribute the survey, with instructions about the date it should be returned and where it should be sent.
3. Average the responses for each statement. If "Our office has clear and well-organized policies and approaches to prescribing and managing chronic opioids" received ratings of 3, 1, 3, 2, 1, 2, 3, 2, 4, 1, 2, 1, 2, 1, and 2, then the average response for this statement is 2.00.
4. For statements 1–5, save the average responses for the team and for use at project completion.
5. For statements 6–18, save the average responses and the comments for the team to use in its work.

STEP 6: COMPLETION OF STAGE 1 WITH TEAM SELECTION AND SCHEDULING

Identify project team leader and team members, set up schedule for team meetings, and identify other resources for the team's work:

1. Identify the Opioid Prescription Management team leader
2. Identify the other members of the team. At a minimum, the team should include a provider who prescribes opioids, a clinical staff member who assists with patient care (rooming patients, following up on patient phone calls, etc.), and a front desk staff member (schedules visits, receives phone calls, greets patients, etc.). When other health professionals are available (pharmacist, psychiatrist, social worker, behavioral health clinician, case manager, etc.), their inclusion may help the team identify new opportunities for improving opioid prescription management and ways of implementing them that assist the practice.
3. Create a schedule of team meetings for eight to ten hours of team work, at times that are convenient for team members and the practice. Team meetings are most effective if they are at least one hour in length and no more than one week apart. Longer meetings that occur more frequently sometimes result in less meeting time overall.
4. Identify the resources that the team has available during its work:
   - Project facilitator, if different than the team leader (Team progress is usually more efficient with a facilitator who is not the team leader or a team member)
   - Team meeting space with table and chairs, in which the team can meet uninterrupted
   - White board and dry erase markers (for workflow process diagrams)
   - Flip chart, flip chart makers, and masking tape (for brainstorming)
   - Blank 11" by 17" paper, pencils, and erasers (for team member documentation of workflow diagrams)
   - Food and beverage (if meeting during meal times and if allowed by practice)
   - One or more patients from the community who have experience with the issues of opioid prescription management and are willing to share their knowledge of what it is like to receive care and what the experiences have been in managing controlled substances

What if: the practice is only able to schedule four hours of team meeting time?

Recommendation: Identify a specific strategy from the Toolkit that the practice is interested in trialing. Use the Quick Start option (Introduction, page 7) to plan and implement that strategy and assess afterwards if there is interest in continuing team work to consider additional strategies.

2 Design

Stage 2: Design

The project team reviews the current issues facing the practice regarding opioid prescriptions and selects specific strategies that can be used by individual providers or the practice as a whole. Each of the steps for the team is described, with examples where appropriate. Appendix D includes a sample of team meeting agendas that can be modified as needed by the team.

This stage is estimated to take up to ten hours of team meeting time using the "Lean" method of quality improvement, but this will vary based on the team's experience with workflow analysis, the quality improvement method used, the number of workflow issues identified, the number of strategies selected, and the complexity of the strategies selected. The nine steps in this stage are listed below, with more detail on the following pages.

Step 1: Team Start Up
Step 2: Confirm the Team Charter
Step 3: Describe the Background Issues
Step 4: Analyze the Flow of Work
Step 5: Identify Reasons for Delays or Errors
Step 6: Review and Select Strategies

Practice-wide strategies

- Strategy 1: Consistent approach across practice
- Strategy 2: Team approach to opioid prescription management
- Strategy 3: Regular visits for chronic pain management
- Strategy 4: Roster of patients with chronic pain
- Strategy 5: Flowsheet for visits
- Strategy 6: Pain management council
- Strategy 7: Update patient agreement

Provider-specific strategies

- Strategy 8: Initial risk assessment (Vermont Medical Practice Board recommendation)
- Strategy 9: Prescribing in multiples of seven days
- Strategy 10: Pre-print prescriptions for future use
- Strategy 11: Bubble pack prescriptions
- Strategy 12: Ongoing risk assessment
- Strategy 13: Urine screens
- Strategy 14: Random urine screens
- Strategy 15: Random pill counts
- Strategy 16: VPMS regular reporting
- Strategy 17: Check patient agreements regularly

Step 7: Design the New Flow of Work
Step 8: Draft Implementation Plan
Step 9: Completion of Stage 2: Check in with Practice Leaders

2

STEP 1: TEAM START UP

Practice leaders meet with the project team leader and team members to confirm the plan for the Opioid Prescription Management project and the preparations completed *(estimated: one hour)*.

Share this toolkit with the project facilitator and team leader ahead of time. Convene the team and complete the following actions:

1. Review the Team Charter with the team
2. Discuss any questions or issues that arise
3. Agree on when and how the project team should communicate progress or challenges with the practice leaders
4. Practice leaders turn the team over to the team leader
5. Practice leaders continue to:
   - Express interest and support
   - Ask questions about progress
   - Provide time and assistance if requested by the leader or members of the team

Please refer to Appendix D for sample team agendas for use by the team facilitator in moving through the remaining steps listed in this chapter.

STEP 2: CONFIRM THE TEAM CHARTER

Strongly recommended – estimated: half an hour

Team members review the materials they have received and create a summary statement of the team's goal. Complete the following actions steps:

1. Review the team charter developed by the practice leaders
2. Review the results of the Impact Measure at Baseline
3. Review the results of the Practice Survey at Baseline

Each team member is responsible for maintaining his/her own set of notes of the team's progress. Together, with one person (facilitator or team leader) documenting on white board or flip chart, complete the following tasks:

1. Based on the information reviewed, summarize the issue from the patient's perspective, in a single sentence
2. Document this "issue" as the start of the team's report

All documentation instructions will be added to each team member's document, which results in a "final report" that each team member owns. This final report is the product of the team and is used to present its recommendations to the practice leaders.

STEP 3: DESCRIBE THE BACKGROUND ISSUES

Strongly recommended – estimated: half an hour

Based on the issue identified by the team, team members create a list of the background issues that are relevant for this practice.

This is an ideal opportunity to invite a patient with long term opioid use experience, or with contacts with similar community members, to talk about/answer questions regarding the perception of the practice's management of opioid prescriptions. Based on previous projects that included a patient in gathering this information, team members have found this to be a very positive and helpful learning experience.

Complete the following steps and document the results on white board or flip chart and in team members' reports:

1. Answer the question: "What do we already know is true about our practice that is related to the issue we identified?"
2. List in "bullet" form, leaving room to add new ideas to previous, related ideas

The purpose of this step is to identify and build consensus around what factors are driving the issue identified by the team. As long as all team members are in agreement, the ideas presented can be added to the list of background items. Issues identified can include:

- 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

STEP 4: ANALYZE THE FLOW OF WORK

Strongly recommended – estimated: two hours

Use the list of background issues from above to describe the current process of caring for a patient using opioids to manage chronic pain in which the team sees these issues occurring. Possible processes that the team may describe:

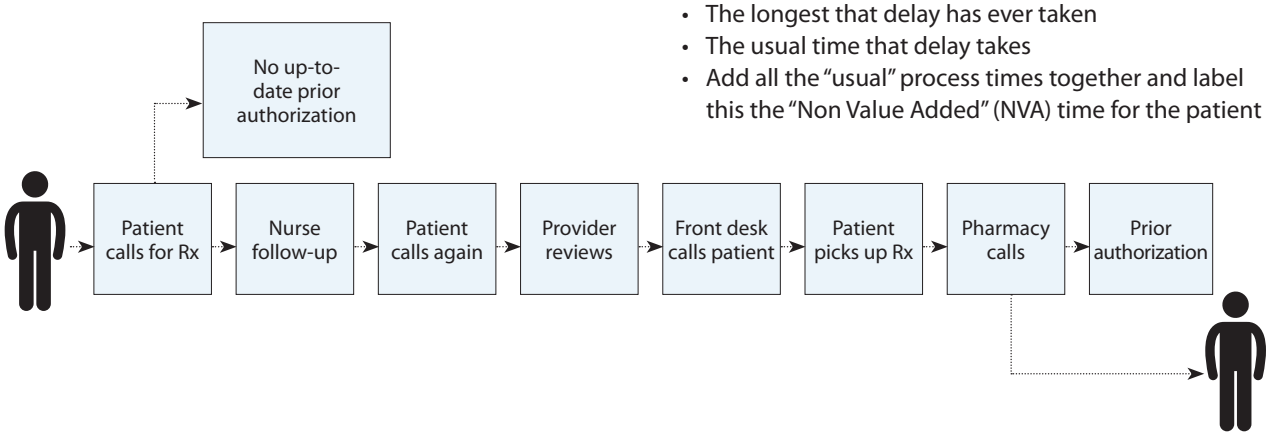
- Patient calls for an early refill
- Patient shows up for an unscheduled visit with the provider
- Patient does not show up for a scheduled visit and calls for a refill later

Choose a patient care process that best fits the issues faced by your practice. Then complete the following steps and document the results on white board or flip chart and in team members' reports:

1. Map the Current Process selected
Strongly recommended
- Make a list of each step in the process, grouping together all tasks done by one job function (receptionist, medical assistant, nurse, provider, etc.). Describe clearly the tasks involved in each process step, so everyone shares a complete understanding.
- Map the steps to visually represent the path taken by the patient and her/his information. See the process from the patient's perspective.
- Example map: *see below*

2. Time Study
Optional – Estimate the amount of time the practice puts into this care process
Add the time needed within each process step to care for the patient:
- The quickest that process step can take
- The longest that process step has ever taken
- The usual time that process step takes
- Add all the "usual" process times together and label this the "Value Added" (VA) time for the patient

Add the time needed between each process step to care for the patient:
- The quickest that delay can take
- The longest that delay has ever taken
- The usual time that delay takes
- Add all the "usual" process times together and label this the "Non Value Added" (NVA) time for the patient

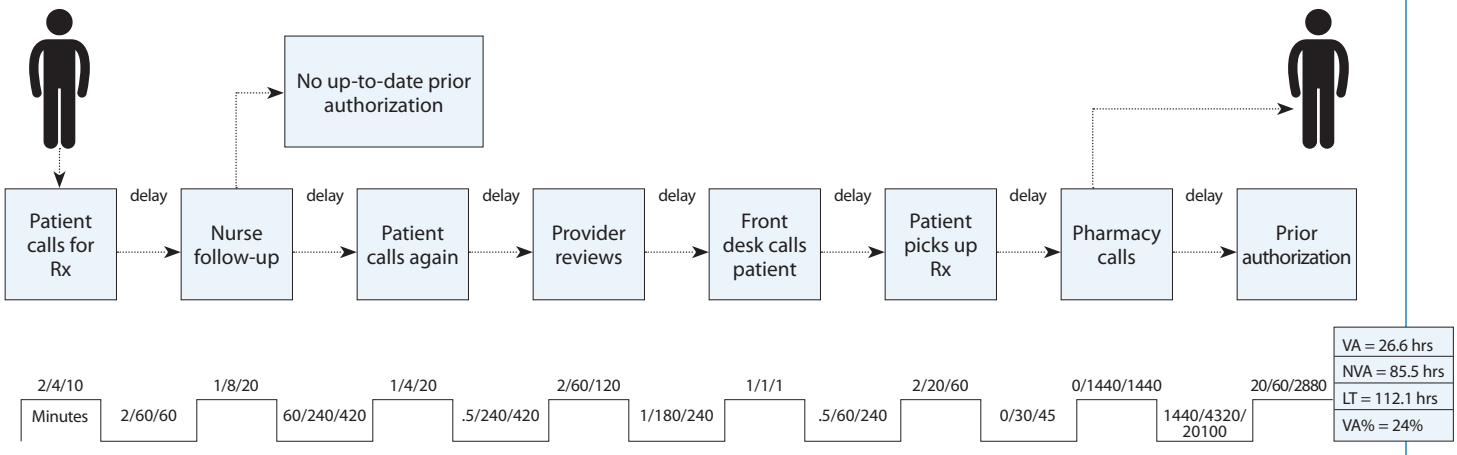


3. Add the Value Added time and the Non Value Added time and label this the "Lead Time" (LT) that the patient experiences in the completion of the current process.

4. Divide the Value Added time by the Lead Time (VA/LT) and label this percent as the Percent Value Added (%VA), or the percentage of time the practice invested in the patient that was spent in a patient care activity. This is an approximate measure of the practice's efficiency in this particular care process.

5. NOTE: There is no "good" or "bad" judgment applied to this number. It is another description of how the care process works, which can be changed depending on the strategies the project team selects to work on for this project.

6. Example map describes a process that is 24% "value added" for the patient: *see below*



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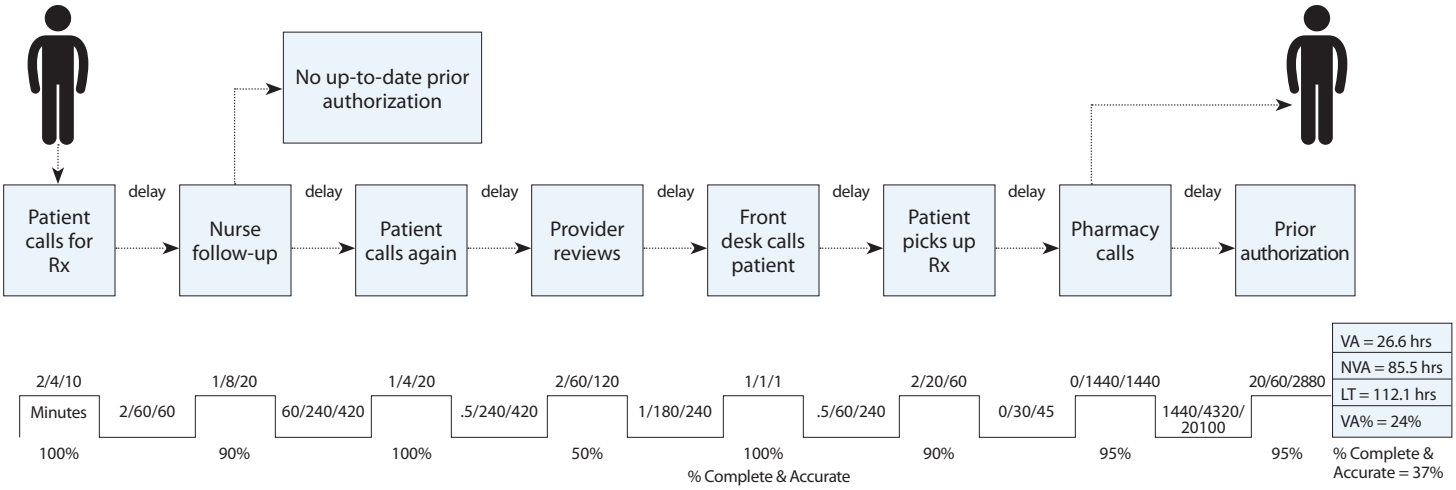
7. Resource Study (optional): Estimate the percentage of time that the person doing each process has all the resources (including information) needed at the start of that process, completely and accurately.
   - For each process step, estimate the percentage of time the person doing that function has all the resources needed, at the start of the process, to complete all the tasks. Label this "% Complete & Accurate" (%C&A)
   - Multiply all % Complete & Accurate into one product. This product is an approximate measure of the practice's effectiveness in providing all the patient care resources needed to complete this particular care process accurately.
   - NOTE: There is no "good" or "bad" judgment applied to this number. It is another description of how the care process works, which can be changed if the project team wishes to work on this during the project.
   - Example map describes a process that is 37% effective in proving complete and accurate information as part of the care process:



STEP 5: IDENTIFY REASONS FOR DELAYS OR INCOMPLETE INFORMATION

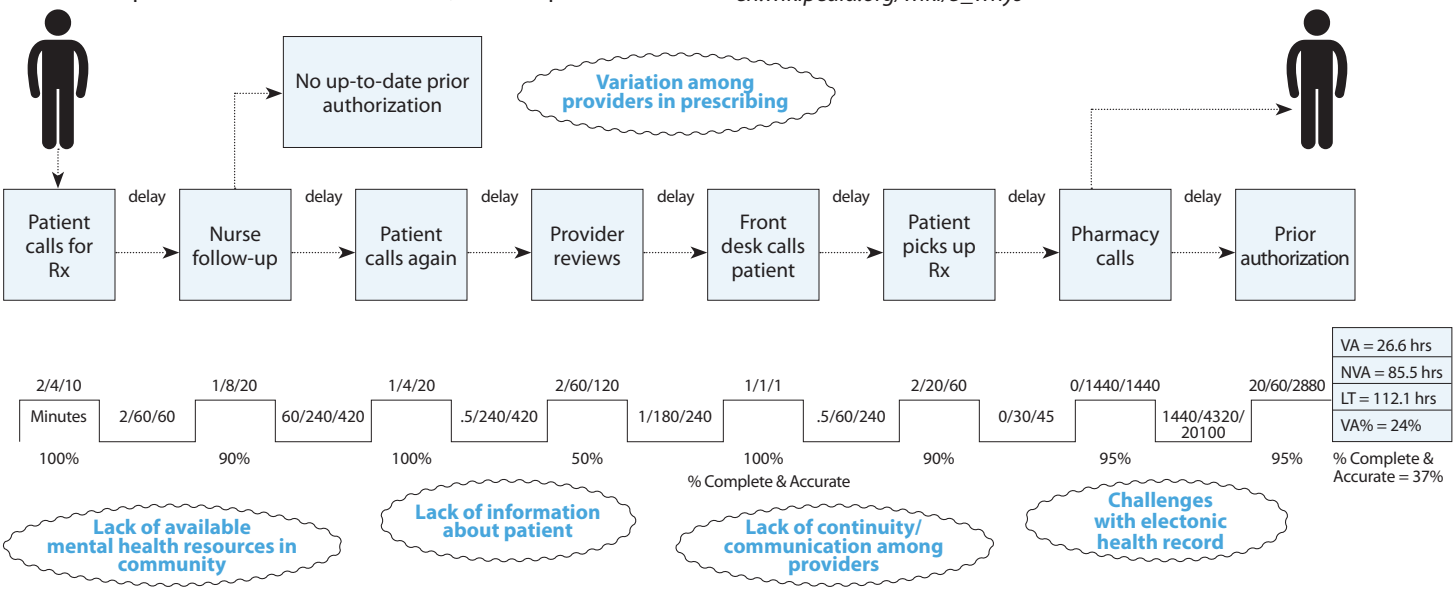
Strongly recommended – Estimated: half an hour

Through the analysis of workflow above, the team members have identified problems or concerns in the way the patient care process currently works. The team brainstorms reasons for those problems. These can be general or specific reasons that identify the "root causes" of the problems that have surfaced. They may address reasons for repeated process steps, long process times, lengthy delays, lack of complete and accurate information, or other problems.

Complete the following steps, documenting the results on white board or flip chart and in team members' reports:

1. List all reasons why the problems identified exist
2. Use the "5 Whys" * process to identify root causes
3. Add root causes to the process map created in the previous step
4. Example map identifies five root causes to the problems identified:

**en.wikipedia.org/wiki/5_whys*



STEP 6: REVIEW AND SELECT STRATEGIES FOR MANAGING OPIOID PRESCRIPTIONS

Based on practice preferences, these strategies are all optional, select at least one – estimated: one and one-half hours

Team members review the following list of strategies, described in more detail on the following pages. Strategies are independent of each other. Selecting any one strategy does not require you to select any of the others.

All strategies work best if utilized by the practice as a whole, but some can be used by individual providers without changing the work of other providers in the practice. Therefore, the strategies are organized into two groups:

Practice-wide strategies: best if implemented by the entire practice

Provider-specific strategies: may be implemented by individual providers

The following table summarizes all the practice-wide strategies in the toolkit:

Practice-wide Strategies

Strategies that are implemented practice-wide (that is, all providers agree to use them consistently across the practice) have significant advantages over those that are adopted by one or a few providers:

- Issues related to cross-covering providers and hand-offs related to patient care are reduced
- Patients perceive consistent care across the practice
- Providers do not have to explain reasons for differences in care; "this is the way we do it here"
- Providers and staff have simpler office systems; few exceptions result in easier management

Many practices have reported advantages to implementing all strategies on a practice-wide basis. The strategies listed in the table below are particularly dependent on practice-wide implementation because they are likely to require changes to infrastructure or organizational policies, which affect everyone.

PRACTICE-WIDE STRATEGIES	DESCRIPTION
1. Consistent approach across practice	Providers agree on a standard of opioid prescription management that all practice members support
2. Team approach to opioid prescription management	All provider and staff roles in the practice take on responsibilities of opioid prescription management
3. Regular visits for chronic pain management for consistency	A unique patient visit type is created for the sole purpose of reviewing chronic pain issues, scheduled at regular intervals
4. Roster of patients with chronic pain	Patients using opioids or other controlled substances for chronic pain are entered on a registry or uniquely flagged for easy identification
5. Flowsheet for visits	Documentation of visits related to chronic pain is consistently charted on a flowsheet or other template that prompts providers for specific kinds of data collection
6. Pain management council	Providers meet to conduct a chart review of long term chronic pain opioid patients at regular meetings or on an as-needed basis
7. Update patient agreement	Patient agreement (contract) is updated to include the expected standard of care of the practice (e.g. the procedure for obtaining a refill prescription) and expected behavior of the patient (e.g. staying with only one prescriber and only one pharmacy)

2

STRATEGY 1

Consistent Approach across Practice

Providers agree on a standard process of opioid prescription management that all practice members can support through a common office practice philosophy and process. This strategy is based on a widely accepted understanding that the risks of opioid therapy are high and the likelihood of harm is great. A protocol consistently applied to all long term, non-palliative care patients with chronic pain in the practice will be easier to apply, manage, monitor, and maintain than protocols that vary by provider and patient. Whatever the practice agrees to (including strategies from this toolkit, their use in face-to-face visits, documentation of patient care, and monitoring of outcomes of care practices) is likely to result in:

- Smooth transitions when providers cross-cover for each other
- Less "doctor shopping" or "splitting" across the practice by patients
- Decisions made with the patient that are based on a standard of care, not on what the patient or provider assume is true about each other

This strategy has the benefit of helping the provider and patient maintain a relationship centered on trust rather than judgment. Being able to say "This is how we do it for everyone" reduces the need to defend whether the provider believes or has sufficient compassion for the patient.

ACTION STEPS

Review and confirm the practice's prescribing philosophy and the underlying expectations

Key points that are usually helpful to review:

- 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 aberrant behavior by the patient? For example, does the practice take a "zero tolerance" perspective or does it allow aberrant 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 will the care related to opioid management be documented?
- What about 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)?

Develop a written document that captures the key elements of the prescribing philosophy

Measure success

- Adherence to philosophy
- Provider and staff satisfaction

STRATEGY 2

Team Approach to Opioid Prescription Management

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.

ACTION STEPS

Review and update existing protocols and procedures related to opioid prescription management. These may include strategies selected from the toolkit, listed on page 13.

Identify the other strategies in this toolkit that the practice will implement, and develop appropriate protocols. (See "Team Approach to Opioid Prescription Management" sample protocol in Appendix E.)

Communicate and educate providers and staff on the tasks involved in carrying out the protocols and procedures.

Monitor how well providers and staff are able to complete the tasks as planned; get feedback from providers and staff.

Measure success

- Feedback on adherence to protocols and procedures across practice
- Phone calls related to policy decisions (e.g. phone calls for refills)
- Staff and provider satisfaction (develop a survey or add new questions to the post-project survey in Appendix F)

STRATEGY 3

Regular Visits for Chronic Pain Management

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. (Appendix A)

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.

ACTION STEPS

Create a unique type of visit for "Chronic Pain Management" within the scheduling or appointment management system.

Establish a practice expectation for how frequently 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:

- Adjustments in medications
- Early refills

2

STRATEGY 4

Roster of Patients with Chronic Pain

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 Vermont Prescription Monitoring System (VPMS) at least annually[A].

The current vendor for VPMS provides a method for searching an entire roster of patients at once through the "Bulk Patient Search" tab. This approach requires that the practice maintain a spreadsheet with name and date of birth. This can be uploaded to the system and reports on all listed patients is returned in one step, thereby saving the step of individual data entry. This step may be performed by a delegate. Reminder: this patient roster contains Protected Health Information (PHI) and must be maintained in an appropriately secure location.

ACTION STEPS

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 or through an electronic reporting system (e.g. patients with a billing code of 304.91 unspecified drug dependence, ICD-9-CM)
- Consider using tools associated with the practice's Electronic Medical Record system, if available (for example, an agreed upon diagnosis such as Chronic Pain Syndrome ICD-9-CM-338 flagged by a special status field)

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 (see Strategy 3), identification for random urine screens (see Strategy 14), 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

A. Vermont Prescription Monitoring Systems (VPMS) is the prescription data monitoring program (PDMP) of Vermont. This document refers to VPMS but providers in other states may apply this strategy to their own state's PDMP.

STRATEGY 5

Flowsheet for Visits Related to Chronic Pain

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 medical 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
- Vermont Prescription Monitoring System (VPMS)[B] result and date
- 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
- Red flag (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

ACTION STEPS

Design flowsheet or template based on the philosophy, protocols, and selected strategies chosen from this toolkit (see "Sample Electronic Flowsheet" in Appendix G)

Plan data entry roles: for example, who enters lab data or updates the 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

STRATEGY 6

Pain Management Council

The 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 red flag incidents 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.

ACTION STEPS

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

B. VPMS is the prescription data monitoring program (PDMP) of Vermont. This document refers to VPMS but providers in other states may apply this strategy to their own state's PDMP.

2

STRATEGY 7

Update Patient Agreement

The patient informed consent and treatment agreement (contract) is created or updated to include the expected standard of care of the practice (for example, the procedure for obtaining a refill prescription) and the expected behavior of the patient (for example, receiving pain medications from only one prescriber and only one pharmacy)[C]. Example agreements from several health care organizations are included in the appendix.

Under the July 2017 Rule, (Appendix A) patient education and a written consent form are required for patients receiving any opioid prescription, acute or chronic. The Vermont Department of Health has published a one-page patient education sheet entitled *Opioid Patient Information Sheet*.

ACTION STEPS

Determine the key policy expectations of the practice for its patients who use opioid therapy for chronic pain management

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 from other organizational members before finalizing the patient agreement.
- Expectations related to this topic are subject to change. Future updates to the patient agreement should be anticipated and considered annually.
- Note that some patients may have low levels of literacy. Keep the language simple, avoid jargon and acronyms, use large font, and make the layout uncrowded (lots of "white space").

Plan how to replace the old agreement with a new one, to be reviewed and signed by the patient. Consider documenting 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.

Plan how to provide a copy for the patient and how to retain a signed copy for the patient's medical record.

Consider whether to share completed agreements with other local health care agencies, 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

C. The Vermont Board of Medical Practice calls for patient agreement to document a shared decision based on risks, benefits, and the patient's responsibilities. A template for a patient agreement is provided by the Medical Practice Board in their Policy for the Use of Controlled Substances for the Treatment of Pain. See Appendix H.

Provider-Specific Strategies

Changes in the management of opioid prescriptions are sometimes more successful, and more rapid, if trialed by an individual provider. The following strategies all occur during the patient's encounter with the provider and are therefore applied at the discretion of the provider. While these strategies will have a greater impact on the practice if acted on by all prescribing providers, they will also be helpful if used by a single, individual provider.

PROVIDER-SPECIFIC STRATEGIES	DESCRIPTION
8. 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
9. Prescribing in multiples of 7 days	Prescribe medication dosages for periods that are multiples of 7 days (28 days, 56 days, 84 days…)
10. Pre-print prescriptions for future use	For a patient on a stable course of treatment with predictable refill intervals, pre-print multiple prescriptions for up to three months
11. Bubble pack prescriptions	Prescribe medications with dispensing instruction limited to secure packaging: bubble packs, bingo cards, tear off strips, etc.
12. Ongoing risk assessment	At regular intervals, and at least annually, conduct an assessment to evaluate the success of opioid treatment
13. Urine screens	Periodically, and at least annually, collect a urine sample from all opioid therapy patients to test for the presence/absence of controlled substances
14. Random urine screens	Randomly collect a urine sample from all opioid therapy patients at unpredictable intervals
15. Random pill counts	Randomly review pill containers or bubble packs to confirm the number of doses remaining in the prescription period
16. Vermont Prescription Monitoring System (VPMS) regular reporting[D]	At regular intervals, and at least annually, review the VPMS record for patient prescriptions
17. Check patient agreements regularly during visits	At regular intervals, and at least annually, review the patient agreement with the patient and confirm patient/provider compliance with the treatment plan

D. VPMS is the prescription data monitoring program (PDMP) of Vermont. This document refers to VPMS but providers in other states may apply this strategy to their own state's PDMP.

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STRATEGY 8

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[E]. These tools are brief and intended to be conducted by the provider during the medical exam. These 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 patient 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 M:

- 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

ACTION STEPS

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?

One provider trials the assessment with 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

Chart audit for an assessment prior to prescription of a new opioid treatment

E. The Vermont Board of Medical Practice calls for an appropriately detailed patient evaluation prior to the decision to prescribe opioids and an evaluation for depression and other mental health disorders.

STRATEGY 9

Prescribing in Multiples of 7 Days

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.

ACTION STEPS

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

Providers 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

STRATEGY 10

Pre-print Prescriptions for Future Use

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 Strategy 9). 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

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

ACTION STEPS

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

2

STRATEGY 11

Bubble Pack Prescriptions

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.

ACTION STEPS

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

STRATEGY 12

Ongoing Risk Assessment

At regular intervals, and at least annually, conduct an assessment to evaluate the success of opioid treatment. 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 behavior, and affect. Tools currently available for ongoing assessment and found in the appendix:

- COMM: Current Opioid Misuse Measure (17 questions to be completed by patient)
- 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)
- PEG: Pain, Enjoyment, and General Activity (3 questions asked by the clinician)
- Rapid 3 Routine Assessment of Patient Index Data

Related tools that are available on the Internet or through professional organizations:

- Patient Pain Management Journal
- Endocrine Monitoring
- Depression Screening

ACTION STEPS

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 (approximately 8)

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 prior to prescribing a new opioid treatment
- Chart audit to verify follow up of results in treatment plan

STRATEGY 13

Urine Screens

Periodically, and at least annually, collect a urine sample from all opioid therapy patients to test for the presence/absence of controlled substances[F]. 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.

ACTION STEPS

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 (see Strategy 14)

Issues to be prepared for:

- Interpretation of results will be affected by the specific detection windows for which substances are being screened
- Some practices report benefits of witnessed samples, in which the collection process is observed by clinical staff. However, some patients and staff may resist witnessed samples due to cultural boundaries or gender barriers.
- 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 the practice.
- Develop a protocol for following up on positive results claimed to be false by the patient
- Cost to the patient or the practice or overall health care system

Plan the logistics of collecting urine samples in the practice

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

Measure success

- Chart audits to confirm the presence of lab results
- Chart audits to confirm follow up in treatment plan for positive results

F. The Vermont Medical Practice Board calls for drug testing as frequently as necessary to ensure therapeutic adherence, preferably urine screening (point of care or laboratory-based) that includes sensitivity to the opioid prescribed. Testing should not be limited to provider perception of a problem; a "universal precautions" approach to all non-palliative care patients on long term opioid therapy for chronic pain is recommended.

STRATEGY 14

Random Urine Screens

Randomly collect a urine sample from all opioid therapy patients 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 completely honest about their medication usage.

ACTION STEPS

Determine type of random urine screening to adopt:

- Random testing at scheduled visits: during visits that have been scheduled for pain management or other purposes, conduct screening at unpredictable intervals.
- Random testing at on-demand visits: with no visit scheduled, randomly call patients to come in within a four or eight hour window after receiving the call.

Develop a plan for how to make decision to obtain a random sample.

- For scheduled visits, the decision can be dependent on any "red flags" 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 the Chronic Pain Roster (see Strategy 4) is used 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

Consider issues and logistics identified in Urine Screens – Strategy 13

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

2

STRATEGY 15

Random Pill Counts

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-Strategy 13 or Random Urine Screens-Strategy 14. 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 decision to conduct a random pill count.

- For scheduled visits, the decision can be dependent on any "red flags" 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 the Chronic Pain Roster (see Strategy 4) is used 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

STRATEGY 16

Vermont Prescription Monitoring System (VPMS) Regular Reporting

The July 2017 VPMS rule now 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: www.healthvermont.gov/adap/VPMS.aspx.

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 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

ACTION STEPS

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

Plan 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 tab as described in Strategy 4 (Roster of Patients with Chronic Pain) on page 20

Determine how the result will be documented in the patient's medical record and how to notify providers of unexpected results

Decide what to do with the VPMS reports, if printed. They may be kept as part of the physical or scanned record, but this is not recommended by the State of Vermont for reasons of information security.

Measure success
- Number of VPMS delegates identified, trained, and able to use the system
- Chart audit of VPMS results documented

STRATEGY 17

Check Patient Agreement Status During Visits at Regular Intervals

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

2

STEP 7: DESIGN THE NEW FLOW OF WORK

estimated: one hour

Based on the strategies selected and developed in Step 6, describe the future process of caring for a patient using opioids to manage chronic pain which represents the ideal care process. Then complete the following steps, documenting the results on white board or flip chart and in team members' reports:

1: Map the new flow of work, including all the selected strategies.

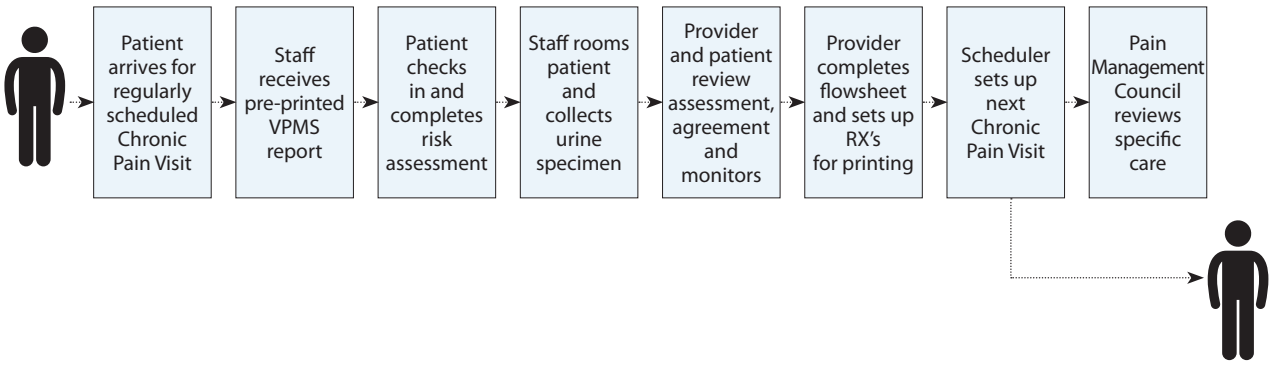
2: Map the steps to visually represent the path taken by the patient and her/his information. See the process from the patient's perspective.

3: Example Map (See diagram below)

4: Consider each of the following possible patient behaviors. If they concern the practice, develop a proposed plan if:

- Established patient disagrees with the new plan for managing opioid prescriptions
- 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
- 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"

5: Develop a protocol for responding to patient behavior for the practice to trial.



STEP 8: DRAFT IMPLEMENTATION PLAN

Strongly recommended – estimated: one hour

Using the new flow of work, list all the strategies selected in the left hand column of the team's Implementation Plan (see examples in Appendix O).

1. For each strategy selected, identify:
- Any additional information needed to use the strategy
- Any resources needed (people, funds, space) to use the strategy
- Provider or staff training (e.g. use of assessments; telephone scripts)
- The measures used to identify successful implementation
- The actions necessary to put the strategy in place
- A plan to communicate what will happen to those affected by these changes

2. List actions identified above next to each strategy in the Implementation Plan and complete with the name of the team member following up on this work and the date he/she will next update the team on progress.

3. Review again the results of the Practice Survey at Baseline for action steps needed for successful implementation in your practice.

4. Document progress for each strategy listed in the right hand column of the Implementation Plan. Add to this worksheet over time.

STEP 9: COMPLETION OF STAGE 2 – CHECK IN WITH PRACTICE LEADERS

The project team meets with the Practice Leaders and reviews, at a minimum, the results of Stage 2, Steps 6, 7, and 8:

Stage 2, Step 6. Review and select strategies: identify the strategies chosen for improving opioid prescription management

Stage 2, Step 7. Design the new flow of work: share the ideal patient care process including new tasks proposed for practice members

Stage 2, Step 8. Draft implementation plan: share the Implementation Plan, including information, resources, and training needed to put it into action

Finalize the Implementation Plan and plan for communication with practice members
(estimated: one hour)

3 Implementation

Stage 3: Implementation, Evaluation, and Closure

Project team and other practice members review the team's work and collaborate in putting some or all of the selected strategies in place. The time necessary to complete this stage depends on the amount of work identified in the Implementation Plan Worksheet, which can vary from one hour/strategy to two hours/strategy. (Changes involving Information Technology support may take longer depending on the software application.) The two steps in this stage are listed below, with more detail on following pages.

1. Implementation plan and measures
- Plan updates
- Progress measures
- Impact measure post-project
- Practice survey post-project
- Chart reviews

2. Evaluation and Closure
- Evaluation
- Closing report
- Long term monitoring
- Completion of Stage 3

STEP 1: IMPLEMENTATION PLAN AND MEASURES

1. Plan Updates: Team members meet separately or together to carry out the Implementation Plan. If meeting separately, the team also meets regularly (weekly or every other week) to update the Implementation Plan Worksheet with progress on and changes to the Implementation Plan.

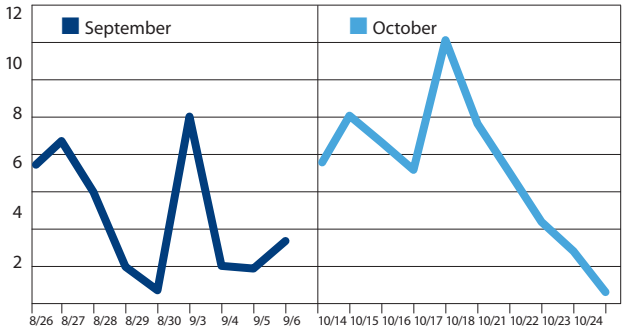
2. Progress Measures: Team members measure the progress for each of the strategies selected, as determined in Stage 2, Step 7 and documented in the Implementation Plan.

3. Impact Measure Post-Project: When the team members determine that implementation has been largely achieved, they measure the impact of their work using the same method of keeping a log or list of the occurrence of the same kinds of events measured before the project started. Select a two week period that is "normal" for the practice (no holidays, vacations, large number of unexpected absences such as illness, etc.). Keep a separate log for each kind of event tracked. Kinds of event logs:
- Front desk or prescription line phone calls received about opioid refills
- Provider interruptions due to questions about an opioid prescription
- Pharmacy phone calls or faxes about an opioid prescription

3

Add up the daily totals for each of the measures and plot the daily numbers on the graph previously created at the start of the project, lengthening the time axis (the horizontal, or "x" axis). Calculate the average daily count of each measure. Compare the daily numbers plotted and the average daily count to the previously collected data. Decide if the practice has experienced a change and, if so, whether it is a change that represents a success or identifies new issues to be addressed. Example:

Calls by Date: August/September & October 2013



4. Practice Survey Post-Project: Survey the entire practice using the same method with which the pre-project survey was conducted. Steps to follow:

- Use the same list of practice providers and staff developed for the previous survey.
- Distribute the survey, with instructions about the date it should be returned and where it should be sent.
- Average the responses for each statement.
- Compare these averages with those calculated for the same statements in the previous survey and review all comments. Decide if the practice has experienced a change and, if so, whether it is a change that represents a success or identifies new issues to be addressed.

5. Chart Reviews: Create a template for future chart reviews based on the strategies selected. Suggested items to collect:

- Pain medications
- Pain assessment and assessment scores
- Monitors based on strategies (for example, urine screen lab results, VPMS reports, and pill counts) and documentation of aberrant patient behavior

STEP 2: EVALUATION AND CLOSURE:

1. Evaluation: The team determines whether the project has achieved the objective identified in its charter or whether the team needs to change the implementation plan or any of the strategies selected. As needed, follow up with practice leaders. If complete, the team develops a recommendation for long term monitoring.

2. Closing Report: When the team has determined that the project is sufficiently complete to bring it to a close, it reviews the results of its work with Practice Leaders and provides recommendations for long term monitoring. Team members organize and submit the notes taken during team meetings to document their progress, measures, outcomes, and recommendations.

3. Long Term Monitoring: Practice leaders determine who in the practice should monitor opioid prescription management by identifying specific measures, an individual to organize data collection, frequency of data collection, and reporting expectations.

4. Completion of Stage 3: Practice leaders confirm the team's work and results. Practice leaders take responsibility for long term monitoring. Everybody celebrates – finishing a project, regardless of size or number of changes, is an accomplishment.

Appendices

A

Managing Opioids Safely and within Vermont Rules

SUMMARY FOR PRIMARY CARE PROVIDERS

Recommend Non-Opioid and Non-Pharmacological Treatment

- Nonsteroidal anti-inflammatory drugs (NSAIDs) and/or acetaminophen
- Acupuncture
- Chiropractic
- Physical therapy

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 the Vermont Prescription Monitoring System (VPMS)*

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, risks 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
- VDH education resources: www.healthvermont.gov/alcohol-drugs/professionals/resources-patients-and-providers
- CDC education resources: 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 for 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, vtmd.org/cme-courses, or check with your professional society for available courses.

** Prescriber registration with the VPMS is mandatory. For the complete rules, visit the Vermont Prescription Monitoring System Rule (7/1/17) and Rule Governing the Prescribing of Opioids for Pain (7/1/17) found at www.healthvermont.gov. CDC Guidelines: Dowell D, et al. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. JAMA. 2016 Apr 19;315(15):1624-45. PMID: 26977696*

Prescribe the Lowest Effective Dose of Immediate-release Opioids

- For acute pain, prescribe 0-5 days of therapy. *See table below.*
- 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
- VPMS query
- VDH Patient Education handout provided
- 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
- Patient discussion about the risk of overdose, including any precautions the patient should take
- *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

Opioid Prescription Limits for Acute Pain (Prescribe Immediate-Release Formulations)

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	**Average Daily**	**Total RX**
MINOR PAIN Examples: Sprains, headaches, dental pain	No opioids	No opioids
MODERATE PAIN Examples: Non-compounded bone fractures, soft tissue surgery, most outpatient laparoscopic surgery		
Hydrocodone 5mg	MME: 24/0-4 tablets	0-5 days/0-20 tablets
Oxycodone 5mg	MME: 24/0-3 tablets	0-5 days/0-15 tablets
SEVERE PAIN Examples: Non-laparoscopic surgery, joint replacement, compound fractures		
Hydrocodone 5mg	MME: 32/0-6 tablets	0-5 days/0-30 tablets
Oxycodone 5mg	MME: 32/0-4 tablets	0-5 days/0-20 tablets

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. Prescribing outside of this table (i.e. exceptions) must be clearly documented. For the complete rules, visit the Rule Governing the Prescribing of Opioids for Pain (7/1/17) found at www.healthvermont.gov. CDC Guidelines: Dowell D, et al. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. JAMA. 2016 Apr 19;315(15):1624-45. PMID: 26977696

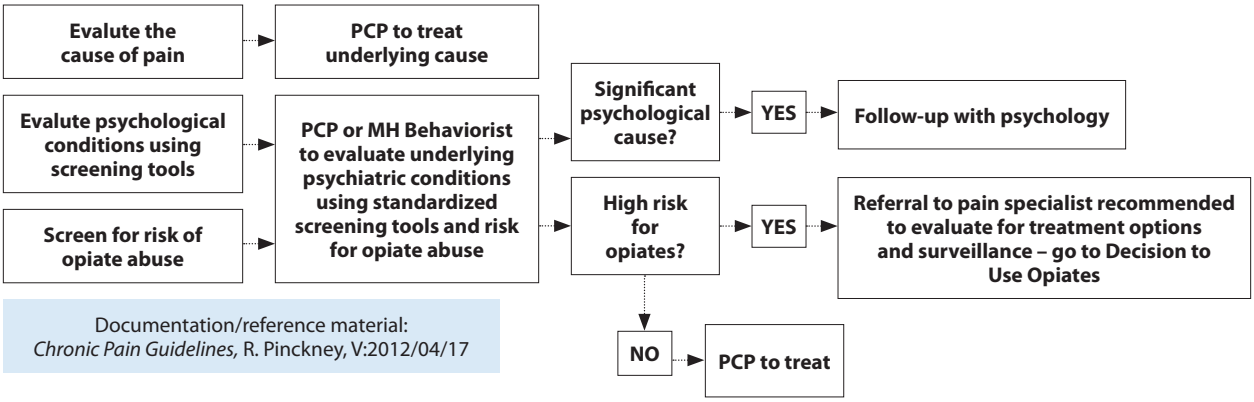
Created by the Vermont Academic Detailing Program, a program of the UVM Larner College of Medicine Office of Primary Care

A

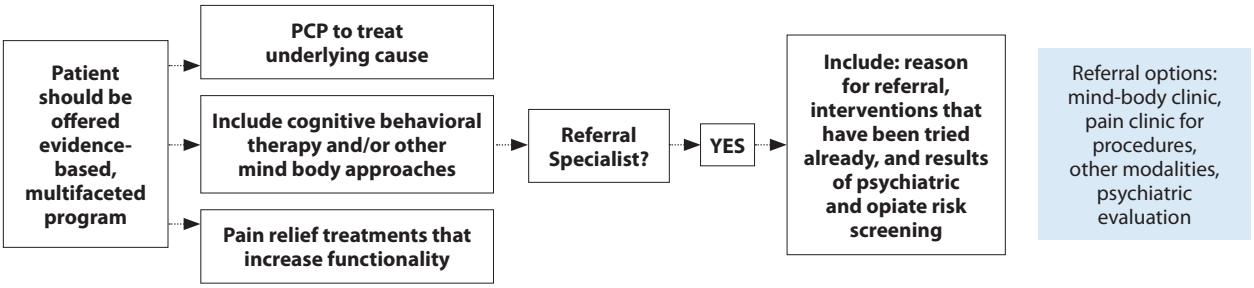
APPENDIX A

Guidelines for Use of Opiates in Chronic Pain

INITIAL EVALUATION



TREATMENT GENERAL

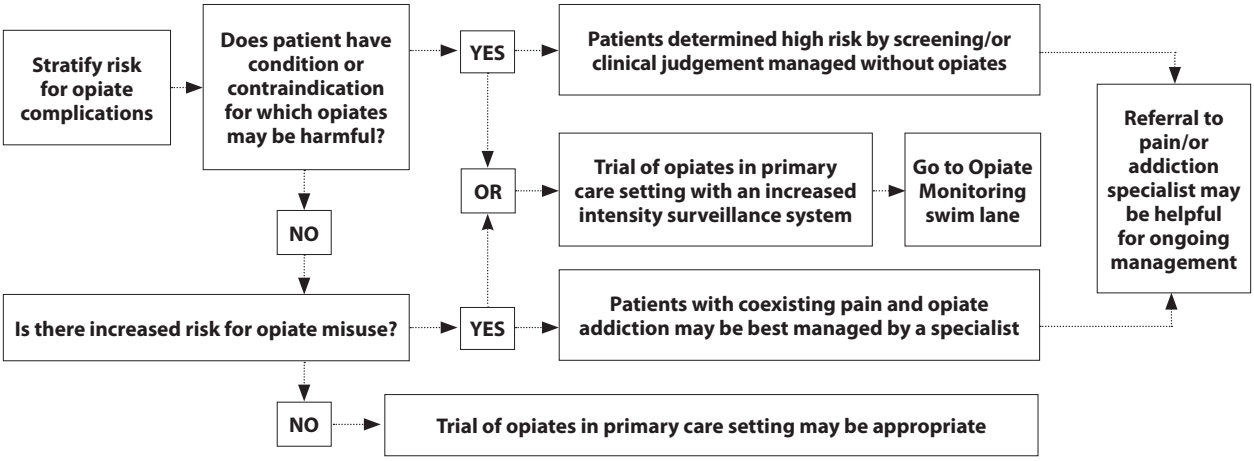


DECISION TO USE OPIATES

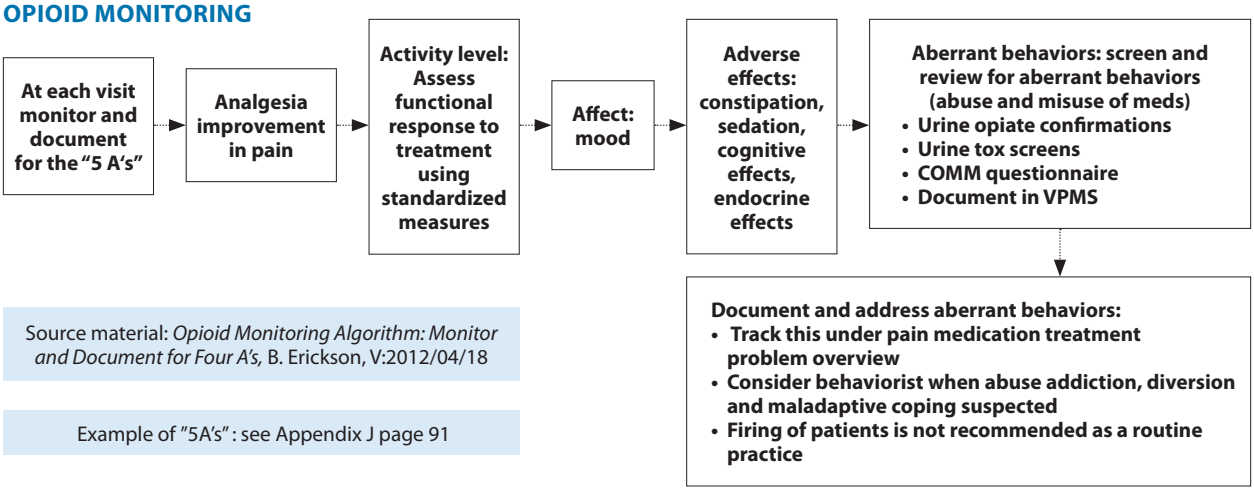
Examples of conditions for which opiates may be harmful: Migraine headache, Fibromyalgia, Sleep Apnea, Diazepam Rx

Examples of conditions for which opiates may be partially harmful: sprain, chronic non-specific low back pain, rotator cuff, tendonitis, myofascial neck pain

Examples of conditions for which opiates are not likely to be harmful



OPIOID MONITORING

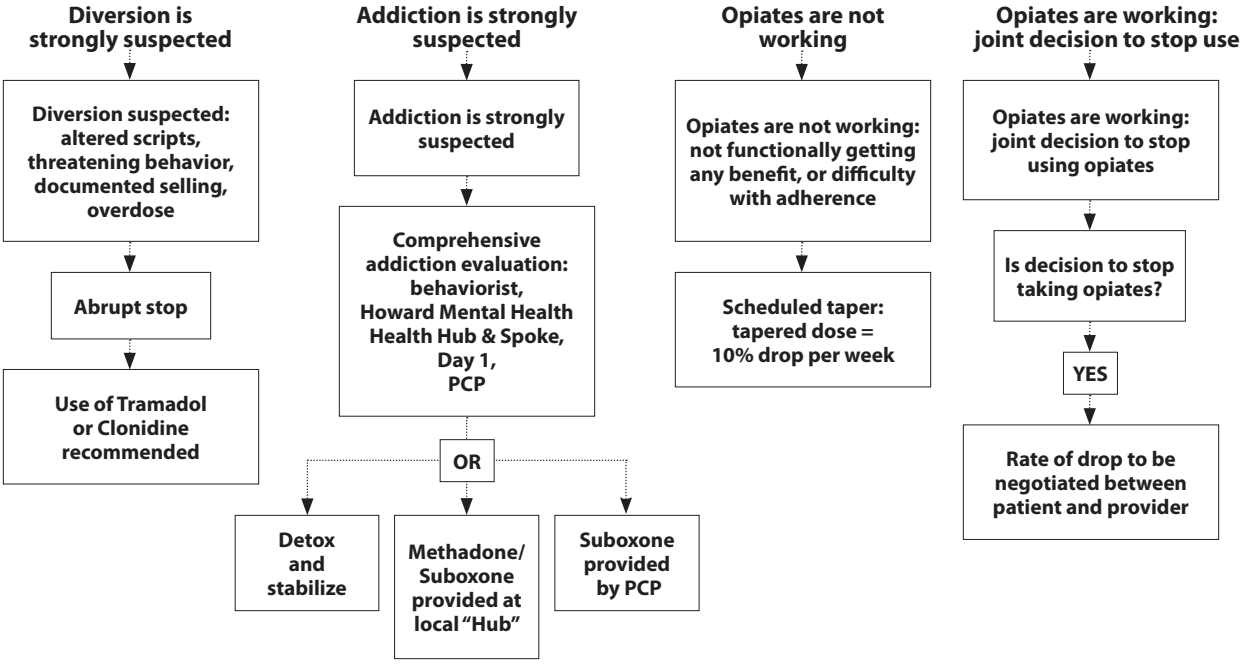


Source material: *Opioid Monitoring Algorithm: Monitor and Document for Four A's,* B. Erickson, V:2012/04/18

Example of "5A's": see Appendix J page 91

Narcotic Prescribing: Tapering Opiates

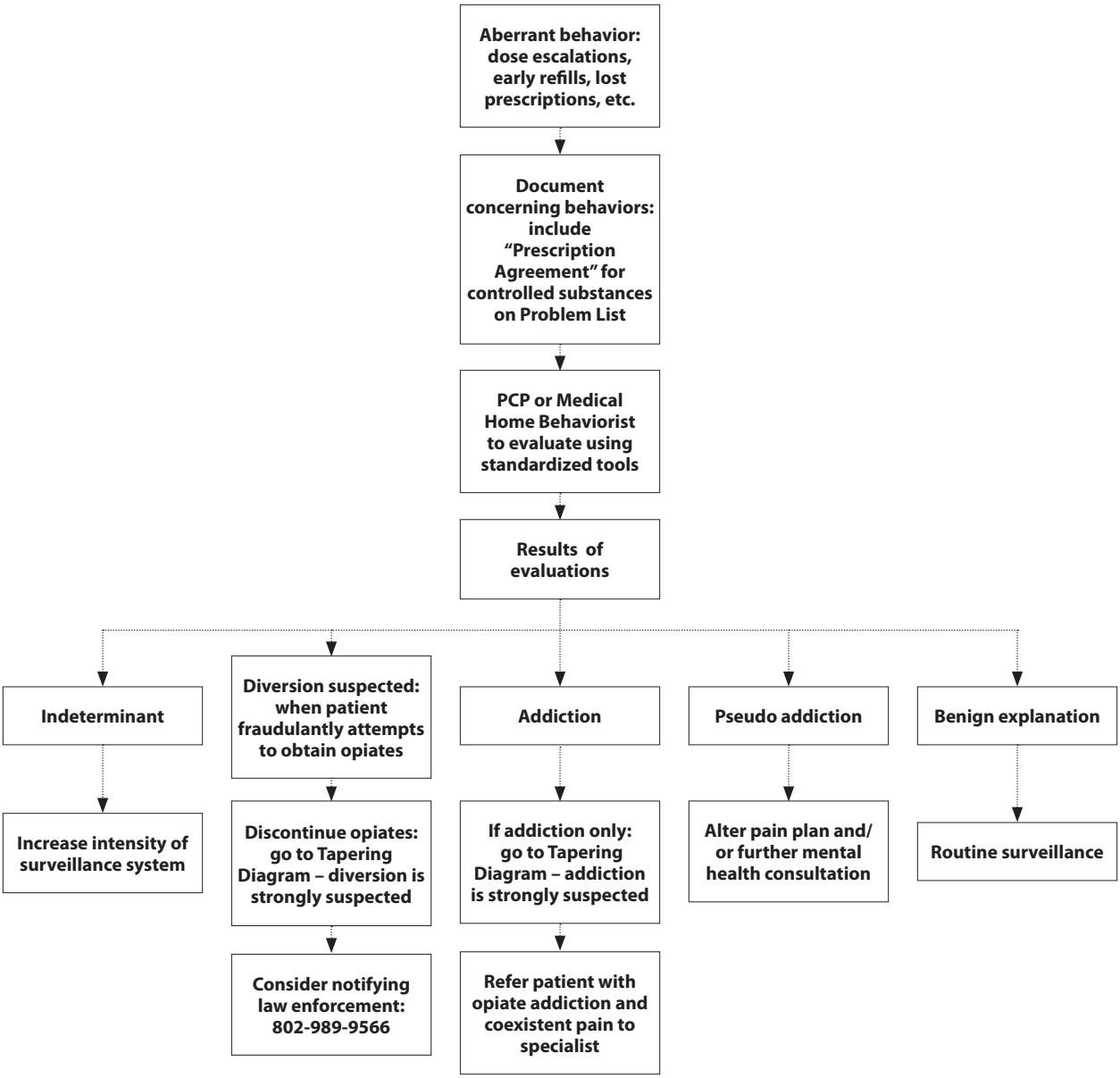
CATEGORIES OF PATIENTS



Additional detox and stabilize resources: Brattleboro Retreat, Howard Mental Health Hub & Spoke, Day 1

APPENDIX A

Narcotic Prescribing: Aberrant Behaviors



Documentation by K. McKnight: Narcotics Prescribing_2012_08

APPENDIX B: Opioid Prescription Management Readiness for Change Assessment

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.*

Check one answer in response to each statement below:

	strongly agree				strongly disagree
1. Our practice's community has a drug abuse/mismanagement problem.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. Our providers and staff often feel burdened by efforts to help patients with chronic pain needs.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. Our providers and staff are willing to use a structured process to plan and make changes to the way we manage prescriptions for chronic pain.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
4. Our practice is able to give at least two providers and two staff time off from regular duties for about 8 hours of team meetings to plan changes.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. We have a provider leader who can share information with other providers and champion the results of a team that works on this.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. We are able to avoid being distracted or overwhelmed by competing demands (such as other big projects) or financial concerns.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
7. The people I work with want to implement changes in how we manage prescriptions for chronic pain.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. The people I work with feel confident that they can handle the challenges of implementing changes in how we manage prescriptions for chronic pain.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
9. The people I work with feel confident that they can keep track of progress in implementing changes in how we manage prescriptions for chronic pain.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. I personally think that changing the way prescriptions for chronic pain are managed in our practice is the right thing to do now.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Please add any ideas or suggestions you have about how we can improve the way we help patients with prescriptions for chronic pain:

Pre-project Practice Survey

Instructions: *Check one answer in response to each statement below.*
All rating scales below are the same: from 1 (strongly disagree) to 5 (strongly agree).
You do not need to put your name on this survey.

	strongly disagree				strongly agree
1. Our office has clear and well-organized policies and approaches to prescribing and managing chronic opioids.	☐1	☐2	☐3	☐4	☐5
2. The providers are satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
3. The staff are satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
4. The patients are satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
5. I am satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
6. Our practice leaders are committed to improving how opioid prescriptions are managed in our practice.	☐1	☐2	☐3	☐4	☐5
7. Our practice leaders are able to implement changes in how opioid prescriptions are managed.	☐1	☐2	☐3	☐4	☐5
8. A project to improve how we manage opioid prescriptions is a good fit for the values of our practice.	☐1	☐2	☐3	☐4	☐5
9. Our practice can support the time needed for ten hours of team meetings involving at least one provider and two staff to work on an opioid prescriptions project.	☐1	☐2	☐3	☐4	☐5
10. When we do a project, we usually have a "champion" to share information and help solve problems.	☐1	☐2	☐3	☐4	☐5
11. When we do a project, our practice usually provides the financial resources to carry it out.	☐1	☐2	☐3	☐4	☐5
12. Our practice cares about conducting projects so that we improve the quality of care.	☐1	☐2	☐3	☐4	☐5
13. During a project, there is usually good communication about what the team is working on and what it is planning.	☐1	☐2	☐3	☐4	☐5
14. After a project is complete, any changes to our work are usually explained in advance of being carried out.	☐1	☐2	☐3	☐4	☐5
15. Our projects usually do not increase the amount of work we do in the practice, but usually reduce or maintain the amount of work we do in the practice.	☐1	☐2	☐3	☐4	☐5
16. After a project is complete, we take the time to think about how it worked.	☐1	☐2	☐3	☐4	☐5

Please give us your thoughts in response to the following questions, using the back for additional space:

17. What improvements could be made in the way opioids are handled in your office?

_____

18. Any other comments or questions?_____

_____

APPENDIX D: Sample Agendas for Team Meetings

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 1
AGENDA

PARTICIPANTS NAMES

1. Introductions (as needed)

2. Purpose of this Quality Improvement (QI) Project
   - Generally: opioid management to prevent diversion and misuse
   - Specifically: (example from practice: improve monitoring for patients with high dose opioids)

3. The QI Process (how the project works)
   Who is involved
   - Practice members
   - Non-practice members

   How long it will take
   - Sources of data, especially, EMR
   - Survey for all providers and staff – emails or paper surveys

4. Background

5. Current State

6. Next steps
   - Email addresses for practice members
   - Communication: who needs to know what and when?
   - Next meeting:

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 2
AGENDA

PARTICIPANTS NAMES

TOPIC	LEADER	TIME
1. Start Up:		
Re-Introductions for new team members	Leader	5 min
Questions since last meeting?	Facilitator	5 min
2. Review: Issue and Background Conversation with one or two patients from the practice who use or have used opioids for chronic pain management. This is a listening and learning exercise, not a time for team talking. Questions that may be used to prompt patient conversation: 1. How long have you been coming to the practice (ice-breaker question) 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? 3. We are worried that some of our prescriptions are misued by other patients in our practice. Do you have any advice for us?	Facilitator	5 min
3. Current State and Measures	Group	30 min
4. Problem Identification	Group	15 min
5. Plan for Next Meeting:	Facilitator	5 min
6. Adjourn	Leader	

Thank you!

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 3
AGENDA

PARTICIPANTS NAMES

TOPIC	LEADER	TIME
1. Start Up:	Leader	5 min
2. Review Current State and Measures	Group	5 min
3. Problem Identification	Group	15 min
4. Best Practice Strategies	Facilitator	20 min
5. Plan for Next Step Follow up steps Next Meeting:	Facilitator	5 min
6. Adjourn	Leader	

Thank you!

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 4
AGENDA

PARTICIPANTS NAMES

TOPIC	LEADER	TIME
1. Start Up	Leader	5 min
2. Review Problem Identification	Group	5 min
3. Discuss Best Practice Strategies	Group	30 min
4. Opportunities & Future State	Group	15 min
5. Plan for Next Step	Facilitator	5 min
6. Measures		
7. Next meeting:		
6. Adjourn	Leader	

Thank you!

APPENDIX D: Sample Agendas for Team Meetings

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 5
AGENDA

PARTICIPANTS NAMES

TOPIC	LEADER	TIME
1. Start Up	Leader	5 min
2. Review Opportunities	Facilitator	5 min
3. Develop Future State	Group	20 min
4. Measures	Group	10 min
5. Implementation Plan	Group	10 min
6. Next Steps • Measures • Next meeting:	Facilitator	5 min
7. Adjourn	Leader	

Thank you!

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 6
AGENDA

PARTICIPANTS NAMES

TOPIC	LEADER	TIME
1. Start Up	Leader	5 min
2. Review and Complete Future State	Facilitator	15 min
4. Measures	Group	10 min
5. Implementation Plan	Group	10 min
6. Next Steps • What if scenarios • Next meeting:	Facilitator	5 min
7. Adjourn	Leader	

Thank you!

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 7
AGENDA

PARTICIPANTS NAMES

TOPIC	LEADER	TIME
1. Start Up	Leader	5 min
2. Review Future State	Facilitator	5 min
3. Update Implementation Plan • How will you know if the plan is successful?	Group	30 min
4. Final Review of Strategies • Add to Implementation Plan • What If Scenarios	Facilitator	15 min
5. Next Steps • Future meetings • Plan for follow up survey	Facilitator	5 min
7. Adjourn	Leader	

Thank you!

NAME OF PRACTICE

DATE TIME

Opioid Prescription Management QI Planning Session 8
AGENDA

PARTICIPANTS NAMES

TOPIC	LEADER	TIME
1. Start Up	Leader	5 min
2. Update Implementation Plan	Facilitator	20 min
3. Measures • Plan for follow up survey?	Group	10 min
4. Additional Issues	Facilitator	20 min
5. Next Steps • Future meetings? • Plan for follow up survey – when?	Facilitator	5 min
6. Adjourn	Leader	

Thank you!

Team Approach to Opioid Prescription Management
(Strategy 2)

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 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

Contracts will only be updated for patients who are scheduled for a Chronic Pain visit, not an acute unrelated issue.

Nurse A will also put into action the Rx prior authorization preparation process.

Provider will review the VPMS patient list and determine who will need a urine sample.

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:
   - 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

Post-Project Practice Survey

Instructions: *Check one answer in response to each statement below.*
All rating scales below are the same: from 1 (strongly disagree) to 5 (strongly agree).
You do not need to put your name on this survey.

	strongly disagree				strongly agree
1. Our office has clear and well-organized policies and approaches to prescribing and managing chronic opioids.	☐1	☐2	☐3	☐4	☐5
2. The providers are satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
3. The staff are satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
4. The patients are satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
5. I am satisfied with the system for prescribing opioids in our office.	☐1	☐2	☐3	☐4	☐5
6. Our practice leaders were committed to improving how opioid prescriptions are managed in our practice.	☐1	☐2	☐3	☐4	☐5
7. Our practice leaders were able to implement changes in how opioid prescriptions are managed.	☐1	☐2	☐3	☐4	☐5
8. The project to improve how we manage opioid prescriptions was a good fit for the values of our practice.	☐1	☐2	☐3	☐4	☐5
9. Our practice was able to support the time needed for ten hours of team meetings involving at least one provider and two staff to work on an opioid prescriptions project.	☐1	☐2	☐3	☐4	☐5
10. The opioid project had a "champion" to share information and help solve problems.	☐1	☐2	☐3	☐4	☐5
11. Our practice provided the financial resources to carry out the opioid project.	☐1	☐2	☐3	☐4	☐5
12. Our practice cares about conducting projects so that they improve the quality of care.	☐1	☐2	☐3	☐4	☐5
13. During the opioid project, there was usually good communication about what the team was working on and what it was planning.	☐1	☐2	☐3	☐4	☐5
14. After the opioid project was complete, any changes to our work were explained in advance of being carried out.	☐1	☐2	☐3	☐4	☐5
15. The opioid projects did not increase the amount of work we do in the practice, but reduced or maintained the amount of work we do in the practice.	☐1	☐2	☐3	☐4	☐5
16. After the project was complete, we took the time to think about how it worked.	☐1	☐2	☐3	☐4	☐5

Please give us your thoughts in response to the following questions, using the back for additional space.

17. What improvements could be made in the way opioids are handled in your office?

_____

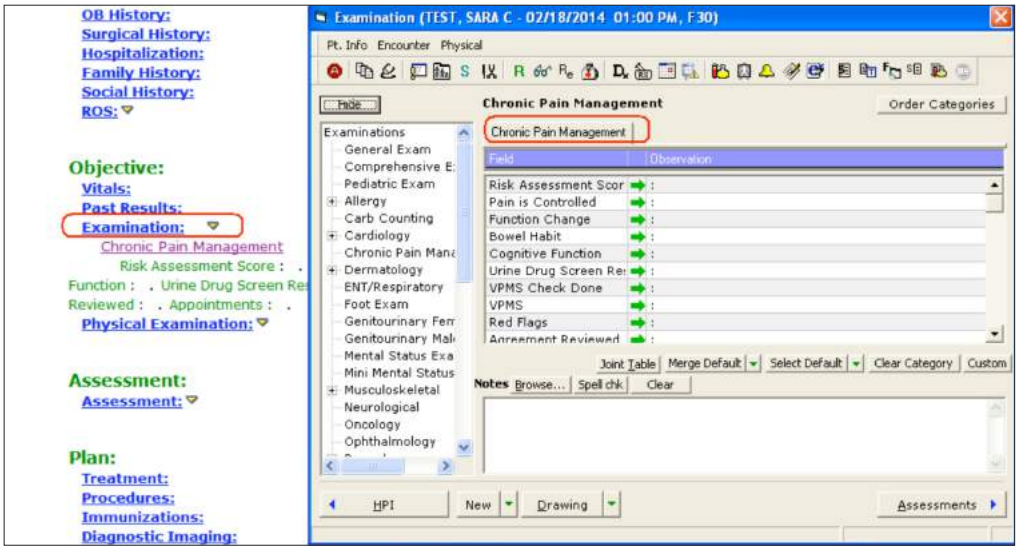
18. Any other comments or questions?_____

_____

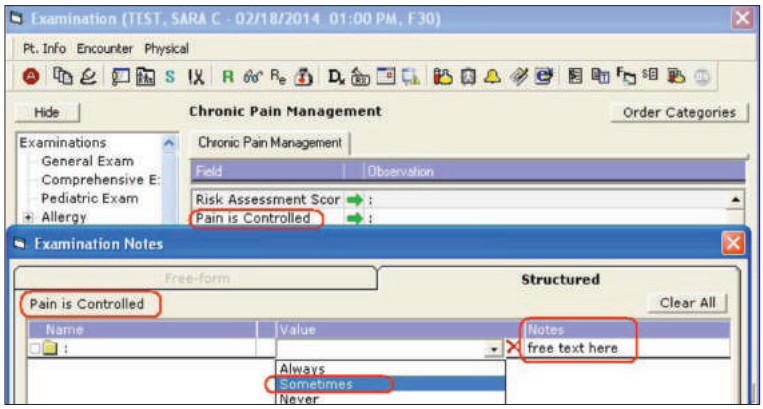
_____

Chronic Pain Management Template

When the "Chronic Pain Management" template is used, a section specifically titled Chronic Pain Management populates in the Examination section in the progress note. This section has a list of questions to answer.



Each question has a drop down box of possible "structured" answers (reports can be run on structured fields). There is also the option to free text an answer as well, but no reports can be done for these fields. To the right is an example of the "Pain is Controlled" question:



This is what it looks like in the note, with the questions answered:

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.

The 2013 FSMB Model Policy reflects the considerable body of research and experience accrued since the 2004 revision was adopted[2]. Significantly, in the introduction to the Model Policy, FSMB recognized that there is a lack of evidence as to the effectiveness and safety of long-term opioid therapy. Despite that lack of evidence, opioids are widely used to treat chronic pain, and FSMB's intent in creating a Model Policy was to promote the public health by encouraging state medical boards to adopt consistent policy regarding the treatment of pain, particularly chronic pain, and to promote patient access to appropriate pain management and, if indicated, substance abuse and addiction treatment. The Model Policy emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate. It also includes references and the definitions of key terms used in pain management. Much of FSMB's work has been incorporated into our Vermont Policy.

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[8-10]. 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[4]. Pain arises from multiple causes and often is categorized as either acute pain (such as that from 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)[4,8]. 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[4,9]. 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[6,10-11].

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[4,8,12]. 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[3]. 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[3-4,12,14-20]. 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[21-22]. 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 [15]). 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[19-23].

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 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 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 passed at the meeting held on April 2, 2014.

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

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[4,8,26].

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[20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain[8,10,12,14,26-41, 80].

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[4,16]. 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[3,12,19]. Whenever federal laws and regulations differ from those of Vermont, the more stringent rule is the one that should be followed[42].

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[7,38,43]. There should be documentation of appropriate referrals as necessary[36-37].

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[14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below)[33].

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 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 analgesic[7] and reflect an appropriately detailed patient evaluation[38]. 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.

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?[14].

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[11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics[56-58]. 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[31]. 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[11,31,45]. Therefore, patients with a history of

[1] It is a recognized goal for the future that states cooperate on interstate and regional basis to share Prescription Monitoring Program information. If and when that occurs, the expectation for use of VPMS will be expanded to include use of available information from other states.

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[31] 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 on how to qualify to prescribe buprenorphine may be found on the U.S. Substance Abuse and Mental Health Services website: http://buprenorphine.samhsa.gov/waiver_qualifications.html.

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[54-55].

If possible, the patient evaluation should include information from family members and/or significant others[22-23,49-50]. 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[34].

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[21-23]. 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[21-23].

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[4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the 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[38]. 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[14,36,47]. 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[21-23,45].

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 [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications[3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is highly recommended[21-23,35,38]. 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) of the medication, such as constipation and cognitive impairment
- 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[35-37] 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

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

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 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[51]. 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[29] 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

[2] The full text of the law enacting the statutory requirements is in Act 75 of the 2013 session of the General Assembly, available online at: www.leg.state.vt.us/DO2014CS//ACTS/ACT075.PDF.

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 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[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[29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment[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[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[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[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[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 chromotography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites[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[54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed[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[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"[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[53].

Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize 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 prescribers[21-23,55,62].

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 employed[35-37,62-63]. 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 physician[19,21-23,32,35]. 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 behaviors[23].

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 others[62-63]. 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 plan[64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response[3] [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 death[23,65-67]. 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 needed[37-38]. 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 available[31,66].

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 needed[23,31,37,39].

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 appropriate[46].

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 use[22-23].

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence

[3] 18 V.S.A. 4223 addresses criminal fraud or deceit in obtaining or attempting to obtain a regulated drug and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) at 45 C.F.R. § 164.512(f)(5) permits disclosure of health information when a crime has occurred at a medical facility. Licensees should check with their organizations or legal counsel for guidance as to what constitutes a good faith belief that there is evidence of criminal conduct.

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[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[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[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[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[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[25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed[23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review[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[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[25]. Physicians licensed by the Board who 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 behaviors[22-23]. 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 harm[29]. 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 prescribed[28].

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 harm"[28].

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 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 Organization[70], and the Diagnostic and Statistical Manual (DSM) of the American Psychiatric Association[71]. 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 ratings[69].

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 addiction[71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution[73-74]. 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 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"[75], 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 system[17,19,74].

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)[4]. 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 common 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].

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 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[38]:

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[41], 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[38].

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

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APPENDIX H: Vermont Board of Medical Practice

Federation of State Medical Boards (FSMB) Work Group on the Appropriate Use of Opioid Analgesics in the Treatment of Chronic Pain

Chair
Janelle Rhyne, M.D.
Immediate Past Board Chair
Federation of State Medical Boards
Cape Fear Health Net Clinic
Wilmington, North Carolina

Medical Board Representatives
Alfred (Al) Anderson, M.D.
Member, Minnesota Board of Medicine
Medical Pain Management Ltd.
St. Louis Park, Minnesota

J. Daniel Gifford, M.D.
Member, Alabama Board of Medicine
Nephrology of North Alabama
Decatur, Alabama

William L. Harp, M.D.
Executive Director
Virginia Board of Medicine
Richmond, Virginia

Lynn S. Hart
Executive Director
New Mexico Medical Board
Santa Fe, New Mexico

Stancel M. Riley, M.D.
Executive Director
Massachusetts Board of Registration in Medicine
Wakefield, Massachusetts

Joel B. Rose, D.O.
Member, Florida Board of Osteopathic Medicine
Tampa, Florida

Dana Shaffer, D.O.
Member, Iowa Board of Medicine
Exira, Iowa

C. Michael Sheppa, M.D.
Associate Medical Director
North Carolina Medical Board
Chapel Hill, North Carolina

Rosaire Verna, M.D.
Member, Maryland Board of Physicians
Easton, Maryland

Invited Experts
James W. Finch, M.D.
Director of Physician Education
Governor's Institute on Alcohol and Drug Abuse, and
Medical Director, Changes by Choice, Inc.
Durham, North Carolina

Howard Heit, M.D., FACP, FASAM
Chronic Pain and Addiction Specialist and Assistant Clinical Professor
Georgetown University School of Medicine
Arlington, Virginia

Margaret M. Kotz, D.O., FASAM
Professor of of Psychiatry & Anesthesiology
Case Western Reserve University School of Medicine, and
Director, Addiction Recovery Services
University Hospitals of Cleveland
Cleveland, Ohio

Federal Agency Representatives
H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM
Director, Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockville, Maryland

Cathy A. Gallagher
Office of Diversion Control
Drug Enforcement Administration
U.S. Department of Justice
Arlington, Virginia

Sharon Hertz, M.D.
Deputy Director
Division of Anesthesia, Analgesia, and Rheumatology Products
Food and Drug Administration
Silver Spring, Maryland

Christopher M. Jones, Pharm.D., M.P.H.
LCDR, U.S. Public Health Service
National Center for Injury Prevention & Control Centers for
Disease Control and Prevention
Atlanta, Georgia

Regina LaBelle
Deputy Chief of Staff for Policy
Office of National Drug Control Policy
Executive Office of the President, The White House
Washington, DC

Robert A. Lubran, M.S., M.P.A.
Director, Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockville, Maryland

Sandrine Pirard, M.D., Ph.D., M.P.H.
Medical Advisor, Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockville, Maryland

Nicholas Reuter, M.P.H.
Team Leader, Certification and Waiver Team
Division of Pharmacologic Therapies
Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockville, Maryland

Alina Salvatore, R.Ph., M.A.
Public Health Advisor, Division of Pharmacologic Therapies Center for Substance Abuse Treatment
Substance Abuse and Mental Health Services Administration
Rockville, Maryland

Project Staff: FSMB
Lis A. Robin
Chief Advocacy Officer
Federation of State Medical Boards
Washington, DC

Project Staff: JBS International
Bonnie B. Wilford, M.S.
Director, Center for Health Services & Outcomes Research, and Senior Principal, JBS International, Inc.
North Bethesda, Maryland

Field Reviewers
Daniel P. Alford, M.D., M.P.H.
Associate Professor of Medicine
Boston University School of Medicine, and
Medical Director, MASBIRT Program
Boston Medical Center
Boston, Massachusetts

James Cleary, M.D.
Director, Pain & Policy Studies Group/WHO
Carbone Cancer Center
University of Wisconsin
Madison, Wisconsin

Edward C. Covington, M.D.
Director, Neurological Center for Pain
Neurological Institute
The Cleveland Clinic Foundation
Cleveland, Ohio

Chinazo O. Cunningham, M.D., M.S.
(for the Association for Medical Education and Research in Substance Abuse: AMERSA)
Associate Professor
Department of Family and Social Medicine
Albert Einstein College of Medicine and Montefiore Medical Center
Bronx, New York

Michael H. Gendel, M.D.
(for the American Academy of Addiction Psychiatry: AAAP)
Private Practice of Psychiatry
Denver, Colorado

Aaron Gilson, Ph.D.
Senior Scientist, Pain & Policy Studies Group/WHO
University of Wisconsin
Carbone Cancer Center
Madison, Wisconsin

J. Harry Isaacson, M.D.
(for the Coalition on Physician Education in Substance Use Disorders: COPE)
Associate Professor of Medicine and
Director of Clinical Education
Department of General Internal Medicine
The Cleveland Clinic Lerner College of Medicine
Cleveland, Ohio

Judith A. Martin, M.D.
(for the California Society of Addiction Medicine: CSAM)
Deputy Medical Director, Community Behavioral Health Services, and Medical Director of Substance Abuse Services
Department of Public Health
City and County of San Francisco, California

Jennifer McNeely, M.D., M.S.
(for the Society of General Internal Medicine Substance Abuse Interest Group: SGIM)
Division of General Internal Medicine
New York University School of Medicine
New York, New York

William Morrone, D.O., M.S.
(for the American Osteopathic Academy of Addiction Medicine: AOAAM)
Department of Family Medicine
Central Michigan University
Saginaw, Michigan

Darius A. Rastegar, M.D.
(for the Society of General Internal Medicine Substance Abuse Interest Group: SGIM)
Associate Professor of Medicine
Johns Hopkins University School of Medicine
Baltimore, Maryland

John D. Patz, D.O., FAAFP, FASAM, ABAM
(for the American Academy of Osteopathic Addiction Medicine: AOAAM)
Behavioral Health Unit
PRMC Everett
Everett, Washington

John A. Renner, Jr., M.D.
(for the American Psychiatric Association: APA)
Associate Professor of Psychiatry
Boston University School of Medicine
Boston, Massachusetts

Richard N. Rosenthal, M.D.
(for the American Academy of Addiction Psychiatry: AAAP)
Arthur J. Antenucci Professor of Clinical Psychiatry, and Chairman, Department of Psychiatry St. Luke's Roosevelt Hospital Center, and Senior Associate Dean for the St. Luke's Roosevelt Hospital Affiliation
New York, New York

Andrew J. Saxon, M.D.
(for the American Psychiatric Association: APA)
Department of Psychiatry
University of Washington Puget Sound
Seattle, Washington

APPENDIX H: Vermont Board of Medical Practice

Joanna L. Starrels, M.D., M.S.
(for the Association for Medical Education and Research in Substance Abuse: AMERSA)
Division of General Internal Medicine
Albert Einstein College of Medicine and Montefiore Medical Center
Bronx, New York

Jeanette Tetrault, M.D.
(for the Society of General Internal Medicine Substance Abuse Interest Group: SGIM)
Department of Internal Medicine
Yale University School of Medicine
New Haven, Connecticut

Alexander Walley, M.D., M.Sc.
(for the Society of General Internal Medicine Substance Abuse Interest Group: SGIM)
Assistant Professor of Medicine
Boston University School of Medicine, and Medical Director,
Opioid Treatment Program
Boston Public Health Commission, and Medical Director,
Opioid Overdose Prevention Program
Massachusetts Department of Public Health
Boston, Massachusetts

Norman Wetterau, M.D., FASAM
(for the Society of Teachers of Family Medicine: STFM)
University of Rochester/Highland Hospital,
and Tricounty Family Medicine
Nunda, New York

Agreement for Opioid Maintenance Therapy for Non-cancer/Cancer Pain

The purpose of this agreement is to give you information about the medications you will be taking for pain management and to assure that you and your physician comply with all state and federal regulations concerning the prescribing of controlled substances. A trial of opioid therapy can be considered for moderate to severe pain with the intent of reducing pain and increasing function. The physician's goal is for you to have the best quality of life possible given the reality of your clinical condition. The success of treatment depends on mutual trust and honesty in the physician/patient relationship and full agreement and understanding of the risks and benefits of using opioids to treat pain.

1. **You should use one** physician to prescribe and monitor all opioid medications and adjunctive analgesics.

2. **You should use one** pharmacy to obtain all opioid prescriptions and adjunctive analgesics prescribed by your physician.

   _____
   Pharmacy

   _____
   Telephone Number

3. You should inform your physician of all medications you are taking, including herbal remedies, since opioid medications can interact with over-the-counter medications and other prescribed medications, especially cough syrup that contains alcohol, codeine or hydrocodone.

4. You will be seen on a regular basis and given prescriptions for enough medication to last from appointment to appointment, plus usually two to three days extra. This extra medication is **not** to be used without the explicit permission of the prescribing physician unless an emergency requires your appointment to be deferred one or two days.

5. Prescriptions for pain medicine or any other prescriptions will be done only during an office visit or during regular office hours. **No** refills of any medications will be done during the evening or on weekends.

6. You must bring back all opioid medications and adjunctive medications prescribed by your physician in the original bottles.

7. You are responsible for keeping your pain medication in a safe and secure place, such as a locked cabinet or safe. You are expected to protect your medications from loss or theft. Stolen medications should be reported to the police and to your physician immediately. If your medications are lost, misplaced or stolen, your physician may choose not to replace the medications or to taper and discontinue the medications.

8. You may not give or sell your medications to any other person under any circumstances. If you do, you may endanger that person's health. It is also against the law.

9. Any evidence of drug hoarding, acquisition of any opioid medication or adjunctive analgesia from other physicians (which includes emergency rooms), uncontrolled dose escalation or reduction, loss of prescriptions, or failure to follow the agreement may result in termination of the doctor/patient relationship.

10. You will communicate fully to your physician to the best of your ability at the initial and all follow-up visits your pain level and functional activity along with any side effects of the medications. This information allows your physician to adjust your treatment plan accordingly.

11. You should not use any illicit substances, such as cocaine, marijuana, etc. while taking these medications. This may result in a change to your treatment plan, including safe discontinuation of your opioid medications when applicable or complete termination of the doctor/patient relationship.

APPENDIX I: Sample Patient Agreement: Pain.edu

12. The use of alcohol and opioid medications is contraindicated.

13. You agree and understand that your physician reserves the right to perform random or unannounced urine drug testing. If requested to provide a urine sample, you agree to cooperate. If you decide not to provide a urine sample, you understand that your doctor may change your treatment plan, including safe discontinuation of your opioid medications when applicable or complete termination of the doctor/patient relationship. The presence of a non-prescribed drug(s) or illicit drug(s) in the urine can be grounds for termination of the doctor/patient relationship. Urine drug testing is not forensic testing, but is done for your benefit as a diagnostic tool and in accordance with certain legal and regulatory materials on the use of controlled substances to treat pain.

14. There are side effects with opioid therapy, which may include, but not exclusively, skin rash, constipation, sexual dysfunction, sleeping abnormalities, sweating, edema, sedation, or the possibility of impaired cognitive (mental status) and/or motor ability. Overuse of opioids can cause decreased respiration (breathing).

15. Physical dependence and/or tolerance can occur with the use of opioid medications.

    Physical dependence means that if the opioid medication is abruptly stopped or not taken as directed, a withdrawal symptom can occur. This is a normal physiological response. The withdrawal syndrome could include, but not exclusively, sweating, nervousness, abdominal cramps, diarrhea, goose bumps, and alterations in one's mood.

    It should be noted that physical dependence does not equal addiction. One can be dependent on insulin to treat diabetes or dependent on prednisone (steroids) to treat asthma, but one is not addicted to the insulin or prednisone.

    Addiction is a primary, chronic neurobiologic disease with genetic, psychosocial and environmental factors influencing its development and manifestation. It is characterized by behavior that includes one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and cravings. This means the drug decreases one's quality of life.

    Tolerance means a state of adaptation in which exposure to the drug induces changes that result in diminution of one or more of the drug's effects over time. The dose of the opioid may have to be titrated up or down to a dose that produces maximum function and a *realistic* decrease of the patient's pain.

16. If you have a history of alcohol or drug misuse/addiction, you must notify the physician of such history since the treatment with opioids for pain **may** increase the possibility of relapse. A history of addiction does not, in most instances, disqualify one for opioid treatment of pain, but starting or continuing a program for recovery is a must.

17. You agree to allow your physician to contact any health care professional, family member, pharmacy, legal authority, or regulatory agency to obtain or provide information about your care or actions *if the physician feels it is necessary*.

18. You agree to a family conference or a conference with a close friend or significant other *if the physician feels it is necessary*.

The above agreement has been explained to me by [INSERT PRESCRIBER NAME HERE]. I agree to its terms so that [INSERT PRESCRIBER NAME HERE] can provide quality pain management using opioid therapy to decrease my pain and increase my function.

Patient's Signature _____ Date _____

Witness's Signature _____ Date _____

Created by Howard A. Heit MD, FACP, FASAM

Management of Chronic Opioid Protocol

PURPOSE

To provide standardized tools and a highly reliable process for caring for patients who require chronic opioid use.

PROCEDURE

The following protocol should be initiated for non-palliative long-term patients whose Schedule II and III opioid use exceeds 90 days or if opioid use exceeding 90 days is anticipated at the initiation of therapy and when prescribing any patient an extended release hydrocodone without Abuse Deterrent Formulations (i.e. Zohydro) of any duration. Protocol initiation for Schedule IV opioids is strongly recommended but not required.

NOTE WELL: VMPS Requirements extend beyond this definition. See VPMS Section of Protocol

IDENT:	MG27
Type of Document	Protocol
Type of Policy	Departmental
Applicability	All
Owner's Department	UVM Medical Group
Title of Owner	Director Medical Group
Title of Approving Official	CMO
Date Released (Published)	October 20, 2014
Next Review Date	October 20, 2015

Appendix A: Prescription Agreement
Appendix B: Informed Consent
Appendix C: Pain Management Smart Phrase
Appendix D: Prescription Pick Up Log
Appendix E: Pill Count Flowsheet
Appendix F: SOAPP-R
Appendix G: 5A's Smart Phrase
Appendix H: SF-8
Appendix I: Oswestry Neck
Appendix J: Revised Oswestry Low Back Pain
Appendix K: Roland Morris - RDQ
Appendix L: CDAI
Appendix M: FIQR
Appendix N: COMM
Appendix O: Tapering/Titration/Weaning Recommendations
Appendix P: VPMS Smart Phrase
Appendix Q: Opioid Withdrawal Smart Phrase
Appendix R: Adverse Effects Document
Appendix S: Documentation Tool Grid
Appendix T: Urine Drug Screen Collection Procedure
Appendix U: Removing Chronic Opioid Modifier
Appendix V: Urine Collection Temperature Cup Instructions
Appendix W: Tip Sheet for Reordering Controlled Substances

APPENDIX A

Prescription Agreement

1. The provider will review and discuss the prescription agreement with the patient and obtain signatures.
2. The prescription agreement will be scanned into PRISM utilizing Consent document type with "Opioid Agreement" as the description.
3. Prescription agreements will be reviewed and updated as needed.
4. Form is available from Print Shop in hard copy or as letter "FA AMB PRESCRIPTION AGREEMENT" in the PRISM system.

MRN _____

Patient Name _____

Date of Birth _____

Prescription Agreement

AGREEMENT FOR USING CONTROLLED SUBSTANCES

____Opioid (narcotic) ____Benzodiazepine (anti-anxiety) ____Stimulant ____Other Class (name)_____

The medications listed above have significant risks associated with them, and therefore they are controlled and limited by both the state and federal law. Both the prescriber and patient have a responsibility for the safe and effective use of controlled substances. To achieve this, the following conditions apply:

- Prescriptions will be filled by only one provider _____. If that provider is unavailable, the office will make appropriate arrangements.
- Prescriptions will be filled at only one pharmacy, _____.
- Prescriptions will be picked up by ____patient _____Designee with identification. Designee name_____.
- Medication will be refilled during: office visits_____ or other_____
- Controlled substances will not be prescribed by the on-call physician.
- Chronic health condition requiring treatments with controlled substances often require comprehensive care with other options besides medications. It is therefore important to include the patient's support structure (such as family and friends) in the treatment process. By signing below, the patient agrees to allow the provider to be in contact with the support person noted below, in relation to the treatment regimen.

The prescribing provider agrees to:

- Treat the patient with concern and respect.
- Formulate a thoughtful and medically appropriate treatment plan for the patient's pain or other symptoms.
- Document the patient's dose, frequency and date of last prescription in the patient's chart.
- If you develop complications from the controlled substances, such as addiction, we will assist you in finding treatment. Please be aware, however, that our practice cooperates fully with law enforcement, the US Drug Enforcement Agency and other agencies in the investigation of controlled substance related crimes including sharing, selling, trading, or other potential harmful use of these powerful medications.

The patient agrees to:

- Take medications as prescribed. Do NOT adjust medications without consulting with the prescribing provider.
- Keep medications locked up to avoid intentional or unintentional use or diversion by others. Dispose of all unused medications appropriately. *Diversion refers to the transfer of any prescribed controlled substances from the intended individual to another person for illegal use.*
- A pill count may be done at your provider's discretion.
- Provide a written summary of the names and frequency of all medications you are taking.
- Allow the prescribing provider to communicate with any consulting provider, including the Emergency Department and any pharmacist.
- Report loss or accidental destruction to the office. Report theft of medication *immediately* to the police and the office. Medication or prescriptions may NOT be replaced. A pattern of loss or theft of prescriptions may be grounds for discontinuation of treatment.
- Inform any other provider the patient may receive care from (for example, the emergency room or an oral surgeon) that there is a controlled substance prescription agreement with the prescribing provider.
- Inform the prescribing provider if the patient receives controlled substances from another provider within 24 hours.
- Fill your prescriptions at one pharmacy only. Inform this practice within 24 hours if you must use another pharmacy.
- Permit unannounced, unscheduled urine drug testing and pill counts, to measure use of medication and to check for illicit drugs. Drug testing may NOT be covered by insurance company, in which case the patient is responsible for those costs.

APPENDIX A

MRN _____

Patient Name _____

Date of Birth _____

Prescription Agreement

- Be honest with your provider about your medication and other drug use. Any methadone or buprenorphine from another provider must be reported.
- Do not abuse alcohol and do not use illegal drugs while being prescribed controlled substances because the substances can interfere with your breathing ability leading to possible overdose and death.
- Do not share, sell, trade or in any way provide your medications to others.
- Follow the prescribing provider's recommendations regarding evaluation, treatment, and follow-up.
- Participate in other pain treatments agreed to with your provider and keep all appointments scheduled for your care.
- Follow the prescribing provider's advice regarding stopping opioid treatment when it is no longer medically advisable.

If either the patient or the provider does not fulfill this agreement, any or all of the following steps may be taken:

- Limited dispensing of medications (such as only a day's or week's supply at one time)
- Gradually decreasing medications until they are discontinued
- Alternative symptom management methods (including non-pharmacologic means)
- Referral for counseling

SELLING YOUR MEDICATION OR GIVING IT TO OTHERS
Opioid medications have a value on the black market and there may come a time when you are tempted to sell your medicine. It is also common for some people to pressure you into giving them some of your medication. Your medication is regulated by the Drug Enforcement Agency and selling it is considered a criminal act. We are not required to report these events, but we want to help.

Your responsibility - We want you to live a safe and productive life. If you have been pressured into selling or giving your medicine to someone, please tell us so that we can help you.

The health care team's responsibility – Through pill counts and our own observations we support all of our patients carefully to make sure they are using their medications appropriately. If you request early refills, lose your medication, or have it stolen, we may request documentation from you.

THEFT
People will want to take your medication from you to get high or sell it. If you have children in the house, it's possible that one of them may take it by accident.

Your responsibility – Keep your paper prescriptions and your medication in a secure location. If your medicine is stolen, report this to the police and provide us with the officer's report. Once you leave our clinic you are responsible for your medication and we will not replace it if stolen. Here are some tips:

- Keep your medicine in a safe or lockbox
- If you need to take some medicine with you for the day, only take the pills that you need with you instead of the whole bottle
- Don't tell people what medication you take

The health care team's responsibility – If your medicine is stolen, we can find other substances that might treat your symptoms and be less likely to be stolen.

I have had the opportunity to review the above agreement for long term controlled substance therapy. I have been given the opportunity to ask questions about the risks and benefits of the proposed treatment. I have been provided an informed consent on this treatment. I accept the risks and conditions outlined above.

Patient Signature _____ Date/Time: _____

Family Member / Support Person Signature _____ Date/Time: _____

Prescriber Signature _____ Date/Time: _____

APPENDIX B

Informed Consent

1. The provider will review and discuss the informed consent with the patient and obtain signatures.
2. The informed consent will be scanned into PRISM utilizing Consent document type, with "Opioid Consent" as the description.
3. Informed consent will be discussed and updated as needed.
4. Form is available from Print Shop in hard copy or as letter "FA AMB INFORMED CONSENT" in the PRISM system.

MRN _____

Patient Name _____

Date of Birth _____

Informed Consent

Opioid use for Chronic and Acute Pain

Chronic and acute pain are conditions that require various treatment approaches that may consist of non-opioid and non-pharmacological (*therapies that do not include medications*) treatments such as:

- physical therapy
- acupuncture
- mind-body counseling
- chiropractic
- and others

If your doctor has recommended using opioids to treat your pain, you should know that some types of pain do not respond to opioids and, in some cases, opioids may actually worsen pain. It is important for you to understand the following:

- The goal of opioid use for pain is to improve function and, if possible, to provide pain relief. Pain relief doesn't mean pain-free. **You still may experience pain** while on opioids.
- There are many different types of opioids and many different kinds of reactions, depending on the person. Opioids have a potential **risk for misuse, abuse, diversion, and addiction**. *Diversion is the transfer of any prescribed controlled substance from the intended individual to another person for illegal use.*
- For your safety, opioids must be **used at the smallest effective dose, and for the shortest length of time** possible.

RISKS AND SIDE EFFECTS OF OPIOIDS:

Common side effects: Opioids may cause **drowsiness, constipation, sweating, itching and cloudy thinking.** Side effects may also include **mood changes (including worsening depression), sleep pattern changes, effects on the hormones resulting in decreased sexual interest, erectile dysfunction and lower body temperature.** Opioids are known to **worsen sleep apnea**. With all opioids, you **may experience withdrawal upon discontinuation**.

Less common side effects: Opioids may have some effects on the immune system. Opioids **may worsen pain and cause increased sensitivity to pain when the opioid wears off.** Opioids may cause hyper-allergic reactions, gall bladder function issues, or interference with smooth muscle function. Opioid use **may be associated with unexpected death.**

Driving/operating machinery: Due to sedating effects, **extreme caution must be used when deciding to drive** or operate any vehicle while taking an opioid. If you are unsure how the medication will affect you, do not drive or operate machinery when taking these medications.

Drug interactions: Opioids **should not be used in combination with alcohol, benzodiazepines (anti-anxiety) or sleeping medications**, because combinations of these substances can interfere with your breathing ability leading to possible **overdose and death**.

Opioid addiction: **Some people can become addicted to opioids** – especially those people who have developed problems with abuse of other substances such as alcohol and tobacco. Signs that you have become addicted include using the drug when you are in a bad mood or under stress, or continuing to use it even when it is no longer useful for your pain.

APPENDIX B

MRN _____

Patient Name _____

Date of Birth _____

Informed Consent

Opioid use for Chronic and Acute Pain

ALTERNATIVE TREATMENT

If opioids are not effective or if there are concerns of misuse, other treatment options may be recommended. They may include:

- Stopping or gradually tapering (decreasing) of your medications until they are discontinued
- Alternative symptom management methods (non-pharmacological - *therapies that do not include medications*)
- Referral for counseling

SAFE STORAGE OF YOUR MEDICINE

Keep your medication in a secure location such as a safe or lockbox and out of reach of children. To safeguard against theft, don't tell people what medication you take. If you need to take some medicine with you for the day, only take the pills you need instead of the entire bottle.

Your responsibility: If you notice that you are using your medication for symptoms other than treating your pain, please share this information with us. We want to help you. Additionally, it is illegal for you to sell or give this medication to others. It is important that you dispose of any leftover opioid medications properly after having completed your course of treatment.

The health care team's responsibility: We have a responsibility to help treat addiction. We will routinely ask you about your medication use, may ask you to bring your medication in for a pill count, ask for urine samples, and ask if you have concerns about addiction. While these questions may feel uncomfortable, it is our job to make sure you stay safe.

Transitions of care of your pain: As part of your treatment plan, your doctor may refer you to your Primary Care Physician or to another specialist for care. This transition of care may include an assessment of whether to continue with opioids or other treatment approaches such as non-opioid and non-pharmacological (*therapies that do not include medications*) treatments.

SPECIFIC CONSIDERATIONS FOR YOUR OPIOID USE

By signing this consent, you are acknowledging an understanding of the patient education material provided and that you have been informed of the risks, and responsibilities, including the opportunity to ask questions. Therefore, you are consenting to accept the risks, and conditions and will abide by the instructions set forth.

Patient / Responsible Party Signature _____ **Date/Time:** _____

Indication for Opioid use: ☐ **Chronic Pain** ☐ **Acute Pain** explain _____

Prescriber Print Name _____

APPENDIX J: Management of Chronic Opioid Protocol: University of Vermont Medical Center

Appendix B

PROBLEM LIST

1. Problem list will be updated to include "Chronic Pain Syndrome (338.4)" as a permanent problem.
2. Add .PAINMANAGEMENT (Appendix C) to the Overview section. Update all fields.
3. Prescription Agreement and Informed Consent must be indicated in the overview section of the problem.
4. Ensure problem list contains appropriate diagnosis explaining location/pain syndrome.
5. Document aberrant patient behaviors in .PAINMANAGEMENT

HEALTH MAINTENANCE

1. The use of "Chronic Pain Syndrome (338.4)" and "Chronic Pain (338.29)" on the problem list will automatically add the Chronic Opioid Management Modifier which consists of:
    a. Opioid Informed Consent – One time occurrence, no interval
    b. Opioid Prescription Agreement – One time occurrence, no interval
    c. Vermont Prescription Monitoring System – Interval defaults to annual
    d. Urine Drug Screen – Interval defaults to annual
    e. Pill Count – Interval defaults to annual
    f. Functional Assessment – Interval defaults to annual
    g. Current Opioid Misuse Measurement (COMM) – Interval defaults to annual
2. For patients not meeting the criteria of the protocol, yet have Chronic Pain on their problem list, the Chronic Opioid Management Modifier may be removed. See Appendix U.

LABORATORY TESTING

Urine Drug Screen

1. Urine drug screens will be completed by utilizing Urine Drug Screen 6 (D6VAL) and appropriate confirmation tests. The frequency of this testing should be guided clinically and it is strongly recommended that this testing be performed at a minimum annually for all patients under this protocol. Frequency may be adjusted as needed.
2. D6VAL will include Urine Creatinine, Specific Gravity Range and temperature of sample to provide screening for possible tampering/adulteration of sample.
    a. Results will include the following validation statements to support provider assessment:
        i. Normal Physiologic Urine Creatinine and Specific Gravity Range
        ii. Suggest Dilute Specimen
        iii. Suggest Adulterated Specimen
3. Urine sample will be collected using Urine Drug Screen Collection procedure.
4. In the event a urine drug screen needs to be complete externally (i.e. utilization of "Blue Water Process"), results will be scanned into PRISM for future reference. Results do not require manual entry. Urine Drug Screen Health Maintenance Topic will need to be overridden.
5. In the event a provider determines that a Urine Creatinine and Specific Gravity Range are not needed, LAB678 will be utilized which does not include Urine Creatinine or Specific Gravity Range with the drug screen.

To Screen for Drugs of Abuse	Urine Drug Screen 6 (D6)	Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Cannabinoids, Opiates (Only Heroin, Codeine and Morphine)
To Screen for Drugs of Abuse RECOMMENDED	Urine Drug Screen 6 Validity (D6VAL)	Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Cannabinoids, Opiates (Only Heroin, Codeine and Morphine) **AND** urine temperature and measurement of specific gravity and creatinine to assess for dilution or adulteration
To Confirm Use of Current Prescription	Opioid Confirmation	Codeine, Hydrocodone, Morphine, Oxycodone, Oxymorphone, Hydromorphone
Items not included in above	Must request each separately	Methadone Confirmation, Fentanyl Confirmation, in above Buprenorphine Confirmation

Note Well: Contact Laboratory for concerns with false positives (H-2 blockers and cannabinoids) false negatives (clonazepam and benzodiazepines) and unusual metabolic pathways (small amount of hydromorphone from morphine)

Appendix B

6. The following link will be utilized to guide clinical interpretation of drug screens. UVM Medical Center Laboratory will serve as a resource to the provider and confirmation testing will be at the discretion of the provider. http://www.pharmacomgroup.com/udt/udt5.pdf

PRESCRIPTION REFILLS

1. Prescription Refills will be provided according to the Prescription Agreement.
2. Prescriptions should be written in increments of 7 to prevent weekend request. (7, 14, 21 or 28 days)
3. Advance planning for refills is strongly recommended to prevent prescribing by multiple providers.
4. Refills will be addressed during office visits (minimum every three months).
5. Prescription refills will not be provided by the on call physician. If the prescribing provider is going to be out of the office, he/she will designate a provider for hand off as appropriate.
6. When writing the prescriptions in PRISM, use the "start", "end" and "fill" dates appropriately.
7. "Earliest Fill Date" will be populated on the order and display at the end of the "Sig" on the printed prescription.
8. Recommend that Fill Date be the same as Start Date, however the prescription may be refilled up to 72 hours prior to start date per provider discretion.
9. For prescriptions that are written as replacements due to loss or theft of medication or prescription, "Replacement Prescription" will be checked in the order and the language will automatically display on the printed prescription.
10. Clinical staff processing refills will complete the following:
    a. Review of Prescription Agreement
    b. Review of fill date/do not fill before start date
    c. VPMS Process as indicated

PRESCRIPTION PICK UP

1. Patient or Parent/Guardian must present proof of identification at time of prescription pick up.
2. Patient identification will be scanned into PRISM. Do not scan parent/guardian/designee ID into patient's record.
3. Patient or Parent/Guardian and staff member will complete log indicating pick up (Appendix D).
4. Per Informed Consent, patient may identify a designee for prescription pick up.
5. It is recommended that a patient pick up a prescription. In the event a prescription needs to be mailed, prescriptions must be mailed to the patient's local pharmacy for pick up.
    a. Prescriptions reported as lost in the mail may not be replaced.

PILL COUNTS

1. Prescribing provider will inform the patient that pill counts may be requested at any time as noted in Prescription Agreement.
2. Pill counts will be obtained when requested by the provider at an office visit and at random times (both in and out of office). Out of office pill counts may be completed in collaboration with the patient's Primary Care Provider.
3. Frequency of pill counts will be determined and tracked utilizing Health Maintenance functionality.
    a. Recommend completion, at a minimum, annually.
4. It is recommended that patients bring all their medications to every visit, in the original bottles.
5. If the patient is selected via randomization, the patient is informed of the request for random pill count via telephone encounter and a nurse visit is scheduled the same business day.
    a. See Registry section of this protocol for randomization process.
6. The patient, a licensed staff member and a staff witness (may be clinical or support staff) must be in the room when the pill count is conducted. All three are considered witnesses.
7. The nurse will perform hand hygiene before/after the pill count and wear gloves.

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8. For pill counts from a prescription bottle, a sterile tray and plastic knife (same as used in a pharmacy) will be used to complete the process and may be ordered through Mediclik.
9. For pill counts from a prescription bottle, empty the medication out onto the tray
10. For pill counts from bubble packs, verify integrity of packaging.
11. Verify by color/shape/size/imprint on the pill and that the pill represents what is on the prescription bottle/bubble pack.
    a. The following web link may be used for verification: http://www.rxlist.com/pill-identification-tool/article.htm
12. The nurse will check the date the prescription was filled and calculate quantity left based upon sig.
13. Document completion of pill count in the patient's record chart using the Pill Count Flowsheet (Appendix E). This documentation will be pulled into a note using .PILLCOUNT.
14. For pill counts from a prescription bottle, return medication to the original container
15. Return prescription bottle/bubble packs to patient in front of patient and witness.
16. For pill counts conducted outside of a provider office visit, send results to PCP for review by routing the nurse visit encounter to the provider.
    a. A discrepancy will be sent to the provider as high priority.
    b. Reason for Visit will be documented as "Pill Count".
17. For pill counts conducted during a provider visit:
    a. Staff will discuss need for pill count during session huddle (Primary Care) or with provider in advance of the visit to facilitate completion of pill count prior to provider interaction with the patient.
    b. For pill counts which fail to match, in addition to documenting in the visit encounter, the provider will be notified verbally by the staff completing the count.
18. Upon completion of pill count, Health Maintenance Topic will be satisfied.

PATIENT ASSESSMENT

Initiation of Therapy

1. Complete initial assessment tool
    a. SOAPP-R (Appendix F)

Continuation of Therapy

1. Level of function will be evaluated at each functional follow up visit.
2. Each functional follow up visit should include a functional evaluation with documentation of the "5 A's": Analgesia, Activities of daily living (i.e., physical, psychological and social functioning), Adverse Effects, Affect and Aberrant drug-related behaviors.
    a. .5AS (Appendix G)
    b. To occur with every visit, which is at a minimum every three months
3. Screening for Aberrant Behavior:
    a. COMM (Appendix N)
4. A re-evaluation should be done annually and will be tracked utilizing Health Maintenance functionality. In addition to using the "5 A's" documentation tool for re-evaluation, the following tools are recommended for annual use, as appropriate:
    a. Functional Assessment:
        i. SF – 8: For general functional assessment if no other specific tool available (Appendix H)
        ii. Oswestry Neck: For functional assessment related to chronic neck pain (Appendix I)
        iii. Revised Oswestry Low Back Pain: For functional assessment related to chronic back pain (Appendix J)
        iv. Roland Morris – RDQ: For functional assessment of chronic, non-specific low back pain (Appendix K)
        v. CDAI: Clinical Disease Activity Index for Arthritis (Appendix L)

Appendix B

vi. FIQR: For functional assessment related to fibromyalgia (Appendix M)

b. Adverse Effects (Appendix R)

i. Recommended use with concerns, dose changes and annually

Titration of Therapy (Appendix O)

1. .OPIOIDWITHDRAWAL

PRESCRIBING PRACTICE EVALUATION

Within each Health Care Service:

1. Provider prescribing practices will be reviewed as part of their Ongoing Professional Practice Evaluation (OPPE) process.
2. Physicians, residents and non-physician providers' prescribing practice will be adequately monitored through panel management reports.
3. Residents: All notes are reviewed by their preceptor.

PANEL MANAGEMENT

1. Three separate reports will be available for review by the prescribing provider on a quarterly basis.
    a. Identification of Patients for Protocol
        i. Primary Care Opioid – PC – Identification Crystal Report
            1. Report compiled by PCP for patients with three or more opioid prescriptions by provider's department, with an active opioid prescription on file and who do not have Chronic Pain Syndrome on their problem list
            a. Data to be reported over a rolling year
            b. Report to be reviewed during Provider/CCA Weekly Meetings
            c. Confirm or add appropriate diagnosis explaining location/pain syndrome
                i. Add "Chronic Pain Syndrome" to the problem list and mark as a permanent problem.
                ii. Add .PAINMANAGEMENT to the Overview section and update all fields to the Overview section as appropriate.
        ii. Specialty Care
            1. Report compiled by Authorizing Provider for patients with three or more opioid prescriptions by provider's department, with an active opioid prescription on file and who do not have Chronic Pain Syndrome on their problem list
            a. Data to be reported over a rolling year
            b. Provider to initiate protocol (Addition of Chronic Pain Syndrome to the Problem List and adding .PAINMANGEMENT to the Overview section) or complete a voice to voice hand off to the patient's Medical Home.
    b. Any Patient on an Opioid without Abuse Deterrent Formulation
    c. Patients on Protocol
        i. Randomization of patients for pill counts and urine drug screens will occur via the report.
        ii. Report data elements:
            1. Number of patients prescribed for (By PCP in Primary Care, by prescriber in Specialty Care)
            2. Amount of opioids prescribed (Rx by Dept. Authorized, Unique Auth Provs, Current Med, Total Rx Last Year)
            3. Last Urine Drug Screen (date)
            4. Last PCP visit (date)
            5. Pain score (result and date)
            6. Last VPMS Query (date)
            7. Prescribing Agreement (y/n)

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8. Consent present (y/n)
9. Completion of Functional Assessment (date)
10. Completion of COMM (date)
11. Pill Count (date)
12. Prevalence of "red flags"
    a. Four or more prescribers
    b. Methadone/Suboxone/Buprenorphine use for pain
    c. High dose Rx (> 100mg morphine equivalents)

iii. Action to take with report:
1. Review and complete Health Maintenance Topics as appropriate
2. If patient has not been seen by prescribing provider within past six months, schedule appointment for follow up.
3. Review "red flags" and missing data elements

VERMONT PRESCRIPTION MONITORING SYSTEM (VPMS)

1. Prescribers must query VPMS in the following four circumstances:
    a. At least annually for patients who are receiving ongoing treatment with Opioid Schedule II, III or IV controlled substance
    b. When starting a patient on a Schedule II, III or IV controlled substance for non-palliative long-term pain therapy of 90 days or more
    c. The first time the provider prescribes an opioid Schedule II, III or IV controlled substance written to treat chronic pain
    d. Prior to writing a replacement prescription for a Scheduled II, III or IV controlled substance
        i. Replacement prescriptions are defined as "an unscheduled prescription request in the event that the document on which a patient's prescription was written or the patient's prescribed medication is reported to the prescriber as having been lost or stolen".
2. VPMS query will be documented in the patient's record using .VPMSQUERY and the health maintenance topic will be updated appropriately.

OPIOIDS WITHOUT ABUSE DETERRENT FORMULATIONS (ADF)

1. When prescribing an opioid without ADF (i.e. Zohydro), in addition to the protocol, the following steps must occur:
    a. Clear documentation that an opioid without an ADF is needed to manage severe pain that requires daily, around-the-clock long-term opioid treatment, and that alternative treatment options are ineffective, not tolerated or would be inadequate to provide sufficient management of pain.
    b. In addition to completing the prescription agreement and informed consent, discuss with the patient the increased risks associated with ADFs such as life-threatening respiratory depression, potentially fatal overdose especially in children, neonatal opioid withdrawal symptoms and potentially fatal overdose when interacting with alcohol.
    c. Urine drug screens must be completed at least every 120 days. Adjust Health Maintenance Urine Drug Screen modifier accordingly.
    d. Additional VPMS considerations:
        i. Query must be completed at least every 120 days for patients prescribed 40 mg or more per day. Adjust Health Maintenance VPMS modifier accordingly.
    e. Determine a maximum daily dose of a not-to-exceed value for the prescription to be transmitted to the pharmacy.
    f. Prescriptions must be filled within 7 days that do not exceed 30 days in duration.

Appendix B

MULTIDISCIPLINARY ROUNDS

1. On at least a quarterly basis, multidisciplinary rounds are recommended at the site level.
2. The following individuals will be included in the process when applicable:
    a. MD Site Leader
    b. Practice Supervisor
    c. Prescribing Providers
    d. Behavioral Health Practitioner
    e. Clinic RN
    f. CHT Team (LCSW)
    g. Hub and Spoke representation
3. Site Registry of patients will be reviewed for the following:
    a. Discrepancies
    b. Joint assessment of coping and engagement in treatment
    c. Joint assessment of risk of opiate use
    d. Treatment plans developed
    e. Identification of patterns of abuse/addiction
    f. Options to be presented back to patient
    g. Review levels of individual patient surveillance
    h. Identification of resources needed for patient

Monitoring Plan:
Practice Supervisor and MD Site Leader are responsible for ensuring protocols are followed. Audits as determined by the UVM Medical Center Opioid Task Force

Related Policies/Procedures:
State of Vermont VPMS Process
Department of Health Emergency Rule Regulating Use of Zohydro

Appendix C

Pain Management Smart Phase

Treatment Diagnosis: ***
Appts every {NUMBER:27962} month(s)
Prescribing Provider: ***
Designee for Prescription Pick Up: ***
Notes:

See the HM for last Urine Drug Screen, Pill Count, VPMS, Functional Assessment, COMM, Prescription Agreement and Informed Consent.

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Appendix D

Prescription Pick-Up Log

CONTROLLED SUBSTANCE PICK-UP VERIFICATION FORM

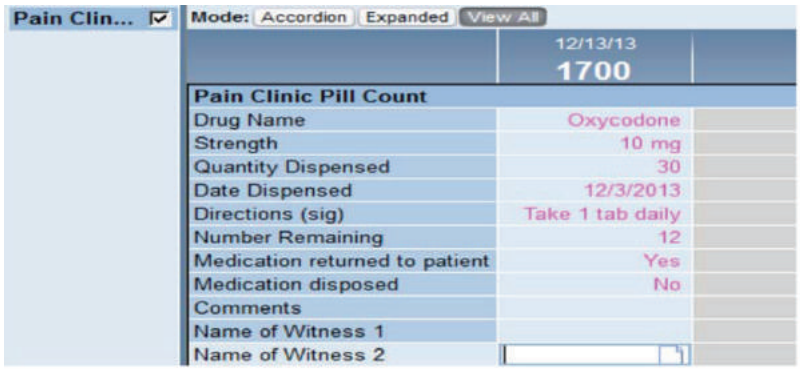
Patient

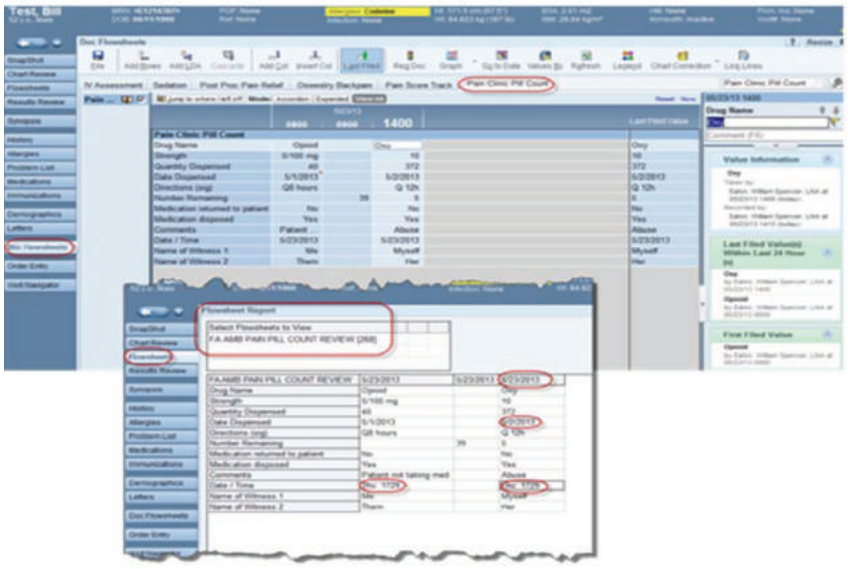
Designee Identified for Pick-Up

Individual Picking Up Script	Relationship to Patient	Signature	Date	ID Verified YES	NO	Staff Initials

Appendix E

Pill Count Flowsheet





PILL COUNT 28936

{ LNK,REVFS[268 1}
{ LNK,REVFS[268 2}
{ LNK,REVFS[268 3}
{ LNK,REVFS[268 4}
{ LNK,REVFS[268 5}

PILLCOUNT
User will select how many Medications have been documented on this encounter from the Smartlist

FA AMB PILL COUNT REVIEW	2/10/2014
Drug Name	Oxycodone
Strength	10 mg
Quantity Dispensed	90
Date Dispensed	1/26/2014
Directions (sig)	Take 1 tablet three times a day as needed
Number Remaining	45
Medication returned to patient	Yes
Medication disposed	No
Comments	Taking as prescribed
Name of Witness 1	Jillian
Name of Witness 2	Gini

Appendix F

SOAPP-R

Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is **NOT** intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

PainEDU.org
IMPROVING PAIN TREATMENT THROUGH EDUCATION

Appendix F

SOAPP-R

SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	○	○	○	○	○
2. How often have you felt a need for higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impatient with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often have you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

Appendix F

SOAPP-R

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	○	○	○	○	○
14. How often have others told you that you had a bad temper?	○	○	○	○	○
15. How often have you felt consumed by the need to get pain medication?	○	○	○	○	○
16. How often have you run out of pain medication early?	○	○	○	○	○
17. How often have others kept you from getting what you deserve?	○	○	○	○	○
18. How often, in your lifetime, have you had legal problems or been arrested?	○	○	○	○	○
19. How often have you attended an AA or NA meeting?	○	○	○	○	○
20. How often have you been in an argument that was so out of control that someone got hurt?	○	○	○	○	○
21. How often have you been sexually abused?	○	○	○	○	○
22. How often have others suggested that you have a drug or alcohol problem?	○	○	○	○	○
23. How often have you had to borrow pain medications from your family or friends?	○	○	○	○	○
24. How often have you been treated for an alcohol or drug problem?	○	○	○	○	○

Please include any additional information you wish about the above answers.
Thank you.

Appendix F

SOAPP-R

Scoring Instructions for the SOAPP®-R®

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is 2.5 times (2.53 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	2.53	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

Appendix F

SOAPP-R

How does the SOAPP-R help determine appropriate treatment?
The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater*)

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician's care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2 weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Appendix F

SOAPP-R

Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21*)

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Who is at a low risk for opioid misuse? (SOAPP-R score < 9*)

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

Appendix F

SOAPP-R

Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Appendix G

5A's Smart Phrase

Opioid Functional Assessment

Analgesia:
What is your **average** pain level? {PAIN SCALE 1-10:20469}
What has been your **worst** pain level? {PAIN SCALE 1-10:20469}
Are you getting enough pain relief to make a difference in your functioning? {YES NO:19456}

ADLs (physical and psychological functioning):
How is your physical ability? {BETTER/WORSE:18031}
How are family/social relationships? {BETTER/WORSE:18031}

has improved
has slightly improved
has moderately improved
has significantly improved
has worsened
has worsened slightly
is moderately worse
has significantly worsened
has improved in some ways and worsened in others
is unchanged
stable
***

Affect:
How is your mood? {BETTER/WORSE:18031}
How is your sleep? {BETTER/WORSE:18031}

Adverse effects:
Have you noted any side effects of you pain medic
EFFECTS:28931}

Aberrant Behavior:
Aberrant drug-related behavior noted? {YES NO:19

Appendix P: VPMS Query Smart Phrase

.VPMSQUERY

The Vermont Prescription Monitoring System query has been completed per the following requirement(s): {VPMS QUERY:29128}

Annual Verification
Non-Palliative Long Term Pain Therapy
Initial Prescription for Chronic Pain
Replacement Prescription
Zohydro 40mg
***

Appendix H

SF-8

Date _____ Name _____

SF-8™ Health Survey

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.
Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.
For each of the following questions, please mark an [x] in the one box that best describes your answer.

1. Overall, how would you rate your health during the **past 4 weeks**?

   Excellent Very Good Good Fair Poor Very Poor

2. During the **past 4 weeks,** how much did physical health problems limit your physical activities (such as walking or climbing stairs)?

   Not at all Very little Somewhat Quite a lot Could not do physical activities

3. During the **past 4 weeks,** how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?

   Not at all Very little Somewhat Quite a lot Could not do daily work

4. How much bodily pain have you had during the **past 4 weeks?**

   None Very mild Mild Moderate Severe Very severe

5. During the **past 4 weeks,** how much energy did you have?

   Very much Quite a lot Some A little None

6. During the **past 4 weeks,** how much did your physical health or emotional problems limit your usual social activities with family or friends?

   Not at all Very little Somewhat Quite a lot Could not do social activities

7. During the **past 4 weeks,** how much have you been bothered by **emotional problems** (such as feeling anxious, depressed or irritable)?

   Not at all Slightly Moderately Quite a lot Extremely

8. During the **past 4 weeks,** how much did personal or emotional problems keep you from doing your usual work, school or other daily activities?

   Not at all Very little Somewhat Quite a lot Could not do daily activities

Thank you for completing these questions.

Appendix I

Oswestry Neck

NAME:_____ DATE: _____

PDR Oswestry Neck Pain Questionnaire

This questionnaire is designed to enable us to understand how much your neck pain has affected your ability to manage everyday activities. Please answer each Section by circling the ONE CHOICE that most applies to you. We realize that you may feel that more than one statement may relate to you, but **Please circle the one choice which closely describes your problem *right now***.

Section 1 – Pain Intensity

A. I have no pain at the moment.
B. The pain is mild at the moment.
C. The pain comes and goes and is moderate
D. The pain is moderate and does not vary much.
E. The pain is severe, but comes and goes.
F. The pain is severe and does not vary much.

Section 2 – Personal Care

A. I can look after myself without causing extra pain.
B. I can look after myself normally, but it causes extra pain.
C. It is painful to look after myself and I am slow and careful.
D. I need some help, but manage most of my personal care.
E. I need help every day in most aspects of self-care.
F. I do not get undressed, I wash with difficulty and stay in bed.

Section 3 – Lifting

A. I can lift heavy weights without extra pain.
B. I can lift heavy weights but it causes extra pain.
C. Pain prevents me from lifting heavy weights off the floor, But I can manage if they are conveniently positioned (e.g on a table).
D. Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
E. I can lift only very light weights.
F. I cannot lift or carry anything at all.

Section 4 – Reading

A. I can read as much as I want to with no pain in my neck.
B. I can read as much as I want to with slight pain in my neck.
C. I can read as much as I want to with moderate pain in my neck.
D. I cannot read as much as I want to because of moderate pain in my neck.
E. I cannot read as much as I want to because of severe pain in my neck.
F. I cannot read at all.

Section 5 – Headache

A. I have no headaches at all.
B. I have slight headaches that come infrequently.
C. I have moderate headaches that come infrequently.
D. I have moderate headaches that come frequently.
E. I have severe headaches that come frequently.
F. I have headaches almost all the time.

Section 6 – Concentration

A. I can concentrate fully when I want to with no difficulty.
B. I can concentrate fully when I want to with slight difficulty.
C. I have a fair degree of difficulty in concentrating when I want to.
D. I have a lot of difficulty in concentrating when I want to.
E. I have a great deal of difficulty in concentrating when I want to.
F. I cannot concentrate at all.

Section 7 – Work

A. I can do as much work as I want to.
B. I can do my usual work but no more.
C. I can do most of my usual work, but no more.
D. I cannot do my usual work.
E. I can hardly do any work at all.
F. I cannot do any work at all.

Section 8 -- Driving

A. I can drive my car without any neck pain.
B. I can drive my car as long as I want with slight pain in my neck.
C. I can drive my car as long as I want with moderate pain in my neck.
D. I cannot drive my car as long as I want because of moderate pain in my neck.
E. I can hardly drive at all because of severe pain in my neck.
F. I cannot drive my car at all.

Section 9 – Sleeping

A. I have no trouble sleeping.
B. My sleep is slightly disturbed (less than 1 hour sleepless).
C. My sleep is mildly disturbed (1-2 hours sleepless).
D. My sleep is moderately disturbed (2-3 hours sleepless).
E. My sleep is greatly disturbed (3-5 hours sleepless).
F. My sleep is completely disturbed (5-7 hours sleepless).

Section 10 – Recreation

A. I am able to engage in all my recreational activities, with no neck pain at all.
B. I am able to engage in all of my recreational activities, with some pain in my neck.
C. I am able to engage in most, but not all of my usual recreational activities because of pain in my neck.
D. I am able to engage in only a few of my usual recreational activities because of pain in my neck.
E. I can hardly do any recreational activities because of pain in my neck.
F. I cannot do any recreational activities at all.

Section 11 – Numeric Rating Scale (NRS)

Try and assign a number from 0 to 10 to your current pain level. If you have no pain, use a 0. As the numbers get higher, they stand for pain that is getting worse. A 10 means the pain is as bad as it can be.

0 1 2 3 4 5 6 7 8 9 10
No pain Mild Moderate Severe Worst Possible Pain

OSW-SCORE:_____%

P-SCORE:_____

Appendix J

Revised Oswestry Low Back Pain

THE REVISED OSWESTRY LOW BACK PAIN QUESTIONNAIRE

PATIENT NAME: _____ **DATE**: _____

Please read: This questionnaire is designed to enable us to understand how much your low back pain has affected your ability to manage your everyday activities. Please answer each section by circling the ONE CHOICE that most applies to you. We realize that you may feel that more than one statement may relate to you, but PLEASE, JUST CIRCLE THE ONE CHOICE WHICH MOST CLOSELY DESCRIBES YOUR PROBLEM RIGHT NOW.

SECTION 1 - Pain Intensity

A The pain comes and goes and is very mild.
B The pain is mild and does not vary much.
C The pain comes and goes and is moderate.
D The pain is moderate and does not vary much.
E The pain comes and goes and is severe.
F The pain is severe and does not vary much.

SECTION 2 - Personal Care

A I do not have to change my way of washing or dressing in order to avoid pain.
B I do not normally change my way of washing or dressing even though it causes some pain.
C Washing and dressing increases the pain but I manage not to change my way of doing it.
D Washing and dressing increases the pain and I find it necessary to change my way of doing it.
E Because of the pain I am unable to do some washing and dressing without help.
F Because of the pain I am unable to do any washing and dressing without help.

SECTION 3 - Lifting

A I can lift heavy weights without extra pain.
B I can lift heavy weights but it causes extra pain.
C Pain prevents me from lifting heavy weights off the floor.
D Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
E Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
F I can only lift very light weights at the most.

SECTION 4 - Walking

A I have no pain on walking.
B I have some pain on walking but it does not increase with distance.
C I cannot walk more than one mile without increasing pain.
D I cannot walk more than 1/2 mile without increasing pain.
E I cannot walk more than 1/4 mile without increasing pain.
F I cannot walk at all without increasing pain

SECTION 5 - Sitting

A I can sit in any chair as long as I like.
B I can sit only in my favorite chair as long as I like.
C Pain prevents me from sitting more than one hour.
D Pain prevents me from sitting more than 1/2 hour.
E Pain prevents me from sitting more than 10 minutes.
F I avoid sitting because it increases pain straight away.

SECTION 6 - Standing

A I can stand as long as I want without pain.
B I have some pain on standing but it does not increase with time.
C I cannot stand for longer than one hour without increasing pain.
D I cannot stand for longer than 1/2 hour without increasing pain.
E I cannot stand for longer than 10 minutes without increasing pain.
F I avoid standing because it increases the pain immediately.

SECTION 7 - Sleeping

A I get no pain in bed.
B I get pain in bed but it does not prevent me from sleeping well.
C Because of pain my normal night's sleep is reduced by less than 1/4.
D Because of pain my normal night's sleep is reduced by less than 1/2.
E Because of pain, my normal night's sleep is reduced by less than 3/4.
F Pain prevents me from sleeping at all.

SECTION 8 - Social Life

A My social life is normal and gives me no pain.
B My social life is normal but increases the degree of my pain.
C Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.
D Pain has restricted my social life, and I do not go out very often.
E Pain has restricted my social life to my home.
F I have hardly any social life because of the pain.

SECTION 9 - Travel

A I get no pain while traveling.
B I get some pain while traveling, but none of my usual forms of travel make it any worse.
C I get extra pain while traveling, but it does not compel me to seek alternative forms of travel.
D I get extra pain while traveling, which compels me to seek alternative forms of travel.
E Pain restricts all forms of travel.
F Pain prevents all forms of travel except that done lying down.

SECTION 10 - Changing degree of pain

A My pain is rapidly getting better.
B My pain fluctuates but overall is definitely getting better.
C My pain seems to be getting better but improvement is slow at present.
D My pain is neither getting better nor worse.
E My pain is gradually worsening.
F My pain is rapidly worsening.

SIGNATURE: _____

Appendix K

Roland Morris – RDQ

RDQ

Name: _____ **Date:** _____

Age: _____ **Score:** _____

When your back hurts, you may find if difficult to do some of the things you normally do.

Mark only the sentences that describe you lately….

1. [ ] I stay at home most of the time because of my back.
2. [ ] I walk more slowly than usual because of my back.
3. [ ] Because of my back, I am not doing any jobs that I usually do around the house.
4. [ ] Because of my back, I use a handrail to get upstairs.
5. [ ] Because of my back, I lie down to rest more often.
6. [ ] Because of my back, I have to hold onto something to get out of an easy chair.
7. [ ] Because of my back, I try to get other people to do things for me.
8. [ ] I get dressed more slowly than usual because of my back.
9. [ ] I stand up only for short periods of time because of my back.
10. [ ] Because of my back, I try not to bend or kneel down.
11. [ ] I find it difficult to get out of a chair because of my back.
12. [ ] My back or leg is painful almost all of the time.
13. [ ] I find it difficult to turn over in bed because of my back.
14. [ ] I have trouble putting on my socks (or stockings) because of pain in my back.
15. [ ] I sleep less well because of my back.
16. [ ] I avoid heavy jobs around the house because of my back.
17. [ ] Because of back pain, I am more irritable and bad tempered with people than usual.
18. [ ] Because of my back, I go upstairs more slowly than usual.

Appendix K

Roland Morris – RDQ

Roland Morris Disability Questionnaire

Scoring: **Instructions for Roland-Morris :**

The patient is instructed to put a mark next to each appropriate statement.
The total number of marked statements are added by the clinician.
Unlike the authors of the Oswestry Disability Questionnaire, Roland and Morris did not provide descriptions of the varying degrees of disability (*e.g.* 40%-60% is severe disability).
Clinical improvements over time can be graded based on the analysis of serial questionnaire scores. If, for example, at the beginning of treatment, a patient's score was 12 and, at the conclusion of treatment, her score was 2 (10 points of improvement), we would calculate an 83% 910/12 x 100) improvement.

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Appendix L

CDAI

Clinical Disease Activity Index (CDAI)

Joint	Left		Right	
	Tender	Swollen	Tender	Swollen
Shoulder				
Elbow				
Wrist				
MCP 1				
MCP 2				
MCP 3				
MCP 4				
MCP 5				
PIP 1				
PIP 2				
PIP 3				
PIP 4				
PIP 5				
Knee				
Total	Tender:		Swollen:	

Patient Global Assessment of Disease Activity

Considering all the ways your arthritis affects you, rate how well you are doing on the following scale:

Very Well 0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 Very Poor

Your Name_____ **Date of Birth** _____ **Today's Date** _____

Provider Global Assessment of Disease Activity

Very Well 0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10 Very Poor

How to Score the CDAI

Variable	Range	Value
Tender joint score	(0-28)	
Swollen joint score	(0-28)	
Patient global score	(0-10)	
Provider global score	(0-10)	
Add the above values to calculate the CDAI score	**(0-76)**	

CDAI Score Interpretation	
0.0 – 2.8	Remission
2.9 – 10.0	Low Activity
10.1 – 22.0	Moderate Activity
22.1 – 76.0	High Activity

Appendix M

FIQR

REVISED FIBROMYALGIA IMPACT QUESTIONNAIRE (FIQR)

Last Name: _____ **Duration of FM symptoms (years):** _____

First Name: _____ **Time since FM was first diagnosed (years):** _____

Age: _____

DOMAIN 1: FUNCTION

Directions: For each of the following 9 questions, check the box that best indicates how much your Fibromyalgia made it difficult to perform each of the following activities during the past 7 days. If you did not perform a particular activity in the last 7 days, rate the difficulty for the last time you performed the activity. If you can't perform an activity, check the last box.

BRUSH OR COMB YOUR HAIR

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

WALK CONTINUOUSLY FOR 20 MINUTES

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

PREPARE A HOMEMADE MEAL

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

VACUUM, SCRUB, OR SWEEP FLOORS

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

LIFT AND CARRY A BAG FULL OF GROCERIES

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

CLIMB ONE FLIGHT OF STAIRS

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

CHANGE BEDSHEETS

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

SIT IN A CHAIR FOR 45 MINUTES

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

SHOP FOR GROCERIES

No difficulty												Very difficult
	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	

DOMAIN 1 SUBTOTAL: _____

Appendix M

FIQR

DOMAIN 2: OVERALL

Directions: For each of the following 2 questions, check the box that best describes the overall impact of your Fibromyalgia over the last 7 days.

FIBROMYALGIA PREVENTED ME FROM ACCOMPLISHING GOALS FOR THE WEEK

Never	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Always**

I WAS COMPLETELY OVERWHELMED BY MY FIBROMYALGIA SYMPTOMS

Never	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Always**

DOMAIN 2 SUBTOTAL: _____

DOMAIN 3: SYMPTOMS

Directions: For each of the following 10 questions, select the box that best indicates your intensity level of these common Fibromyalgia symptoms over the past 7 days.

PLEASE RATE THE LEVEL OF PAIN

No pain	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Unbearable pain**

PLEASE RATE YOUR LEVEL OF ENERGY

Lots of energy	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**No energy**

PLEASE RATE YOUR LEVEL OF STIFFNESS

No stiffness	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Severe stiffness**

PLEASE RATE THE QUALITY OF YOUR SLEEP

Awoke well rested	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Awoke very tired**

PLEASE RATE YOUR LEVEL OF DEPRESSION

No depression	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Very depressed**

PLEASE RATE YOUR LEVEL OF MEMORY PROBLEMS

Good memory	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Very poor memory**

PLEASE RATE YOUR LEVEL OF ANXIETY

Not anxious	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Very anxious**

Appendix M

FIQR

PLEASE RATE YOUR LEVEL OF TENDERNESS TO TOUCH

No tenderness	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Very tender**

PLEASE RATE YOUR LEVEL OF BALANCE PROBLEMS

No imbalance	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Severe imbalance**

PLEASE RATE YOUR LEVEL OF SENSITIVITY TO LOUD NOISES, BRIGHT LIGHTS, ODORS, AND COLD

No sensitivity	❑ 0	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5	❑ 6	❑ 7	❑ 8	❑ 9	❑ 10	**Extreme sensitivity**

DOMAIN 3 SUBTOTAL: _____

SCORING:

1) Sum the scores for each of the 3 domains (function, overall, and symptoms).

2) Divide domain 1 score by 3, leave domain 2 score unchanged, and divide domain 3 score by 2.

3) Add the 3 resulting domain scores to obtain the total FIQR score.

DOMAIN 1 SUBTOTAL _____ ÷ 3 = _____

DOMAIN 2 SUBTOTAL _____ CARRY OVER SUBTOTAL = _____

DOMAIN 3 SUBTOTAL _____ ÷ 2 = _____

TOTAL FIQR SCORE

Appendix N

COMM

Current Opioid Misuse Measure (COMM)™

The Current Opioid Misuse Measure (COMM)™ is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM™ was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM™ will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM™ examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM™ is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM™ is for clinician use only. The tool is not meant for commercial distribution.
- The COMM™ is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM™ scores to decide if and when modifications to a particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

Appendix N

COMM

COMM™

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

Appendix N

COMM

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O

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Appendix N

COMM

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

Appendix N

COMM

Scoring Instructions for the COMM™

To score the COMM™, simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
> or = 9	+
< 9	-

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM™ was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM™ will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM™ is at different cutoff values. These values suggest that the COMM™ is a sensitive test. This confirms that the COMM™ is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM™ are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM™ score (at a cutoff of 9) is nearly 3 times (3.48 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM™ score suggests the patient is really at low-risk, while a high COMM™ score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM™ Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 9 or above	.77	.66	.66	.95	3.48	.08

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Appendix O

Tapering/Titration/Weaning Recommendations

IDENTIFYING RISK POINTS

1. Risk increases over 50 mg morphine equivalents though concern may be warranted in some patients on lower doses.
    a. A dose over 50 mg morphine equivalents may confer high risk for some patients; even if not, should certainly be monitored to watch for any signs of sedation, non-adherence, etc. It should be considered a "YELLOW LIGHT"
    b. Patients prescribed doses over 100 mg morphine equivalents should have closer surveillance. It should be considered a "RED LIGHT".

EVALUATION THRESHOLDS

1. Dose =/> 50 mg morphine equivalents/day triggers a yellow light.
2. Dose =/> 100 mg morphine equivalents/day triggers increased surveillance.
3. Aberrant behavior triggers an addiction evaluation.

RECOMMENDATIONS FOR WHEN TO CONSIDER TAPERING

1. Increase surveillance system with 50-100 mg morphine equivalents/day.
2. Over 100 mg morphine equivalents without improvement in pain or function, providers should consider tapering, referrals to specialists, and consultations with colleagues.
3. In cases of doses greater than 100 mg morphine equivalents/day, a peer-review discussion with a colleague or consultation with specialists (addiction, pain management, behaviorist, etc.).
4. Signs of aberrant behavior or diversion is strongly suspected

WEANING / TAPERING

1. Taper in 10% drops (increments) per week.
2. Smaller amounts and slower weans may be better for some patients.
3. Tapers by units of 10% are easier when patient is on doses higher than on 40mg or 50mg morphine equivalents to start with.
    a. Lower doses could instead taper by 5% step reductions if needed.
4. Assessment: Assess at each reduction (taper) to detect side effects and treat symptoms.

ABERRANT BEHAVIOR

1. Call-backs are a strong predictor of aberrant behavior or struggling with dose.
2. Strategic use of pill counts, random call-backs and pill counts are recommended.
3. Pill counts are ineffective unless they are random and with only a couple hours' notice.
4. The practice/use of bubble packs and call-backs works well.
5. If aberrant behavior is suspected, see patient more frequently. Consider evaluating frequency of random call-backs, and involve partner or spouse for assistance.

If diversion is strongly suspected (such as failed pill count & test negative in urine):

1. Abrupt stop:

    Clonidine: 0.1-0.3 mg 2-3 times a day; 7-10 days.
    .OPIOIDWITHDRAWALPTINSTRUCTIONS
    Immodium AD
    Atarax (Hydroxyzine Hydrochloride): 25-50 mg; Q6.
    Benadryl (diphenhydramine) 25-50 mg; Q6.

Appendix O

2. Resources:
   ACT I (Howard Center) 802-488-6425.
   May contact State Police to discuss cases with concerns.
   Contact: Prescription Diversion: Lee Hodsden, 802-989-9566

REFERRALS/MANAGEMENT PLAN

1. 100 mg morphine equivalents/day dose without adequate pain relief or improved function is reasonable to start considering referrals to specialists or weaning due to failure of therapy.
2. Increase caution as amount of dose approaches 50mg - 100 mg morphine equivalents/day.

Addiction is strongly suspected

1. Comprehensive addiction evaluation: (Behaviorist, Howard Mental Health Hub & Spoke Intake, Day 1, PCP):
   a. Detox and stabilize
   b. Methadone/suboxone provided at local Hub and Spoke Program
   c. Suboxone provided by PCP, if appropriate
2. Additional Resources: Brattleboro Retreat

Opiates are not working (functionally not getting any benefit or difficulty with adherence):

1. Recommend a scheduled tapered dose of 10% drop per week for a total of 8 weeks to wean.

Opiates are working (joint decision to stop using opiates for other reasons)

1. Reasons may include side effects, desire to "get off" controlled substances, don't want to become addicted, etc.):
   a. Rate of drop is negotiated between patient and provider.

Management of Patient Who is Unable to Wean

1. When weaning patients down, it is the last lower doses that are the hardest.
2. It is recommended that other modes of treatment be used.
3. Consider referral to provider that will/can prescribe suboxone.
4. Consider referral to a Hub and Spoke Program

REFERRAL RESOURCES

1. Community Health Team, Behaviorists and Social Work
2. Howard Mental Health
3. Hub and Spoke: Chittenden area Outpatient Treatment at Pine Street with Howard Mental Health, Methadone program Intake
   a. Intake: Michael Lawrence, 802-488-7352; Cell: 802-355-9814
   b. Program Director: Dan Hall, 802-488-6161
   c. Director: Dawn Poverman, 802-488-6155
4. University of Vermont Medical Center Mental Health-DayOne: Opioid abuse and resources in area for treatment, methadone and suboxone
   a. Intake: Bill Keithcart , 802-847-3333
5. Brattleboro Retreat
6. Berlin (BAART/CVSAS) 802-223-2003

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Appendix Q

Opioid Withdrawal Smart Phrase

.OPIOIDWITHDRAWALPATIENTINSTRUCTIONS

PATIENT INSTRUCTIONS FOR SELF-MANAGEMENT OF OPIOID WITHDRAWAL:

For restlessness:
Use clonidine 0.1 mg tablet:
Start by taking 1 tab (0.1 mg) twice daily. If tolerated, you may wean up to 2-3 tabs (0.2-0.3 mg) every four hours as needed. If you are light headed at all, decrease your dose. You may expect to take this medication for 7-10 days.

For diarrhea or loose stools:
Use over-the-counter Imodium AD:
You may take 1-2 tabs (2-4 mg) orally with every loose or watery bowel movement. The maximum dose is 8 tabs per day.

For insomnia:
You may take diphenhydramine (Benadryl) 1-2 tabs (25-50 mg) orally up to 4 times a day. Alternatively, your health care provider may prescribe hydroxyzine in the same doses (25-50 mg orally 4 times a day as needed).

Please call with any questions or concerns on dosing or symptoms.

Appendix S

Documentation Tool Grid

Stage of Therapy	Tool	Indication for Use	Frequency	Location of Tool
Initiation	SOAPP–R	Initiation of Therapy	Once	Paper
	Informed Consent	Initiation of Therapy	Complete once, review annually	Paper or PRISM Letter "FA AMB INFORMED CONSENT"
	Prescription Agreement	Initiation of Therapy	Complete once, review annually	Paper or PRISM Letter "FA AMB PRESCRIPTION AGREEMENT"
Continuation	5 A's	Functional Evaluation	Every visit, to occur at a minimum every 3 months	PRISM Smart Phrase – .5As
	COMM	Screening for aberrant behavior	Annual	Paper
	SF-8	General functional assessment, no specific tool available	Annually, in addition to 5As	Paper
	Oswestry Neck	Functional Assessment Chronic Neck Pain	Annually, in addition to 5As	Paper
	Revised Oswestry	Functional Assessment Chronic Back Pain	Annually, in addition to 5As	Paper
	Roland Morris – RDQ	Functional Assessment Chronic, Non-Specific Low Back Pain	Annually, in addition to 5As	Paper
	CDAI	Functional Assessment Arthritis	Annually, in addition to 5As	Paper
	FIQR	Functional Assessment Fibromyalgia	Annually, in addition to 5As	Paper
	Adverse Effects	Concerns, Dose Changes and Annual Assessment	Minimum annually, more frequently if indicated	Paper
Titration	Withdrawal Patient Instructions	Titration of Therapy	As Indicated	PRISM Smart Phrase – .OPIOIDWITHDRAWAL

Appendix T

Urine Drug Screen Collection Procedure

PURPOSE

To instruct staff in the proper collection technique and patient instruction for the collection of urine drug screen samples.

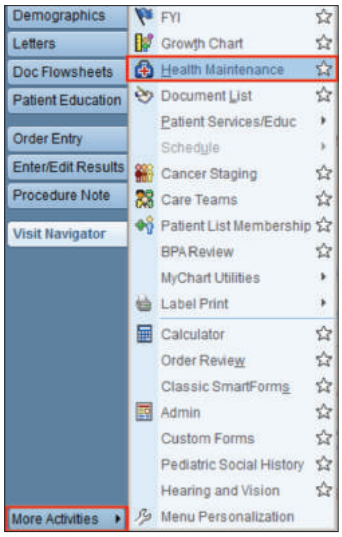
PROCEDURE

1. Provide patient urine collection cup with temperature monitoring strip.
2. Verify information contained on label with patient and label the collection cup in the presence of the patient.
3. Instruct patient that they cannot bring packages, bags, purses and coats into restroom.
4. Instruct patient to empty pockets.
5. Instruct patient that they cannot bring another individual into the restroom.
6. Ensure restroom is free of anything that could be used to adulterate or substitute a urine sample.
7. Patient must provide at least 30 ml of urine, preferred amount is 50ml. The minimum fill level for the temperature strip cups is just over the top of the strip.
    a. Clean catch procedure does NOT need to be utilized.
    b. Collection hats may be utilized to ensure sample volume.
    c. In the event the patient is unable to provide 30ml, the patient will be asked to hydrate, wait 30 minutes and attempt to produce another sample.
        i. Multiple samples from the patient CANNOT be combined to produce a minimum of 30ml.
8. Instruct patient to wash hands with soap and water. The use of hand sanitizer may yield false positive results and should be used with caution.
9. Staff member to remain outside the door to allow for immediate patient hand off of sample.
    a. Staff member to record temperature of urine, date and time on transmittal slip.
        i. Temperature of urine should read between 90F and 100F.
            1. NOTE WELL: Temperature of urine sample must be recorded within 2 to 4 minutes of collection for accuracy
    b. In the event the staff member suspects tampering or temperature and volume are not within defined range, will notify provider for further instructions.
        i. Indications the urine specimen has been tampered with include an unusual appearance (bubbly, cloudy, clear or dark).
        ii. Specific Gravity and Creatinine are a component of the Drug Screen Order (D6VAL) to provide additional detail for interpretation.
        iii. If unable to obtain a temperature, note on transmittal slip for inclusion on result using the following options:
            1. Temperature not documented
            2. Temperature recorded outside of 4 minute window
            3. Quantity insufficient for temperature recording
10. If the provider requests that the collection of the urine sample be directly observed, the person must be a clinical staff member of the same gender.

Appendix U

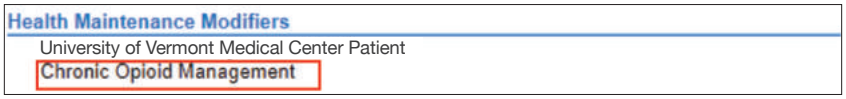
Removing Chronic Opioid Modifier

In support of the Chronic Opioid Protocol, patients are automatically enrolled in a set of Health Maintenance topics when the diagnosis of Chronic Pain Syndrome (338.4) is added to the Problem List. The topics are grouped under the modifier "Chronic Opioid Management", which consists of seven topics that aid in monitoring patients prescribed opioids for pain management. For patients with Chronic Pain syndrome on their Problem List but who are not prescribed opioids, this modifier may be removed. The following steps outline this process.

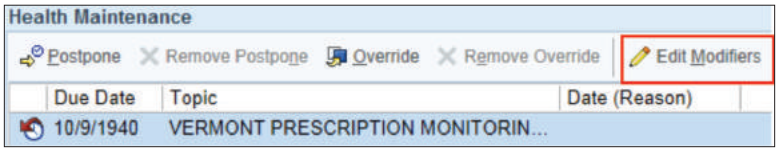


1. Open the patient's Health Maintenance module from the More Activities menu.

2. The presence of the modifier is denoted by Chronic Opioid Management under Health Maintenance Modifiers in the lower pane of the activity.

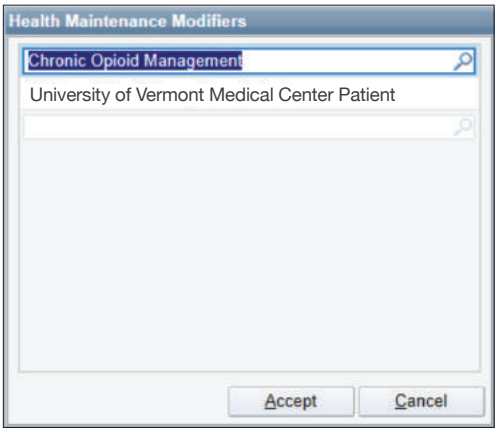


3. Click the Edit Modifiers button.



4. Highlight the field containing the Chronic Opioid Management modifier and press delete/back space. This will leave an empty field.

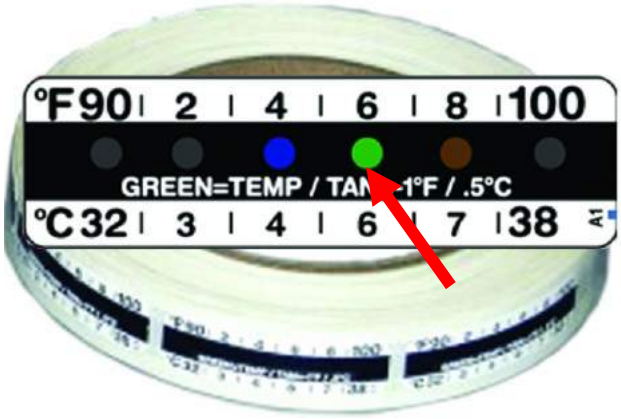
5. Click accept. The seven chronic opioid topics will no longer appear on the patient's Health Maintenance module.



Note: The reverse of this process may be completed for patients prescribed opioids but for whom Chronic Pain Syndrome is not an appropriate diagnosis on the Problem List. The modifier can be added to those patients' charts in order to monitor the associated topics (presence of a Prescription Agreement and an Informed Consent, Urine Drug Screens, Pill Counts, Functional Assessments, Current Opioid Misuse Measurement and query of Vermont Prescription Monitioring System).

Appendix V

Urine Collection Temperature Cup Instructions

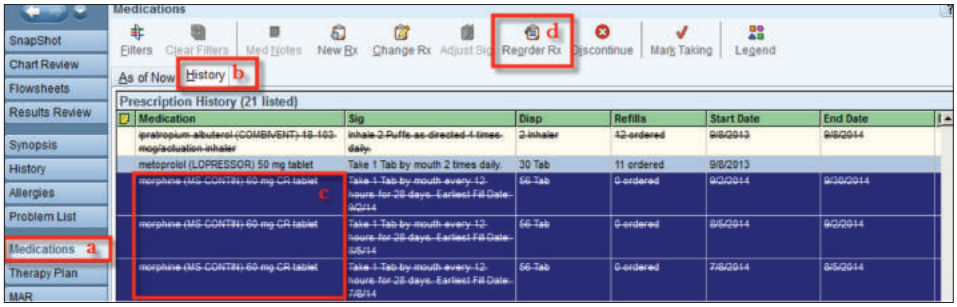


- The temperature strips are not light sensitive.
- The temperature strip reads the temperature of the liquid directly behind the strip, so the **minimum fill level is just over the top of the strip.**
- Read the temperature strip **between 2 to 4 minutes** after the sample is collected.
- Green color indicates temperature. The display is reading 96°F/36°C.
- Record urine temperature in <u>whole numbers</u> on the transmittal slip within <u>4 minutes of collection,.</u>
- Temperature should read between 90°F/32°C and 100°F/38°C.

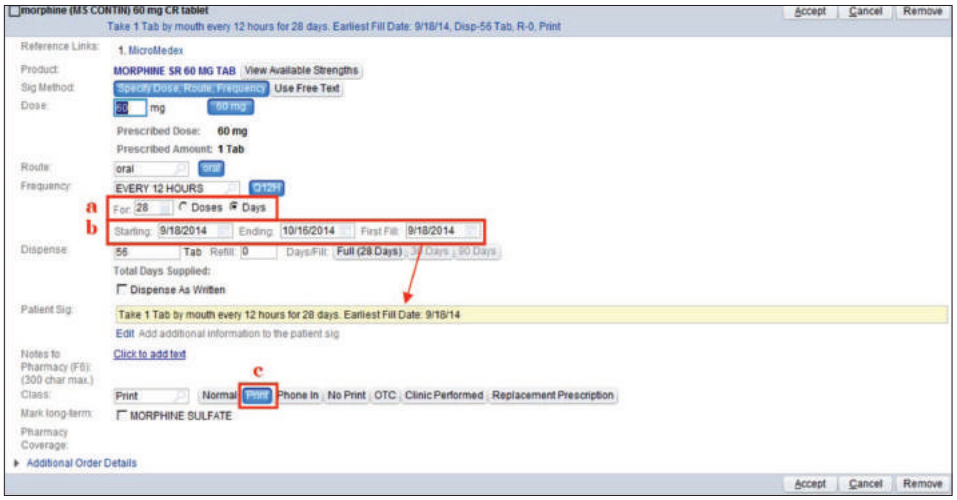
Appendix W

Tip Sheet for Reordering Controlled Substances

1. To re-order the prescription for controlled substances, perform the following steps:
   a. Open Medication Activity in the far left hand column.
   b. Click the "History" tab.
   c. Hold the Ctrl key down and select the three scripts to refill.
      - Ensure that the highlighted medications have a strikethrough, indicating they are inactive medications
      - If a medication you have selected has previously been discontinued, you will likely encounter a BPA. If the medication was discontinued due to an error, select an alternate past prescription to highlight and reorder.
   d. Click on Reorder Rx button. This will bring you to the Order Entry activity.



2. Once in the Order Entry activity, open a prescription by clicking on the entry.
   Review the following and adjust as needed:
   a. The "For" field: Prescriptions should be written in increments of 7 to prevent weekend refill requests (7, 14, 21 or 28 days). Populating this field will help to automatically calculate the prescription Ending Date.
   b. The Starting, Ending and First Fill Dates: It is recommended that the First Fill Date be the same as Start Date. However, the prescription may be refilled up to 72 hours prior to start date per provider discretion. The date entered will display as "Earliest Fill Date" at the end of the "Patient Sig" on the printed prescription.
   c. The order Class: This will typically be set to Print, unless the prescription is being written as a replacement prescription (see #5 below).



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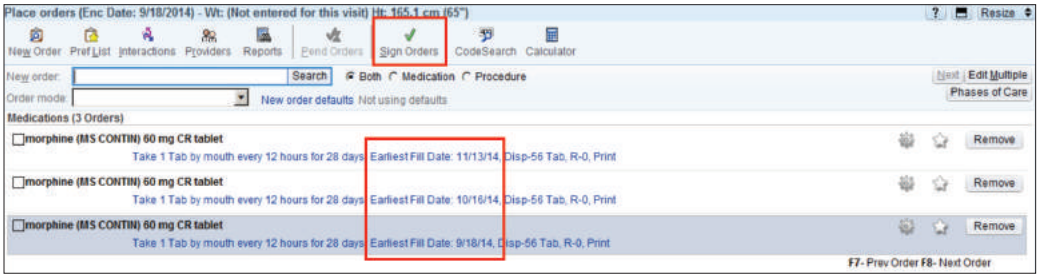
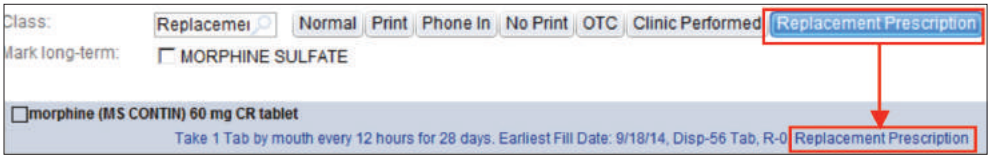
Appendix W

3. Complete this review and adjustment for each medication. Use the Ending Date on the first prescription as the Starting Date for the second prescription. Use the Ending Date on the second prescription as the Starting Date for the third prescription. The result will be three consecutive months of prescriptions:



4. Once all three prescriptions have been reviewed for accuracy, click Sign Orders. Note: Clinical Staff may pend medication refills with the direction of the provider.

5. For prescriptions written as replacements due to loss or theft of medication or prescription, "Replacement Prescription" will be selected as the order Class, and the language will automatically display on the printed prescription. A VPMS query should be completed prior to providing a replacement prescription.



Dartmouth-Hitchcock Medical Center Adult Chronic Opioid Therapy Pain Management Plan

The purpose of this plan is to protect our patients' access to and our clinicians' ability to safely prescribe controlled substances for chronic nonterminal pain.

Patient Name A#

I understand and agree to follow the DHMC policies regarding the use of controlled substances for management of chronic pain as set forth below. I understand that DHMC is under no obligation to prescribe these medications for me. I also understand that there are other treatment options available and the risks and benefits of these alternatives have been discussed.

RISKS OF OPIOID MEDICATION FOR CHRONIC PAIN
I understand that these medications have potential risks, the most significant being:

1. **Physical dependence** means that abrupt discontinuation of the opioid medication could lead to withdrawal symptoms such as abdominal cramping, diarrhea, anxiety, seizures, and death.
2. **Psychological dependence or addiction** means that your behavior may become focused on obtaining opioid medication. Addiction is the use of a medicine even if it causes harm, having cravings for a drug, and the need to use a drug despite suffering harm and a decreased quality of life while using the drug.
3. **Overdose** of the opioid medication may lead to respiratory arrest and death. This risk is increased if opioids are used with alcohol or other sedating substances.
4. **This class of drugs may cause** confusion, sedation, drowsiness, problems with coordination, changes in thinking ability, nausea, constipation, unsteadiness, problems urinating, depression, sexual dysfunction in both men and women, allergic reaction, slowing of reflexes or reaction time, and tolerance to pain relief. It may be unsafe for you to drive a vehicle, operate hazardous equipment, work at unprotected heights, be responsible for another individual who is unable to care for him or herself, or do other dangerous activities while using these medicines.

Under NH State Law, Title XXI Motor Vehicles, Chapter 265-A:2: No person shall drive or attempt to drive a vehicle upon any way or operate or attempt to operate an OHRV while such person is under the influence of intoxicating liquor or any controlled drug or any combination of intoxicating liquor and controlled drugs. In NH this may be grounds for prosecution of a DWI offense. This may be true for other states as well.

(**males only**) Chronic opioid use has been associated with low testosterone levels in males. This may affect mood, stamina, sexual desire and physical and sexual performance. Your clinician may check your blood to see if your testosterone level is normal.

(**females only**) If you plan to become pregnant or become pregnant while taking this pain medicine, you should immediately call your obstetric provider and this office to inform us. Opioids are not generally associated with a risk of birth defects. However, birth defects can occur whether or not the mother is on medicines and there is always the possibility that your child will have a birth defect while you are taking an opioid. If you carry a baby to delivery while taking these medicines, the baby will be physically dependent upon opioids.

CONDITIONS OF CONTRACT
1. I have told my clinician my complete and honest personal drug history and relevant elements of my family's history of drug use. I am not involved in the use, sale, possession, diversion, or transport of controlled substances (narcotics and/or illegal drugs).
2. Treatment with opioids is started as a trial and continued treatment is contingent on evidence of benefit. Benefit may not be limited to pain relief and may include improvement in function.
3. If it appears to my clinician that there are no demonstrable benefits in daily function from the opioid medication, or that addiction, rapid loss of effect, or significant side effects are developing, I agree to gradually taper my medication as prescribed. If a substance abuse problem is suspected, I will be referred for evaluation and management of the problem.

APPENDIX K: Dartmouth-Hitchcock Medical Center Adult Chronic Opioid Therapy Pain Management Plan

4. Prescriptions and bottles of these medications may be sought by other individuals. It is expected that I will take the highest possible degree of care to protect my medication and prescriptions. I understand they should not be left where others may see or otherwise have access to them. This may mean keeping them in a locked container.
5. I understand that if responsible legal authorities have questions concerning my treatment, as might occur, for example, if one were obtaining medications from several clinicians, all confidentiality is waived and these authorities may be given full access to my prescribing clinician's records of controlled substance administration. I also understand that any information, indicating I am engaged in an illegal drug-related activity, may be forwarded to the appropriate law enforcement agency.
6. For purposes of maintaining accountability, my prescribing clinician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide my health care. I agree to use one pharmacy to obtain my opioid prescriptions.
7. I agree to come to my scheduled appointments prepared to provide a urine sample to assess compliance with my treatment plan. I understand that results inconsistent with reported use of drugs might necessitate termination of opioid treatment and referral for assessment for addictive disorder.
8. I understand that chronic pain represents a complex problem that benefits from injections and operations, physical therapy, psychotherapy, and behavioral medicine strategies. I recognize that my active participation in the management of my pain is extremely important to improve my functioning and ability to cope. I agree to actively participate in important aspects of treatment recommended by my clinician and will provide documentation of compliance if requested. I agree to see other health care providers for evaluation and treatment of related and other medical conditions if my clinician thinks it is necessary.
9. Except in cases of an emergency, I agree to receive opioid medication only from the clinician whose signature appears below, or during his or her absence from the covering clinician and not from any other source unless specific authorization is obtained for an exception.
10. I agree to use the opioid medication only as prescribed to me and will not take more medication than instructed. I agree to not allow other individuals to take my medication nor will I take medication prescribed for another person.

I understand I will not receive additional opioid medication outside the plan set forth by my prescribing clinician. It is my responsibility to ensure that my supply will cover the time period between scheduled prescription renewals.

I understand that State law provides that it shall be unlawful for any person to knowingly acquire, obtain possession of or attempt to acquire or obtain possession of a controlled drug by misrepresentation, fraud, forgery, deception or subterfuge. This prohibition includes the situation in which a person independently consults two or more practitioners solely to obtain additional controlled drugs or prescriptions for controlled drugs.

I agree that changes in my prescriptions, including dose adjustments and new medication, will be made only during scheduled office visits and not over the phone or during unscheduled visits. Telephone calls regarding opioid medication should, except in exceptional circumstances, be limited to reports of significant side effects necessitating decreasing or stopping the medication. Lost or stolen medication will be replaced at the discretion of the clinician.

I understand any violation of this agreement poses a health risk and may result in a discontinuation of controlled substance treatment, or tapering the medication dose if deemed medically necessary. I also understand that, based on the clinical judgment of my clinician, treatment with opioid medication may be discontinued at any time.

I have read this document or have had it read to me. I understand all of it. I have had all questions regarding risks and conditions answered satisfactorily, and I agree to abide by all conditions of this controlled substance agreement. By signing this form voluntarily, I give my consent for the treatment of my pain with opioid pain medicines.

Patient	Signature	Date
Clinician	Signature	Date

Informed Consent and Agreement for Opioid Therapy of Pain

Reason for Review and Signing of this Document
Pain relief is an important goal for your care. Opioid medications may be a helpful part of chronic pain treatment for some people; however, misuse of opioid medications may result in serious harm to patients prescribed them and, when the medications are diverted, to the public at large. As opioid use for pain management has increased in recent years, injury, addiction, and death due to misuse of opioids have also increased.

Patients and health care providers both have responsibilities for the safe use of opioid medications when they are prescribed for pain. This agreement provides important information on the potential benefits and risks of opioid medications and serves to document that both you and your provider agree on a care plan so that opioid medications are used in a way that is safe and effective in treating your pain. This agreement is reviewed and signed by all patients in our practice who receive opioids for chronic pain.

Expected Benefits or Goals of Opioid Treatment
Common goals in using opioids to treat pain include:
• Improved pain
• Improved ability to engage in work, social, recreational and/or physical activities
• Improved quality of life
Your provider may discuss more specific goals for pain treatment with you as well. Goals:

_____

_____

_____

Potential Risks or Side Effects of Opioid Treatment
Physical side effects: May include mood changes, drowsiness, nausea, constipation, urination difficulties, depressed breathing, itching, bone thinning and sexual difficulties, such as lowering of male hormone in men and cessation of menstrual periods in women.

Physical dependence: Sudden stopping of an opioid may lead to withdrawal symptoms including abdominal cramping, pain, diarrhea, sweating, anxiety, irritability and aching.

Tolerance: A dose of an opioid may become less effective over time even though there is no change in your physical condition. If this happens repeatedly, your medication may need to be changed or discontinued.

Addiction: Is more common in people with personal or family history of addiction, but can occur in anyone. It is suggested by drug craving, loss of control and poor outcomes of use.

Hyperalgesia: Increased sensitivity to and/or increasing experience of pain caused by the use of opioids may require change or discontinuation of medication.

Overdose: Taking more than the prescribed amount of medication or using with alcohol or other drugs can cause you to stop breathing resulting in coma, brain damage, or even death.

Sleep apnea: *(periods of not breathing while asleep)* may be caused or worsened by opioids.

Risk to unborn child: Risks to unborn children may include: physical dependence at birth, possible alterations in pain perception, possible increased risk for development of addiction, among others. *Tell your provider if you are or intend to become pregnant*.

Victimization: There is a risk that you or your household may be subject to theft, deceit, assault or abuse by persons seeking to obtain your medications for purposes of misuse.

Life-threatening irregular heartbeat: Can occur with methadone, EKG may be needed.

APPENDIX L: New Hampshire Medical Society, Informed Consent and Treatment Agreement

Responsibilities in Opioid Therapy of Chronic Pain

Your provider's responsibilities include: listening carefully to your concerns, treating you with care and with due respect, and making clinical decisions based on what he/she believes is in your best interest.

Your responsibilities: In order to maximize the potential benefits of opioid medications and to minimize the potential risks, it is important that you accept the following responsibilities. In signing this agreement, *you agree to*:

1. **Use your opioid medications as prescribed** for the purpose of relieving pain
2. **Keep your medications locked up** to avoid intentional or unintentional use or diversion by others. **Discard** all unused medications.
3. **Be honest** with your providers about your medication or other drug use.
4. **Use no illegal drugs and not abuse alcohol** while being prescribed opioids.
5. **Not share, sell, trade or in any way provide your medications to others**.
6. **Receive opioid medications from this practice only**. If opioids are prescribed unexpectedly by another office (for example due to an accident or dental procedure), inform this office within 24 hours.
7. **Fill your opioid medications at one pharmacy only**. Inform this practice within 24 hours if you must use a pharmacy different from your usual one.
8. **Have urine drugs tests on a random basis and as requested by your provider**. (Opioid may be discontinued if illicit drugs found or medication not present when it should be.)
9. **Bring your opioid medications** to the practice when requested.
10. **Participate in other pain treatments** agreed to with your provider and **keep all appointments** scheduled for your care.
11. **Permit this practice to communicate with other care providers and/or your significant others** as needed to assure opioids are being used appropriately and are beneficial to your health and well-being

Your medications may be continued if they improve your pain, help you engage in valued activities, and/or enhance your quality of life and if you adhere to the above responsibilities. They may be discontinued if your goals for treatment are not met, if you experience negative effects from using them, or if you do not adhere to this agreement.

If you develop complications of opioid use, such as addiction, we will assist you in finding treatment. Please be aware, however, that our practice cooperates fully with law enforcement, the US Drug Enforcement Agency and other agencies in the investigation of opioid-related crimes including sharing, selling, trading or other potential harmful use of these powerful medications.

Consent to treatment and agreement to responsibilities outlined above
I have reviewed this document and been given the opportunity to have any questions answered. I understand the possible benefits and risks of opioid medications and I accept the responsibilities described above.

Patient Name _____ Date _____

Healthcare Staff _____ Date _____

Seddon R. Savage, MD, MS

Opioid Risk Tool

Patient _____ Date _____

			Female Score	Male Score
Instructions: *Mark each box that applies*				
1. Family History of Substance Abuse	Alcohol	☐	1	3
	Illegal Drugs	☐	2	3
	Prescription Drugs	☐	4	4
2. Personal History of Substance Abuse	Alcohol	☐	3	3
	Illegal Drugs	☐	4	4
	Prescription Drugs	☐	5	5
3. Age (Mark box if 16-45)		☐	1	1
4. History of Preadolescent Sexual Abuse		☐	3	0
5. Psychological Disease (Any one of)	Attention Deficit Disorder Obsessive Compulsive Disorder Bipolar Schizophrenia	☐	2	2
	Depression	☐	1	1
	Total		_____	_____

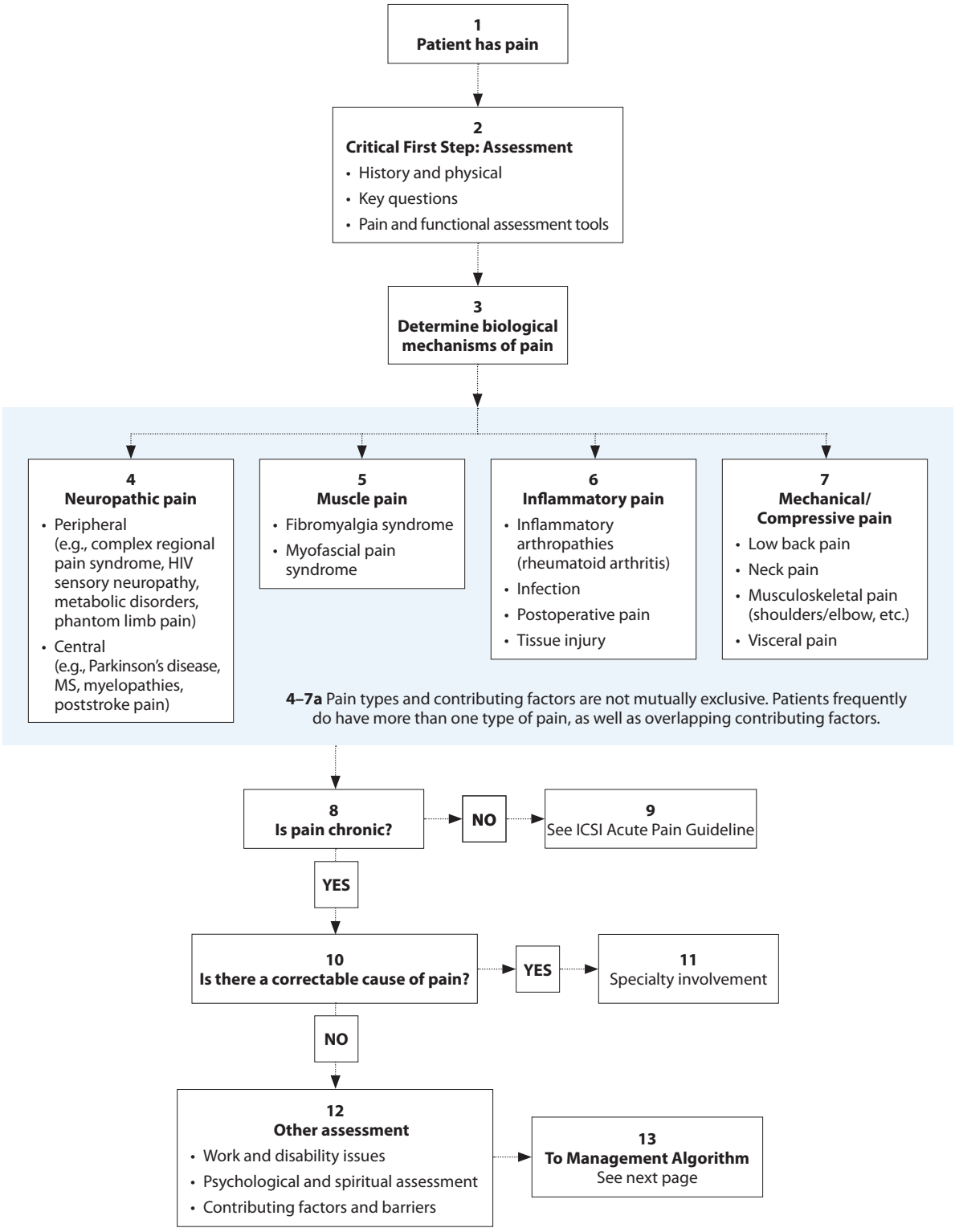
Total Score Risk Category

Low Risk	0–3
Moderate Risk	4–7
High Risk	≥8

Reference: Webster LR. Predicting aberrant behaviors in opioid-treated patients: Preliminary validation of the opioid risk tool. Pain Medicine. 2005;6(6):432-442. Used with permission.

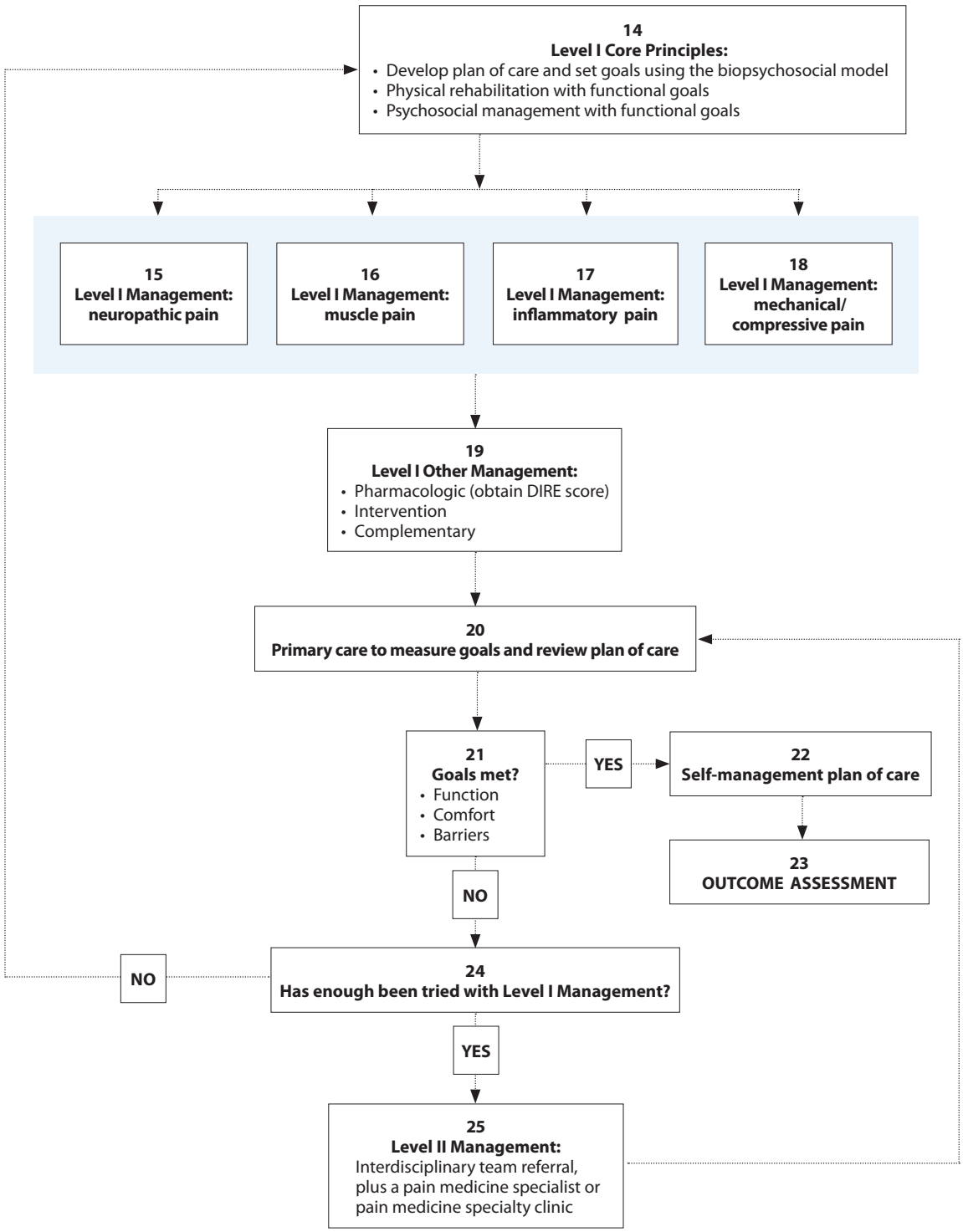
Implementation Tool: Assessment and Management of Chronic Pain Guideline Summary

Assessment Algorithm



Implementation Tool: Assessment and Management of Chronic Pain Guideline Summary

Management Algorithm



Implementation Tool: Assessment and Management of Chronic Pain Guideline Summary

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.

- See ICSI Chronic Pain Guideline, Appendix A, "Brief Pain Inventory."
- See ICSI Chronic Pain Guideline, Annotation #12, "Other Assessment," for example of questions regarding behavioral health, chemical health, spirituality and occupational health.

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.

- A variety of assessment tools have been used in the medical literature for measuring, estimating or describing aspects of a patient's functional ability. See ICSI Chronic Pain Guideline, Appendix C, for an example.

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.
- See ICSI Chronic Pain Guideline, Appendix D, "Personal Care Plan for Chronic Pain."

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 aberrant 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.

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 consultant 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 a 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.
- 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. See ICSI Chronic Pain Guideline Appendix E, "DIRE Score: Patient Selection for Chronic Opioid Analgesia."

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.

Implementation Tool: Assessment and Management of Chronic Pain Guideline Summary

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

Implementation Tool: Assessment and Management of Chronic Pain Guideline Summary

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.

Score	Factor	Explanation
	DIAGNOSIS	1 = Benign chronic condition with minimal objective findings or no definite medical diagnosis. Examples: fibromyalgia, migraine headaches, non-specific back pain.
		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.
		3 = Advanced condition concordant with severe pain with objective findings. Examples: severe ischemic vascular disease, advanced neuropathy, severe spinal stenosis.
	INTRACTABILITY	1 = Few therapies have been tried and the patient takes a passive role in his/her pain management process.
		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).
		3 = Patient fully engaged in a spectrum of appropriate treatments but with inadequate response.
	RISK	(R= Total of P+C+R+S below)
	Psychological	1 = Serious personality dysfunction or mental illness interfering with care. Example: personality disorder, severe affective disorder, significant personality issues.
		2 = Personality or mental health interferes moderately. Example: depression or anxiety disorder.
		3 = Good communication with clinic. No significant personality dysfunction or mental illness.
	Chemical Health	1 = Active or very recent use of illicit drugs, excessive alcohol, or prescription drug abuse.
		2 = Chemical coper (uses medications to cope with stress) or history of CD in remission.
		3 = No CD history. Not drug focused or chemically reliant.
	Reliability	1 = History of numerous problems: medication misuse, missed appointments, rarely follows through.
		2 = Occasional difficulties with compliance, but generally reliable.
		3 = Highly reliable patient with meds, appointments & treatment.
	Social Support	1 = Life in chaos. Little family support and few close relationships. Loss of most normal life roles.
		2 = Reduction in some relationships and life roles.
		3 = Supportive family/close relationships. Involved in work or school and no social isolation.
	EFFICACY SCORE	1 = Poor function or minimal pain relief despite moderate to high doses.
		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).
		3 = Good improvement in pain and function and quality of life with stable doses over time.
		Total score = D + I + R + E

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

Used with permission by Miles J. Belgade, MD

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?

- ☐ 1 no pain
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 8
- ☐ 9
- ☐ 10 pain as bad as you can imagine

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

- ☐ 1 no pain
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 8
- ☐ 9
- ☐ 10 pain as bad as you can imagine

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

- ☐ 1 no pain
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5
- ☐ 6
- ☐ 7
- ☐ 8
- ☐ 9
- ☐ 10 pain as bad as you can imagine

From Krebs et al., 2009

RAPID3
ROUTINE ASSESSMENT OF PATIENT INDEX DATA

The RAPID3 includes a subset of core variables found in the Multi-dimensional 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. PLEASE CHECK THE ONE BEST ANSWER FOR YOUR ABILITIES AT THIS TIME:

OVER THE LAST WEEK, WERE YOU ABLE TO:	WITHOUT ANY DIFFICULTY	WITH SOME DIFFICULTY	WITH MUCH DIFFICULTY	UNABLE TO DO
a. Dress yourself, including tying shoelaces and doing buttons?	___ 0	___ 1	___ 2	___ 3
b. Get in and out of bed?	___ 0	___ 1	___ 2	___ 3
c. Lift a full cup or glass to your mouth?	___ 0	___ 1	___ 2	___ 3
d. Walk outdoors on flat ground?	___ 0	___ 1	___ 2	___ 3
e. Wash and dry your entire body?	___ 0	___ 1	___ 2	___ 3
f. Bend down to pick up clothing from the floor?	___ 0	___ 1	___ 2	___ 3
g. Turn regular faucets on and off?	___ 0	___ 1	___ 2	___ 3
h. Get in and out of a car, bus, train, or airplane?	___ 0	___ 1	___ 2	___ 3
i. Walk two miles or three kilometers, if you wish?	___ 0	___ 1	___ 2	___ 3
j. Participate in recreational activities and sports as you would like, if you wish?	___ 0	___ 1	___ 2	___ 3
k. Get a good night's sleep?	___ 0	___ 1.1	___ 2.2	___ 3.3
l. Deal with feelings of anxiety or being nervous?	___ 0	___ 1.1	___ 2.2	___ 3.3
m. Deal with feelings of depression or feeling blue?	___ 0	___ 1.1	___ 2.2	___ 3.3

1. a-j FN (0-10):

1=0.3 16=5.3
2=0.7 17=5.7
3=1.0 18=6.0
4=1.3 19=6.3
5=1.7 20=6.7
6=2.0 21=7.0
7=2.3 22=7.3
8=2.7 23=7.7
9=3.0 24=8.0
10=3.3 25=8.3
11=3.7 26=8.7
12=4.0 27=9.0
13=4.3 28=9.3
14=4.7 29=9.7
15=5.0 30=10

2. PN (0-10):

3. PTGE (0-10):

RAPID3 (0-30)

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

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

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

0 0.5 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

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
High Severity (HS): 13=4.3; 14=4.7; 15=5.0; 16=5.3; 17=5.7; 18=6.0; 19=6.3; 20=6.7; 21=7.0; 22=7.3; 23=7.7; 24=8.0; 25=8.3; 26=8.7; 27=9.0; 28=9.3; 29=9.7; 30=10.0

HOW TO CALCULATE RAPID 3 SCORES

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 formal score (0-10). For example, a patient whose answers total 19 would score a 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 RAPID 3 cumulative score. Use the final conversion table to simplify the patient's weighed RAPID 3 score. For example, a patient who scores 11 on the cumulative RAPID 3 scale would score a weighed 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).

RAPID3 EXAMPLE

ROUTINE ASSESSMENT OF PATIENT INDEX DATA

The RAPID includes a subset of core variables found in the Multi-dimensional 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). RAPID scores are quickly tallied by adding subsets of the MD-HAQ as follows:

1. PLEASE CHECK THE ONE BEST ANSWER FOR YOUR ABILITIES AT THIS TIME:

OVER THE LAST WEEK, WERE YOU ABLE TO:	WITHOUT ANY DIFFICULTY	WITH SOME DIFFICULTY	WITH MUCH DIFFICULTY	UNABLE TO DO
a. Dress yourself, including tying shoelaces and doing buttons?	X 0	1	2	3
b. Get in and out of bed?	0	X 1	2	3
c. Lift a full cup or glass to your mouth?	0	1	2	X 3
d. Walk outdoors on flat ground?	X 0	1	2	3
e. Wash and dry your entire body?	X 0	1	2	3
f. Bend down to pick up clothing from the floor?	0	X 1	2	3
g. Turn regular faucets on and off?	0	1	X 2	3
h. Get in and out of a car, bus, train, or airplane?	0	1	X 2	3
i. Walk two miles or three kilometers, if you wish?	0	X 1	2	3
j. Participate in recreational activities and sports as you would like, if you wish?	0	X 1	2	3
k. Get a good night's sleep?	X 0	1.1	2.2	3.3
l. Deal with feelings of anxiety or being nervous?	0	1.1	2.2	X 3.3
m. Deal with feelings of depression or feeling blue?	0	1.1	X 2.2	3.3

1. a-j FN (0-10): 3.7

1=0.3 16=5.3
2=0.7 17=5.7
3=1.0 18=6.0
4=1.3 19=6.3
5=1.7 20=6.7
6=2.0 21=7.0
7=2.3 22=7.3
8=2.7 23=7.7
9=3.0 24=8.0
10=3.3 25=8.3
11=3.7 26=8.7
12=4.0 27=9.0
13=4.3 28=9.3
14=4.7 29=9.7
15=5.0 30=10

2. PN (0-10): 2.5

3. PTGE (0-10): 1.0

RAPID3 (0-30) 7.2

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

0 0.5 1.0 1.5 2.0 **X** 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

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

0 0.5 **X** 1.0 1.5 2.0 2.5 3.0 3.5 4.0 4.5 5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 9.0 9.5 10

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
High Severity (HS): 13=4.3; 14=4.7; 15=5.0; 16=5.3; 17=5.7; 18=6.0; 19=6.3; 20=6.7; 21=7.0; 22=7.3; 23=7.7; 24=8.0; 25=8.3; 26=8.7; 27=9.0; 28=9.3; 29=9.7; 30=10.0

HOW TO CALCULATE RAPID 3 SCORES

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 formal score (0-10). For example, a patient whose answers total 19 would score a 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 RAPID 3 cumulative score. Use the final conversion table to simplify the patient's weighed RAPID 3 score. For example, a patient who scores 11 on the cumulative RAPID 3 scale would score a weighed 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).

Opioid Prescription Management Project

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.

What	Who	By When	Outcome & Next Step
NEW FLOW OF WORK			
(list selected strategies)			
MEASURES TO TRACK			
(based on selected strategies)			

O

APPENDIX O: Implementation Plan Sample

Opioid Prescription Management Project

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.

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

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