

Sample Policies

Chronic Pain Management Policies in Five Settings

5/2/2013

San Francisco Safety Net Pain Education Day
Finding Common Ground in the Gray Zones

Table of Contents

COPC Chronic Pain Policy	2
Southeast Health Center Pain Policy	4
SFGH Primary Care Clinics Chronic Pain Policy	14
Family Health Center Pain Policy	16
Potrero Hill Health Center DRAFT Policy	33
Central City Old Town Clinic Pain Policy	51
California Medical Board Guidelines	69

USE OF CONTROLLED SUBSTANCES IN CHRONIC PAIN MANAGEMENT

1. Purpose:

The purpose of this policy is to define minimum standards for the use of controlled substances in chronic pain management within the Community Health Network (CHN) - Community Oriented Primary Care (COPC) clinics. This document outlines the procedure by which clinics assess chronic pain, develop and monitor individualized treatment plans and document pain management in the medical record that include the use of controlled substances.

2. Statement Of Policy:

I. **It is the** policy of COPC that all that all providers follow an approach to the use of controlled substance in chronic pain management that:

- A. conforms to standards of practice set by the Medical, Nursing and Pharmacy Boards of California
- B. promotes the safe, adequate, appropriate and effective management of chronic pain that optimizes patients' functional status, addresses the risks, benefits and side effects of therapy and attempts to minimize patient misuse of prescribed medications;
- C. facilitates sharing of information and coordination of care of patients with chronic pain within the CHN and with other safety net sites (e.g., the San Francisco Community Clinic Consortium (SFCCC) through the use of a shared electronic medical record (EMR);

3. Procedure:

I. Initial Pain Assessment- Providers will perform and document an initial comprehensive biopsychosocial pain assessment that follows Medical Board of California guidelines. The evaluation should include:

- A. Assessment of the pain and any prior diagnostic evaluation
- B. Impact of pain on physical and psychological functioning
- C. history of prior pain treatment
- D. assessment of coexisting medical and/or mental health conditions
- E. substance use history
- F. documentation of the presence of one or more recognized medical indications for the use of a controlled substance
- G. relevant physical exam, including musculoskeletal and neurologic exam if indicated

II. **Treatment Plan Objectives-** Providers will design and document an individualized treatment plan in consultation with the patient that outlines:

- A. Any planned diagnostic evaluations and/or specialty consultation (including mental health referral)
- B. Any and all prescribed therapeutic modalities (e.g., medications, physical therapy, acupuncture)
- C. Treatment goals by which the plan will be evaluated, such as level of pain relief, improved physical and psychosocial functioning and/or improved quality of life

III. **Informed Consent**- Providers will document their discussion with the patient of the risks, benefits and side effects of prescribed treatment(s) and how these issues will be monitored and addressed.

IV. **Pain Management Agreement**- Providers will complete and include in the medical record a pain management agreement that is signed by the provider and the patient that outlines components of the treatment plan and situations in which the plan may be reviewed, altered or discontinued.

V. **Periodic Review**- Providers will perform and document a periodic reassessment of chronic pain that focuses on the patient's progress toward the Treatment Plan Objectives (see above) on an annual basis (or more frequently as deemed necessary by the provider) to determine the appropriateness, continuation or modification of the treatment plan.

VI. **Documentation in the Electronic Medical Record (EMR)** - Providers will use the EMR to:

A. Keep an up-to-date medication list that includes all current and previously prescribed medications noting the reason(s) for medication changes and discontinuations

B. Enter a clinical alert in the EMR that indicates that a pain management agreement has been signed and that current and previously prescribed pain medications are documented in the medication list in the EMR (this may include any special circumstances or considerations regarding the patient's pain management history and/or treatment plan)

C. Form: COPC will disseminate template forms that outline the minimum standards for executing Initial Pain Assessment, Treatment Plan Objectives, Informed Consent, Pain Management Agreement and Periodic Review. Clinics may adopt these forms as is or adapt them to suit site-specific purposes as long as the revisions preserve the minimum standards set out in the templates.

VII. **Site specific policy**- Each COPC site will develop individualized policies and procedures as appropriate to address:

A. Creation and maintenance of chronic pain registries

B. Monitoring for patient misuse of controlled substances that may include the use of urine toxicology screening and/or prescription monitoring programs (e.g., CURES reports)

C. Situations or conditions that constitute grounds for suspension or termination of the pain management agreement (i.e., "contract breaks")

4. Signed by:

Michael Drennan, MD, Medical Director, Primary Care Service; Barbara Garcia, MPA, Deputy Director, SFDPH; Sheila Kerr, RN, MS, Nursing Director, Primary Care Service

5. Approval date:

This policy was originally approved by Primary Care Quality Improvement Committee on October 16, 2009

Southeast Health Center Chronic Pain Management Protocols

Version 2/19/2013

Table of Contents

Chronic Pain Management at Southeast H.C. Protocols	page 3-6
Ground rules	page 7
SEHC Patient Care Agreement Breaks	page 8
Recognition and response to abnormal medication taking behaviors	page 7-9
Annual assessment and documentation of agreement breaks	page 10-11

Chronic Pain Management Protocols at Southeast Health Center

Version 2/19/2013

At our last provider meeting we discussed chronic pain management and we agreed that it would be beneficial to have a standardized protocol that all providers would agree to sign. We acknowledge that at times situations may arise which are in conflict with the policy, in these situations, which should be infrequent; the provider may use their clinical judgment in regard to prescribing a controlled substance. The rationale for the exemption to the policy must be documented on a flow sheet attached to the agreement and assessment pages. The number of policy breaks will be periodically audited and should be taken into consideration on whether or not to continue opiates.

Patients who are included in this protocol are those who are chronically (> 3months) taking > 60 tabs of acetaminophen with codeine or hydrocodone, or any controlled prescriptions requiring a secure rx. Patients with acute pain or pain associated with a terminal illness are exempt.

Basic Elements. All chronic pain patients need the following:

- Be entered into the chronic pain registry, enter 338.99 into LCR problem list
- Have a signed pain agreement and informed consent annually
- Have a clinical alert placed in the LCR under controlled substance agreement
- Have an annual assessment/plan of their pain with emphasis on their functional status, quality of life. Multiple modalities of pain relief should be utilized, including non-opiate medications, alternative measures like acupuncture, mindfulness meditation, physical therapy, pain groups, specialty management like nerve blocks, mental health assessment and treatment, surgery, etc.
- Urine toxicology testing within the first month of opiate prescribing and annually, more frequently as determined by the provider
- Every controlled rx must be entered into the electronic medical record
- Quarterly i2i registry report to the provider and an annual yellow flag committee review of patients with urine toxicology indicating substance use, patients with concerning behaviors, and those on high dose opiates (>200 mg of morphine equivalent per day).

New opiate prescriptions

The provider must do an appropriate assessment before prescribing. It includes a history, indication for pain meds, a targeted physical exam, a review of available records and a discussion of the risks and benefits of opiate pain medication. If the patient is new to the clinic and there are not available records, the patient will have a responsibility to obtain records documenting the need for continued opiates. It is recommended that the provider review a DOJ CURES report. The patient will sign a release to obtain prior records. Patients with clear documentation from hospital discharge or jail/prison release may receive a limited refill supply until a more thorough assessment can be accomplished. A patient should have utox sent within 1 month and as a minimum, annually.

Refill Policy

As a rule no refills are given for lost or stolen medications. This is in the pain agreement and informed consent the patients sign. We acknowledge that at times situations may arise with are in conflict with the policy, in these situations, which should be infrequent; the provider may use their clinical judgment in regard to prescribing a controlled substance. The rationale for the exemption to the policy must be documented on a flow sheet attached to the agreement and assessment pages. The number of policy breaks will be periodically audited and should be taken into consideration on whether or not to continue opiates. By having a designated place to log exemptions and agreement breaks, it is clear if this is a onetime event or a series of events.

Management of abnormal urine toxicology reports

All patients will do a urine toxicology test within 1 month of starting opiates and at least once yearly. They will be performed more often at the providers request when concerning behaviors have occurred. Interpretation of abnormal results should be standardized. Any exemptions need to be documented on the flow sheet and explained. I2i will be used to track abnormal utox results

See Abnormal Utox Algorithm and action.

Concerning Behaviors

All providers agree on what defines a high priority concerning behavior.

- Repeated lost or stolen medications
- Repeated requests for early refills
- Missing appts with provider
- Presenting in clinic intoxicated
- History of overdose of controlled substances
- Not adhering to the treatment plan
- Toxicology is refused or altered
- Forgery of controlled substance rx
- Abusive or threatening behavior towards staff
- Urine tox tests showing illicit substances or unprescribed medications or does not show the prescribed medications.

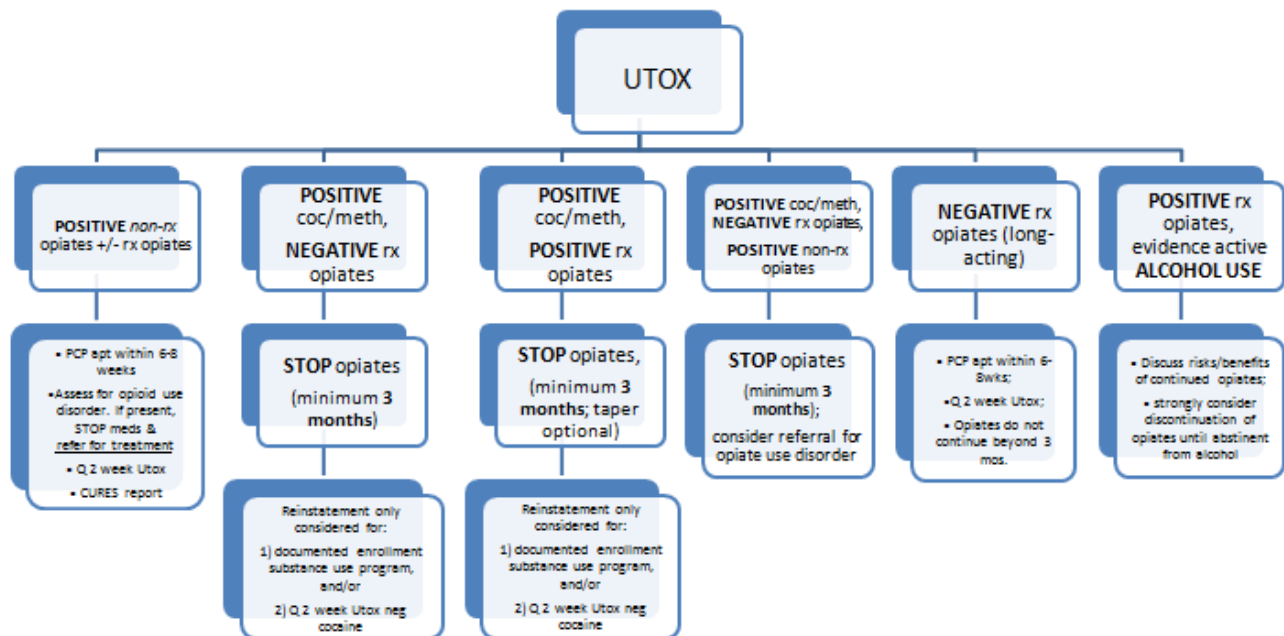
Any one of the above is grounds for stopping opiate prescribing. The provider will document their action on the flow sheet and the chart should be given to the medical director or their designee. Alternatively the provider may seek consultation with the medical director or peer in formulating a plan. Treating clinicians must use sound clinical judgment in the prescription of all medications. Nothing in this protocol should be construed as requiring a clinician to continue to prescribe a medication that is contraindicated or no longer indicated, for whatever reason.

Tools for Chronic Pain Management

- I2i registry and quarterly reports
- Annual yellow flag committee review
- Annual audit of registry charts
- Use of in clinic and community resources for substance use and counseling
- Chronic pain registry
- Annual agreement and informed consent
- Annual assessment
- Urine toxicology testing

Abnormal Utox Algorithm:

Key: **coc/meth** = cocaine and/or methamphetamine positive Utox; **rx opiates** = prescribed opiates; **non-rx opiates** = non-prescribed opiates



SEHC Ground-rules—Chronic Controlled Meds

1. Yellow flag behaviors will be documented behind the annual assessment and referred for peer review.
2. Red flag behaviors will be documented behind the annual assessment, referred for peer review and should in almost all cases lead to termination of opiate prescription.
3. Minor Contract Breaks will be documented behind the annual assessment#
 - a. With date and reason
 - b. i.e. Missed Appointments
 - c. >3 minor breaks (in <12months)→taper off controlled meds
 - i. Reevaluation in 3 months
4. Major Contract Breaks will be documented behind the annual assessment#
 - a. i.e. Lost/stolen meds
 - b. ≥3 major breaks→taper off controlled meds (or simply do not fill if appropriate)
 - i. Reevaluation tbd
5. Urine Toxicology at 1 month after initiation and at least once yearly and strongly recommend at initiation of opiates
6. Up to 3 months of prescriptions for stable patients
7. Patient Care Agreement and informed consent annually
 - a. Give copy of agreement and informed consent to patient
8. Annual treatment plan/assessment
9. CURES report recommended, but not required on all of these patients
10. Enter patient in chronic pain registry, enter 338.99 into LCR problem list
11. Place clinical alert “controlled substance plan” in LCR or to be determined in eCW.
12. See utox algorithm for action on abnormal urine toxicology results
13. Treating clinicians must use sound clinical judgment in the prescription of all medications.
Nothing in this protocol should be construed as requiring a clinician to continue to prescribe a medication that is contraindicated or no longer indicated, for whatever reason."
14. After you document agreement breaks behind the annual assessment, put the chart in Dan Wlodarczyk's box outside of medical records for peer review.

SEHC PATIENT CARE AGREEMENT BREAKS

*You must log all agreement breaks on the back of the pain assessment form flow sheet.

Minor Contract Breaks

- Patient fills prescriptions at more > 1 pharmacy
- No f/u appointment made as directed by provider
- Misses appointment
- Lack of verifiable documentation of going to a rehab
- Not adhering to plan (PT, psych)
- Requests Early Refill
- Drops in for meds and requests immediate refill (72 hr notice is needed, in general)
- >3 minor break, start discontinuation

Major Contract Breaks

- Urine or serum drug screen is refused
- Loses meds or is stolen
- Drug screen shows no prescribed med (need to be flexible...)
- Request for pill count is refused or pill count discrepancy
- Patient is abusive to staff
- Illegal or non-prescribed substance in urine (Consider standard practice...)
- Controlled meds from another provider
- >2 major breaks, start discontinuation

After 3 minor breaks or any major breaks put the chart in Dan Wlodarczyk's box and it will be distributed for peer review.

SEHC Chronic Pain Protocols: RECOGNITION OF AND RESPONSE TO ABNORMAL MEDICATION TAKING BEHAVIORS

Abnormal medication taking behavior has a differential that includes

- prescription opioid abuse
- inadequately treated pain or progression of chronic pain disease (“pseudoaddiction”)
- diversion (selling rather than taking the prescribed medication)
 - strictly profit motive—may need to address homelessness, joblessness, poverty
 - exchange for other drugs of choice
 - “sharing” with others in need
 - coercion, often in an abusive relationship
- victim of theft, lost medications
- opioid analgesic tolerance
- self-medication of psychiatric and physical symptoms other than pain

It is difficult to distinguish among these possibilities, though *pseudoaddiction resolves as opioid doses are increased and pain is better controlled*. Diversion and opioid abuse continue to escalate in this setting.

Yellow Flags

These are behaviors that might suggest opioid abuse or diversion, but might also be rational and normal responses to undertreated pain or to fear of pain. They have a **low specificity** for abuse and diversion.

- Anger or irritability when questioned closely about pain
- More concern about controlled substance than about the underlying medical problem that persists beyond the first few visits
 - may indicate inadequate treatment of pain
- Report of multiple medication sensitivities
 - may be true, or may be the patients’ way of making sure to get the medications that they know work best for their pain
- Request for specific drugs or refusal to take generic medications
 - may be a truly significant observation by the patient that his/her genes/receptor population can utilize specific opioid more effectively than other opioids
- Unsanctioned dose escalation one or two times
 - may indicate inadequate treatment of pain
- Aggressive complaints about the need for more drug
 - may be a true need for increased dose
- Open acquisition of similar drugs from other medical sources one or two times, e.g. in the ER
 - may indicate inadequate treatment of pain or inadequate coverage of flares
- Drug hoarding during periods of reduced symptoms
 - may indicate unsatisfactory dosing during flares pain and is also a rational response to difficulty scheduling timely appointments and concerns about emergency preparedness.
- Resistance to a change in therapy associated with “tolerable” adverse effects, with expressions of anxiety related to the return of severe symptoms
 - reasonable reaction when patient has experienced increased pain as part of withdrawal

Response: Consider the differential diagnosis. Remember that the goal of therapy is improvement of function and quality of life. If evidence suggests that opioid therapy is contributing to an addiction, then it is not serving the patient’s quality of life or function and should be discontinued.

- Inform the patient of your concern and made a plan to address it.
- The plan can include any of the following:
 - Increased monitoring with increased visit or utox frequency, or a CURES report
 - Discontinuation of controlled substances with a taper.
 - A specific risk minimization plan, such as enrollment in a drug treatment program, weekly dispensing by the pharmacy, or physician collaboration with case managers, mental health providers, hotel staff, family, etc.
- Regardless of the plan for opioid prescription, the patient should be encouraged to continue medical care with the PCP and to continue non-opioid treatments for pain.
- Yellow flags should be documented, included in the annual reassessment, and referred for peer review

Red Flags

- Manipulative or abusive behavior directed at caregivers, including intimidation or coercion, and aimed at acquisition and continuance of the substance abuse
- Urine drug screen negative for the prescribed medication
- Urine drug screen positive for other controlled substances
 - see urine toxicology guidelines for a complete discussion of this issue, as not all positive urine toxicology screens must result in suspension of opioid prescription
- Refusal of diagnostic workup or consultation
- Frequent dose escalations after being told this is inappropriate
- Multiple (>2) episodes of lost or stolen prescriptions or medications
- Prescription forgery
- Stealing drugs from others
- Selling prescription drugs
- Obtaining prescription drugs from non-medical sources
- Injecting, snorting or smoking oral formulations
- Concurrent abuse of alcohol or illicit drugs
 - Some providers will continue to prescribe chronic opioids if the patient provides proof of enrollment in a drug treatment program and subsequent consistently negative urine toxicology screens.
 - In rare cases, the provider may find that that continued opioid prescription will lead to increased function in life rather than decreased function and will continue prescribing opiates despite concurrent abuse of other substances. Patients in whom this strategy is employed require close monitoring and frequent assessment of overall function.
- Repeatedly seeking prescriptions from other clinicians or from ERs without informing the PCP
- Evidence of deterioration in the ability to function at work, in the family, or socially that appears to be related to drug use
- Evidence of loss of control: use of more than intended or for longer than intended or repeated use in unsafe situations

Response: Red flag behaviors strongly suggest addiction or diversion.

- In this setting, the risks of harm from opioid prescription generally outweigh the benefits and it is recommended that opioids be discontinued with a taper.
- In rare cases, the assessment of the treating provider will be that continued prescription in the setting of red flag behaviors is of overall benefit to the patient. This decision is at the discretion of the treating provider but *should be the exception*.
- It is common and natural for PCPs to feel manipulated, betrayed and angry when patients display red flag behaviors. It is important for the PCP to remain in the medical model and stay focused on *minimizing risk of harm and maximizing benefit to the patient* when making decisions regarding opioid prescriptions
- Patients with addictions still require a medical home and medical care, and should be encouraged to continue to see their PCPs for medical visits.
- Red flags should be documented clearly and included in the patient's annual reassessment
- Refer for peer review

Name: _____

MRN: _____

SEHC Annual Pain Assessment

Where is the pain?
 What is it caused by?

How intense is the pain on an average day? 0 1 2 3 4 5 6 7 8 9 10
Mild Mod Severe Worst

What activities are most difficult because of pain? Walking Sitting ADLs _____ Other _____
 What does the pain stop you from doing?

Pick an activity: _____ Change since last yr: I can do __more __less __no change
 Rate your Quality of Life: Poor Fair Good Excellent Why? _____

Psychosocial Health History			
Any use of: Substance	How often?	Plan?	CAGE
Alcohol			
Cocaine			
Other			

Psychosocial Health History (Continued)

In the last 2 weeks, how often have you been bothered by any of the following (0 to 3)?
 0: Not at all 1: Several Days 2: More than half the days 3: Nearly Every Day

Little interest or pleasure in doing things
 Feeling Down, depressed, or hopeless

Physical Exam

Key Physical Findings:

Xrays, imaging, studies pertinent to chronic pain:

Treatment Plan

- U. tox: A/P: _____
- CURES: _____

Include non-pharmacological measures (acupuncture, PT etc, counseling, specialty referral, groups therapy, substance use referral, mental health referral)

Is there concern about opioid use? Yes No If yes: Misuse Tolerance Dependence Toxicity/Side Effects

Patient Goals/Overall Assessment

- Patient Goals _____
- Based on review of this patient’s chronic pain, continued opiates are indicated to improve their function and quality of life and benefits outweigh the risks of opiate treatment.
 - Provider name and date: _____

Patient Care Agreement Breaks/Policy Exemption Flow Sheet

Event Date: _____ Outcome: _____
Comment:

Event Date: _____ Outcome: _____
Comment:

Event Date: _____ Outcome: _____
Comment:

Event Date: _____ Outcome: _____
Comment:

Event Date: _____ Outcome: _____
Comment:

For event list the concerning behavior or utox finding. In outcome enter what happened and in comment put your action and/or why the continued opiates are indicated and exempt from our policy

SFGH PRIMARY CARE POLICY AND PROCEDURE

TITLE: USE OF CONTROLLED SUBSTANCES IN CHRONIC PAIN MANAGEMENT

PURPOSE

The purpose of this policy is to define minimum standards for the use of controlled substances in chronic pain management in the primary care clinics at San Francisco General Hospital. This document outlines the procedure by which clinics assess chronic pain, develop and monitor individualized treatment plans and document pain management in the medical records of patients whose plans include the long term use of controlled substances for pain.

STATEMENT OF POLICY

It is the policy of SFGH primary care clinics that all providers follow an approach to the use of controlled substance in chronic pain management that:

- conforms to standards of practice set by the Medical, Nursing and Pharmacy Boards of California;
- promotes the safe, adequate, appropriate and effective management of chronic pain that optimizes patients' functional status, addresses the risks, benefits and side effects of therapy and attempts to minimize patient misuse of prescribed medications;
- facilitates sharing of information and coordination of care of patients with chronic pain within the CHN and with other safety net sites (e.g., the San Francisco Community Clinic Consortium (SFCCC)) through the use of a shared electronic medical record (EMR)

PROCEDURE

- I. Initial Pain Assessment- Providers will perform and document an initial comprehensive biopsychosocial pain assessment that follows Medical Board of California guidelines. The evaluation should include:
 - assessment of the pain and any prior diagnostic evaluation
 - impact of pain on physical and psychological functioning
 - history of prior pain treatment
 - assessment of coexisting medical and/or mental health conditions
 - substance use history
 - documentation of the presence of one or more recognized medical indications for the use of a controlled substance
 - relevant physical exam, including musculoskeletal and neurologic exam if indicated
- II. Treatment Plan Objectives- Providers will design and document an individualized treatment plan in consultation with the patient that outlines:
 - any planned diagnostic evaluations and/or specialty consultation (including mental health referral)
 - any and all prescribed therapeutic modalities (e.g., medications, physical therapy, acupuncture)
 - treatment goals by which the plan will be evaluated, such as level of pain relief, improved physical and psychosocial functioning and/or improved quality of life

- III. Informed Consent- Providers will document their discussion with the patient of the risks, benefits and side effects of prescribed treatment(s) and how these issues will be monitored and addressed.
- IV. Pain Management Agreement- Providers will complete and include in the medical record a pain management agreement that is signed by the provider and the patient that outlines components of the treatment plan and situations in which the plan may be reviewed, altered or discontinued.
- V. Periodic Review- Providers will perform and document a periodic reassessment of chronic pain that focuses on the patient's progress toward the Treatment Plan Objectives (see above) on an annual basis (or more frequently as deemed necessary by the provider) to determine the appropriateness, continuation or modification of the treatment plan.
- VI. Documentation in the Electronic Medical Record (EMR)- Providers will use the EMR to:
 - a. keep an up-to-date medication list that includes all current and previously prescribed medications noting the reason(s) for medication changes and discontinuations
 - b. enter a clinical alert in the EMR that indicates that a pain management agreement has been signed and that current and previously prescribed pain medications are documented in the medication list in the EMR (this may include any special circumstances or considerations regarding the patient's pain management history and/or treatment plan)
- VII. Forms- SFGH primary care clinics will adopt forms that outline the minimum standards for executing Initial Pain Assessment, Treatment Plan Objectives, Informed Consent, Pain Management Agreement and Periodic Review. These will be based on the existing COPC template forms with minor site-specific changes.
- VIII. SFGH primary care clinics will develop individualized guidelines to address:
 - a. monitoring for patient misuse of controlled substances that may include the use of urine toxicology screening, intermittent pill counts, and/or prescription monitoring programs (e.g., CURES reports)
 - b. situations or conditions that are indications for suspension or termination of the pain management agreement
 - c. situations or conditions that are indications for clinical case review
- IX. If the particular clinic cares for a significant number of patients on chronic opiate therapy, a tracking system (i.e., registry) for such patients should be developed and used to monitor for safe prescribing practices.

Family Health Center, San Francisco General Hospital

Chronic Pain Management Policy and Procedure

Purpose:

- to establish FHC's approach to chronic pain management involving the prescription of chronic opioids
- to assist FHC providers in the appropriate prescribing of opioids for chronic pain in accordance with California medical board prescribing guidelines, San Francisco DPH guidelines, and national clinical guidelines
- to ensure the appropriate assessment, management and monitoring of patients treated with chronic opioids
- to assure that patients are aware of the risks, benefits, side effects, and responsibilities of chronic opioid treatment.

FHC chronic pain management philosophy: The effective and safe treatment of chronic pain is an important part of the medical care we provide at the Family Health Center. The existing evidence supports a multimodal approach to pain that combines physical, psychological, procedural, and pharmacologic treatments. We strongly recommend that all patients with chronic pain be engaged in a multimodal program to address their pain and function.

When pain is moderate to severe, causes functional impairment and has failed to respond to non-opioid analgesic treatment, appropriate therapy for chronic pain may include chronic prescription opioids. The goal of this therapy is two-fold: to reduce pain and to improve function. Therefore, measures of the efficacy of treatment and decisions about changes in treatment must be based on a clinical assessment of the therapy's effects on *function* as well as *pain*.

There is real risk of harm with the use of opioids, including risks of addiction, overdose, and diversion. It is the goal of the Family Health Center to provide optimal treatment of pain for our patients while minimizing these risks.

Policy: The management of patients with chronic pain that is deemed to require the use of chronic opioid therapy includes the following elements:

1. Standardized **initial assessment** of pain, functional impairment and pain-related diagnoses, with appropriate documentation.
2. **Patient education** and **informed consent** regarding goals and expectations of treatment; risks, benefits, and adverse effects of treatment, as well as discussion of patient rights and responsibilities.
3. Development of a multimodal **individualized treatment plan** that maximizes the benefit while minimizing the risks of chronic opioid treatment.
4. Completion of a **controlled substances contract**.
5. Enrollment into FHC controlled substances **registry** and placement of LCR **clinical alert**.
6. Universal use of **urine toxicology** screens and **Patient Activity Reports** prior to initiation of therapy and periodically thereafter.
7. **Reassessment** of chronic pain, functional impairment and effectiveness of treatment regimen **using standardized assessment tools at least annually**.
8. Monitoring for **high risk behaviors** that may suggest misuse and resultant risk of harm .
9. Appropriate ancillary and specialty **consultation** for challenging cases.
10. Ongoing **education** regarding evaluation and management of chronic pain for resident providers.
11. Recording & updating prescriptions of opiate medications in LCR's **medication list**.

INITIAL ASSESSMENT

Initiation of chronic opioid therapy

It is recommended that any patient who is being evaluated for chronic opioid therapy have a dedicated visit for this purpose. The following are required for any patient who is initiated on chronic opioid therapy:

- A complete history including:
 - ◆ onset and description of pain
 - ◆ impact of pain on physical and psychological functioning—consider using BPI (Appendix C)
 - ◆ prior diagnostic evaluation
 - ◆ previous treatments and responses to treatment
 - ◆ history of mental health conditions
 - ◆ history of substance abuse
 - ◆ documentation of the presence of one or more recognized medical indications for the use of a controlled substance
- Relevant physical exam
- Documentation either in the patient's LCR record using the Chronic Pain Assessment Template or in the patient's paper chart using the FHC Chronic Pain Assessment form, found in the exam room drawers (see Appendix A)
- Initial urine toxicology screen
- Patient education and informed consent using the Chronic Opioid Pain Medication Patient Information and Informed Consent form (see Appendix B).
- Completion of a signed Controlled Substances Agreement (contract) that includes the medication name and dose as well as the prescription interval (e.g. every 2 weeks, every month). The white copy is placed in the patient's chart and the yellow copy is given to the patient
- Entry of a Clinical Alert describing medication dosing, frequency, and number to be dispensed
- Entry of medication prescription in LCR
- Entry into the Chronic Pain Registry by entering Chronic Pain into the LCR problem list
- Completion of a Patient Activity Report request
- Brief follow up should be arranged in approximately one month to reassess

Continuation of opioids in a transferred patient with an established chronic opioid regimen

New transfers to FHC from outside clinics:

Patients new to FHC who request continuation of a previously prescribed chronic opioid regimen have the same requirements as patients who are being initiated on chronic opioid therapy (see above). It is strongly recommended that the patient bring previous outside records to his/her new primary care provider before any controlled substances are prescribed.

If documentation of a previous prescription for chronic opioid therapy is not available, we do not recommend initiating therapy on the first visit. Exception can be made to this requirement at the discretion of the provider if one of the following can be satisfied at the time of the visit:

- The previous provider can be contacted and confirms that the patient is an appropriate candidate for chronic opioids.
- or
- The current pharmacy can be contacted and confirms a history of of stable opioid prescriptions from a single provider.

If the new provider disagrees with the use of opioids for the patient's condition, it is his/her right to discontinue opioids. A taper should be used.

Established FHC patients who transfer to a new FHC provider:

For established FHC patients who are transferring to a new provider (e.g. from a graduating resident), the following steps should be taken by the new PCP at the time of initial appointment or shortly thereafter (within 4 months):

- Review of patient records regarding history and etiology of pain, treatments tried and their results, and prior pain treatment plans established by former PCP. If there is no Chronic Pain Assessment in the patient's LCR record, the new PCP should complete one, as well as review the educational handout and complete an informed consent form and a Controlled Substance Agreement with the patient.
- Review of any history of aberrant medication taking behaviors or pain contract violations.
- If the new provider disagrees with the use of opioids for the patient's condition, it is his or her right and responsibility to discontinue opioids with a taper. In the case of trainees, the case should be fully discussed with an attending.

PATIENT EDUCATION AND INFORMED CONSENT

All patients taking ongoing controlled substances for chronic pain will receive the following:

- Chronic Opioid Pain Medication Patient Information Handout and Informed Consent Form, which includes information about the benefits, risks, side effects, and goals of chronic opioid therapy, as well as information about the patient's rights and responsibilities regarding this therapy (including periodic urine toxicology protocol). Patients should sign this form indicating that they understand the included information. The form will be filed in the chart.
- A copy of their controlled substance agreement (signed by patient and PCP); original is filed in their chart.
- A discussion with the PCP regarding goals of treatment, as well as risks of treatment with chronic opioid.

All patients will have the opportunity to discuss their treatment plan on an ongoing basis as needed.

DEVELOPMENT OF AN INDIVIDUALIZED TREATMENT PLAN

Evidence strongly supports multimodal therapy as the optimal treatment for chronic pain, and the FHC recommends developing an individualized treatment plan with a multimodal approach. This might include

- physical therapy
- manual medicine
- local injections
- surgical procedures
- individual or group therapy
- imagery and breathing techniques or meditation classes
- complementary and alternative medicines
- pharmacotherapy
- numerous other tools that are available to individual patients depending on their personal, financial, cultural and social resources

Remember that the ultimate goal of treatment is to *increase function while decreasing pain*. Non-pharmacologic approaches are often much more effective than opioid therapy at increasing function and quality of life, and may lead to a decrease in dose of opioids and related risk of harm.

The individualized treatment plan and objective goals that will be assessed should be documented on the initial visit.

ONGOING ASSESSMENT

Regular Follow-up

All patients maintained on chronic opioid therapy must have an established primary care relationship, and should see their PCP regularly. The default visit frequency will be monthly, though patients who, after 6 months of care, are found to be at low risk of harm may be seen at intervals as far apart as 3 months. Monthly visits may occur at refill or pain clinic, but the PCP should see the patient at a minimum every three months. Another provider is acceptable if the PCP is unavailable.

Prescriptions can be refilled in the Refill Clinic or in the Chronic Pain Clinic if there is a clinical alert and the LCR medication list is up to date.

Every 3-6 months, the following should be assessed:

- **Analgesia** – degree of control of pain. We recommend the regular use of the Brief Pain Inventory (BPI) every 3-6 months. The BPI can be found in exam room drawers. (Appendix C)
- **Activities of daily living** – level of functional capacity limited by pain. Again, the BPI can serve this function.
- **Adverse effects of medications**
- **Aberrant drug-taking behavior**

If the patient is found to have red-flag aberrant drug-taking behaviors that put the patient at risk of serious harm from opiate prescription (i.e. overdose, addiction or diversion), a taper should be initiated immediately. If the patient is found to have yellow-flag behaviors that suggest the possibility of harm, the physician should inform the patient of his/her concern and either initiate a taper or increase surveillance for evidence of misuse. See the guidelines below for further details about decision-making around risk of harm.

If pain control and level of function are found to be inadequate, medications may be increased. Use of the BPI before and after dose increases is recommended to document changes in pain and function.

Annual Assessment

Annually, the PCP should schedule a dedicated visit for review and renewal of the treatment plan and document this via the Chronic Pain Assessment template in the patient's LCR record, or in the paper chart using the Chronic Pain Assessment Form (see Appendix A). Re-assessment can occur more frequently if necessary to achieve adequate analgesia and functional status.

At the Annual Assessment, the clinician may reference the initial assessment regarding previous diagnostic workup and history of pain rather than re-documenting this information. The Annual Assessment should instead focus on and document

- New diagnostic studies
- Assessment of pain and function
- List of aberrant medication taking behaviors in the last year
- Assessment of whether the objectives of treatment established the previous year are being met and whether these objectives should be modified
- Assessment of whether the approach to treatment should be modified

CHRONIC OPIOID PRESCRIPTIONS

The default frequency for prescriptions will be one month. For patients found after 6 months to be at very low risk for harm from opioid therapy, the PCP may prescribe up to three months at a time.

It is illegal to put any date other than the current actual date in the date field for secure prescriptions. Instead, to predate prescriptions, providers can put the current date in the date field and write: "Please fill on [future date]". For example, to write a three month prescription for MSContin, write one secure prescription for today's date, 11/1/09. On the second secure prescription, also write 11/1/09 with a note that says "Please fill on 11/31/09". The third secure prescription also contains the current date with a note saying "Please fill on 12/30/09". In the LCR, note each of these dates in the comments field for the prescription.

Another option for stable patients who do not need to be seen every month is to leave a secure prescription waiting at the clerk's desk for the patient each month. A third option is to leave prescriptions for them to pick up without seeing a provider at the refill clinic.

These options are only appropriate in patients who are deemed to be at a very low risk for addiction, diversion or overdose. For most patients, it is recommended to see the patient on a monthly basis.

Chronic controlled substances will not be refilled for patients who drop in to clinic. It is therefore important that FHC providers assist their patients in receiving monthly appointments. These appointments can occur in the PCP's continuity clinic, in the FHC Pain Clinic, or in the Refill Clinic. It may help patients receive monthly appointments if the PCP gives a list of such patients to the clerk, who can then ensure that the patients do not go beyond the 30 days they have been prescribed.

RECOGNITION OF AND RESPONSE TO ABERRANT MEDICATION TAKING BEHAVIORS

Aberrant medication taking behavior has a differential that includes

- prescription opioid abuse
- inadequately treated pain or progression of chronic pain disease (“pseudoaddiction”)
- diversion (selling rather than taking the prescribed medication)
- opioid analgesic tolerance
- self-medication of psychiatric and physical symptoms other than pain

It is difficult to distinguish among these possibilities, though *pseudoaddiction resolves as opioid doses are increased and pain is better controlled*. Diversion and opioid abuse continue to escalate in this setting.

Yellow Flags

These are behaviors that might suggest opioid abuse or diversion, but might also be rational and normal responses to undertreated pain or to fear of pain. They have a low specificity for abuse and diversion.

- Anger or irritability when questioned closely about pain
- More concern about controlled substance than about the underlying medical problem that persists beyond the first few visits
 - may indicate inadequate treatment of pain
- Report of multiple medication sensitivities
 - may be true, or may be the patients’ way of making sure to get the medications that they know work best for their pain
- Request for specific drugs or refusal to take generic medications
 - may be a truly significant observation by the patient that his/her genes/receptor population can utilize specific opioid more effectively than other opioids
- Unsanctioned dose escalation one or two times
 - may indicate inadequate treatment of pain
- Aggressive complaints about the need for more drug
 - may be a true need for increased dose
- Open acquisition of similar drugs from other medical sources one or two times, e.g. in the ER
 - may indicate inadequate treatment of pain or inadequate coverage of flares
- Drug hoarding during periods of reduced symptoms
 - rational response to difficulty scheduling appointments and emergency preparedness needs.
- Resistance to a change in therapy associated with “tolerable” adverse effects, with expressions of anxiety related to the return of severe symptoms

Response: Consider the differential diagnosis: inadequately treated pain, prescription opioid abuse, or diversion. Remember that the goal of therapy is improvement of function and quality of life. If evidence suggests that opioid therapy is contributing to an addiction, then it is not serving the patient’s quality of life or function and should be discontinued.

- The patient should be informed of the PCP’s concern and a plan should be made together to address it. This plan can include increasing the frequency of visits and urine toxicology screening.
- If the PCP’s suspicion for opioid misuse is high, the PCP has the right to discontinue opioids with a taper rather than increase monitoring as described above.
- See section on discontinuation of therapy for taper rates and treatment of withdrawal symptoms.
- Regardless of the plan for opioid prescription, the patient should be encouraged to continue medical care with the PCP and to continue non-opioid treatments for pain.
- Yellow flags should be documented clearly and included in the patient’s annual reassessment

Red Flags

- Manipulative or abusive behavior directed at caregivers, including intimidation or coercion, and aimed at acquisition and continuance of the substance abuse
- Urine drug screen negative for the prescribed medication
- Urine drug screen positive for other controlled substances
 - see urine toxicology guidelines for a complete discussion of this issue, as not all positive urine toxicology screens must result in suspension of opioid prescription
- Refusal of diagnostic workup or consultation
- Frequent dose escalations after being told this is inappropriate
- Multiple (>2) episodes of lost or stolen prescriptions or medications
- Prescription forgery
- Stealing drugs from others
- Selling prescription drugs
- Obtaining prescription drugs from non-medical sources
- Injecting, snorting or smoking oral formulations
- Concurrent abuse of alcohol or illicit drugs
 - Some providers continue to prescribe opioids if the patient is able to provide proof of enrollment in a drug treatment program and subsequent consistently negative urine toxicology screens.
- Repeatedly seeking prescriptions from other clinicians or from ERs without informing the PCP
- Evidence of deterioration in the ability to function at work, in the family, or socially that appears to be related to drug use
- Evidence of loss of control: use of more than intended or for longer than intended or repeated use in unsafe situations

Response: Red flag behaviors strongly suggest addiction or diversion.

- In this setting, the risks of harm from opioid prescription generally outweigh the benefits and it is recommended that opioids be discontinued *with a taper to minimize withdrawal symptoms*.
- In rare cases, the assessment of the treating provider will be that continued prescription in the setting of red flag behaviors is of overall benefit to the patient. This decision is at the discretion of the treating provider but should be the exception.
- In the case of prescription tampering, abusive behavior toward staff, and diversion, immediate discontinuation with treatment of withdrawal symptoms is warranted.
- See section on discontinuation of therapy for taper rates and treatment of withdrawal symptoms.
- It is common for PCPs to feel manipulated and angry when patients display red flag behaviors. It is important for the PCP to remain in the medical model and stay focused on *minimizing risk of harm and maximizing benefit to the patient* when making decisions regarding opioid prescriptions
- Patients with addictions need medical care and should be encouraged to continue with their PCPs,

Factors that predispose to addiction, diversion and risk of overdose

These factors place patients at an increased risk of opioid misuse and should lower the threshold for discontinuation of opioid therapy in the setting of red and yellow flag behaviors.

- History of legal problems
- History of diversion
- History of addiction
- Family history of substance abuse
- Psychiatric illness, including depression and anxiety

URINE TOXICOLOGY SCREENING

The FHC takes a “universal precautions” approach to urine toxicology screening. All patients who are prescribed chronic opioid therapy are required to undergo urine toxicology screening to ensure that patients are using the prescribed controlled substance(s) and are not using illicit drugs. Urine toxicology screening does not imply that these patients are suspected of contract violations.

Urine samples should be warm to the touch. If there is any suspicion that the urine sample is not valid, you can check a specific gravity and creatinine concentration. If the specific gravity is less than 1.003 and the creatinine is less than 20 mg/dl, it is likely an altered specimen. This is considered a positive screen.

Frequency of testing:

- Upon initiation of therapy
- Within the first 3 months of treatment
- At least annually thereafter at random intervals
- More frequent testing can be done at the provider’s discretion
- A urine toxicology screen should be performed at the annual reassessment visit

Urine toxicology screen results: Interpreting urine toxicology screen results is not always straightforward. Many opiates have expected metabolites that can appear to signify use of non-prescribed substances if the clinician is not aware. See Appendix A for a chart of expected metabolites and timeframe for detections.

- **Absence of the prescribed medication** is a red flag for possible diversion. It is important to obtain a careful history from the patient regarding the timing of the last dose of the medication.

Response: If the absence of medication is not explained by history, discontinue therapy.

- **Presence of non-prescribed opioid** may indicate undertreated pain, but suggests addiction and carries a high risk that the patient is selling the prescribed opioid to buy another opioid.

Response:

- ◆ Document the contract violation and include it in the next annual re-assessment.
- ◆ Inform the patient of contract violation and concerns for increased risk of harm from opioid prescription.
- ◆ Increase visit frequency and urine toxicology screen frequency.
- ◆ Consider increasing dose of pain medication if the patient reports untreated pain.
- ◆ If urine toxicology screens are persistently positive for non-prescribed opiates, even after dose increases and attempts to address continued pain, discontinue therapy with a taper.

- **Presence of non-opioid drugs of abuse such as cocaine, methamphetamines, or benzodiazepenes** is evidence of a substance abuse disorder. Patients who do not have addictions are able to control their use and make sure not to use before appointments. Patients with addictions are unable to do this and will have positive toxicology screens. There is an extremely high risk of diversion, abuse and overdose with these patients, and the risk of opioid prescriptions generally outweighs the harm.

Response: There are three choices for clinicians in these situations:

- ◆ Discontinue opioid prescription with a taper.
- ◆ Refer the patient to substance abuse treatment and provide further opioid prescriptions only after the patient provides proof of enrollment and participation. Abstinence is not expected immediately, but if the patient continues to have positive urine toxicology screens for six months, opioid therapy should be discontinued.
- ◆ Rarely, the provider will find that in spite of concurrent substance abuse, the prescription of opioids is benefiting the patient’s function more than harming it. In these cases, the provider may continue prescribing opioids with frequent assessments of function and risk/benefits.

- **Failure or refusal to submit a urine drug test** is considered a positive test for a drug of abuse.

DISCONTINUATION OF CHRONIC OPIOIDS

Chronic opioid therapy should be discontinued when:

- Evaluation demonstrates lack of efficacy of therapy, the patient desires to discontinue therapy, or the cause of the pain has resolved
- The detrimental effects or side effects of therapy are greater than its benefits, as determined in consultation with the patient and family
- There are serious safety issues as a result of treatment, such as danger to self or others
- The patient displays red flag behaviors
- The patient has a toxicology screen positive for stimulants and does not enter drug treatment
- The patient has a toxicology screen positive for stimulants, enters drug treatment, but has persistently positive toxicology screens after 6 months
- The patient has a toxicology screen negative for the prescribed medication
- The patient has toxicology screens persistently positive for non-prescribed opiates in spite of efforts to change dose and address continued pain on the part of the clinician

Procedures for discontinuation of opioid therapy

- In most cases, the tapers described below are recommended.
- In the setting of dangerous, illegal or criminal behaviors, including diversion or alteration of prescriptions, immediate discontinuation with treatment of withdrawal symptoms is recommended.
- The PCP should not terminate the patient from care unless the patient has been abusive. The patient will still require medical attention and a medical home.
- The reason for the discontinuation of opioid therapy should be documented in a progress note, a clinical alert, and the problem list. The PCP should discuss and document treatment alternatives.

Guidelines for Tapering Opioid Therapy

If there is concern that the patient has an active substance addiction, it may be best to consult with an addiction specialist prior to tapering the patient. It is difficult for addicted outpatients to comply with tapering schedule, since loss of control is part of the illness.

- Fast taper: taper by 25% of the original dose every 2-3 days over a total period of 10-14 days. Rapid detoxification literature shows that patients need 25% of previous day's dose to prevent withdrawal symptoms.
- Slow taper: taper by 25% of the original dose every week over a total period of 1 month.
- Remain engaged with the patient during the tapering process and provide support.
- Consult with a pain specialist if the patient is on high dose opioids (>500mg morphine equivalent/day) or has co-morbidities that need to be addressed in relation to the taper.

Guidelines for Treatment of Withdrawal Symptoms

- Opioid withdrawal is not life-threatening but is extremely uncomfortable. Symptoms include abdominal cramping, nausea, vomiting, diarrhea, anorexia, rhinorrhea, insomnia, anxiety, irritability, dysphoria, diaphoresis, tachycardia, fever, and elevated blood pressures.
- Clonidine can be effective in suppressing symptoms. Initial dose is 0.1mg 2x to 4x daily.
- For GI symptoms, options include:
 - ◆ loperamide 4mg po after first loose stool, then 2mg po each additional loose stool, up to 16mg/24 hours
 - ◆ dicyclomine 20mg po q 6 hours prn stomach cramps
 - ◆ prochlorperazine 10mg po or 25mg suppository q 6 hours prn nausea or vomiting.

GRIEVANCE PROCEDURES

Patients have the right to review the decision to discontinue chronic opioid therapy with the Medical Director or his/her designee. Additional staff (SW, RN, MD, clerical staff) will be included on a case-by-case basis.

QUALITY ASSURANCE AND ONGOING TRAINING

The FHC will have the following systems in place:

- An electronic registry of all patients receiving chronic opioid therapy that includes:
 - ◆ patient name, MRN, and date of birth
 - ◆ medication name and dose and any changes to medication or dose
 - ◆ urine toxicology results
- Ongoing education for trainees about treatment of chronic pain that includes:
 - ◆ WHO analgesic ladder
 - ◆ Clinical guidelines for chronic opioid therapy
 - ◆ Interaction of substance use, mental health, and chronic pain
 - ◆ Public health effects of opioid abuse

Credit to:

General Medicine Clinic, SFGH

South of Market Health Center

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APPENDIX A

FHC CHRONIC PAIN ASSESSMENT AND TREATMENT PLAN

DATE:

check one:

- INITIAL
- PERIODIC REVIEW *(at least annual)*

History of Pain and Description of Pain Symptoms

Functional Impact

Physical Activities/Mobility:

Social Functioning:

Mood:

Sleep:

Other:

Diagnostic Studies

Medications	Degree of Relief	Adverse Events

Pharmacologic Treatment

Non-pharmacologic Treatment (e.g. PT/OT, acupuncture, mindfulness, psychotherapy, substance use tx)

Substance Use History/ Relevant Medical History

Past Substance use:

Current Substance use:

Relevant medical history

Aberrant Drug-Related Behavior/Agreement Violations

Relevant Physical Exam or see note dated _____

FHC CHRONIC PAIN ASSESSMENT AND TREATMENT PLAN

Assessment

Level of Pain Control

Functional Status

Agreement Violations

Treatment Goals

Analgesia

Physical Functioning

Social Functioning

Mental Health/Substance Use

Treatment Plan

Pharmacologic Therapy:

Non-pharmacologic Therapy:

Diagnostic Studies:

Consultation:

Documentation Checklist

- Initiation or continuation of prescribed controlled substances for the treatment of this patient's condition is justified.
- Informed Consent for Long-Term Controlled Substance Therapy for Chronic Pain signed on:
- Patient-Provider Agreement for Long-Term Controlled Substance Therapy for Chronic Pain signed on:
- Medication list in LCR up-to-date with current and discontinued medications noting reasons for changes
- Clinical Alert for controlled substances therapy entered/updated
- Pain Management Registry Code (338.99) entered into LCR problem list
- Patient Activity Report ordered/reviewed since last assessment

Provider Signature: _____ **CHN #:** _____ **Date:** _____

APPENDIX B

INFORMED CONSENT FOR LONG-TERM CONTROLLED SUBSTANCES THERAPY FOR CHRONIC PAIN

I, _____, and _____, have decided to use controlled substances
(Patient) (Provider)

to treat: _____.
(symptom, cause)

This document explains what I can expect when I use opioids (also known as narcotics) and/or other controlled substances prescribed to treat my chronic pain condition.

The purpose of treating my condition with controlled substances is to reduce my suffering and improve my physical and psychological functioning. This decision was made because my condition is chronic and other treatments have not helped.

I may notice that my symptoms improve on this treatment. I am aware, however, that it may not be possible to make my symptoms go away completely. In order to pick the best treatment for my condition, from time to time, I may need to undergo additional tests and consider changes in treatment. As with any treatment, there are risks involved including:

Risk of misuse or use by others:

These medications may cause serious harm (including death) if not taken as prescribed (especially overdose) or if taken by others (adults and/or children) for whom they were not prescribed.

Side-effects:

The side effects of opioids include drowsiness, constipation, nausea, vomiting, itching, allergic reaction, slowing of my breathing (including the possibility that I might stop breathing in case of overdose) and/or slowing of my reaction time. I should not drive a motor vehicle or operate machinery until I know how this treatment will affect me. These medications can interact with other prescription and non-prescription medication, and I should talk to my provider about possible interactions. Some of these medications may contain Tylenol as well as opioids, and high levels of Tylenol can damage my liver.

- **For Men Only:** Chronic opioid use can lead to low testosterone levels in men. This may affect my bones, mood, stamina, sexual desire, and physical and sexual performance.
- **For Women Only:** If I plan to become pregnant or believe that I am pregnant while taking opioids, I will immediately inform my provider. Should I carry the baby to term, the baby will be physically dependent on opioids. The use of opioids is not usually associated with birth defects.

Side effects that I may experience from the use of other (non-opioid) prescribed controlled substances include:

Physical Dependence:

It is normal for my body to become dependent on these medications. That means if the treatment is stopped or the dose lowered suddenly, I may experience withdrawal. Symptoms of opioid withdrawal include: abdominal pain, anxiety, diarrhea, pain, palpitations, runny nose and vomiting. These symptoms may be uncomfortable but are not life threatening and can be treated. In most cases, medications should be tapered when they are stopped. If medications are stopped, I should talk to my provider before restarting them because of the risk of overdose.

Withdrawal symptoms that I may experience from stopping other (non-opioid) prescribed controlled substances include:

Tolerance/Worsening of pain:

My body may become “used-to” or tolerant to these medications. Opioid medications may also cause my body to become more sensitive to pain. If this happens, even high doses of the medication may not help. Should this happen, the medication may be changed, tapered or discontinued.

Addiction:

Becoming addicted (using or craving a drug even when it causes harm) to the medication prescribed to treat my condition is more common in people with a history of drug addiction. I agree to tell my provider my complete drug history.

I understand this form and have had a chance to have my questions about this treatment answered. By signing this form voluntarily, I agree to the treatment of my condition with controlled substances.

Patient Signature: _____ Witness Signature: _____ Date: _____

APPENDIX C

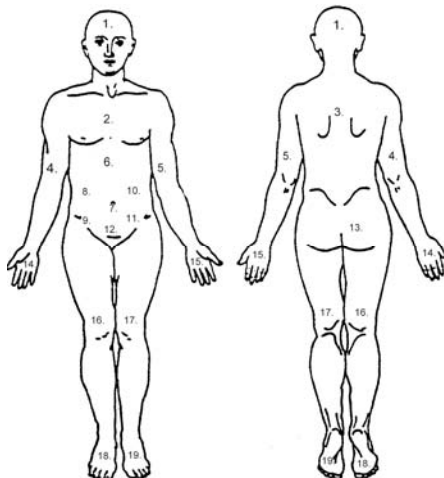
BRIEF PAIN INVENTORY, SHORT FORM

Name _____ DOB _____ MRN _____ Date _____

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains and toothaches). Have you had pain other than these everyday kinds of pain today?

Yes No

2. On the diagram, shade the Areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by circling the one number that best describes your pain as at its **worst** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

4. Please rate your pain by circling the one number that best describes your pain as at its **least** in the last 24 hours.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

5. Please rate your pain by circling the one number that best describes your pain as on the **average**.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

6. Please rate your pain by circling the one number that tells how much pain you have **right now**.

0 1 2 3 4 5 6 7 8 9 10
 No Pain Pain as bad as you can imagine

7. What treatments and medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please circle the one percentage that most shows how much relief you have received.

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%
No Complete
Relief Relief

9. Circle the one number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

B. Mood

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

C. Walking Ability

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

D. Normal Work (includes work inside and outside the home, and housework)

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

E. Relations with other people

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

F. Sleep

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

G. Enjoyment of life

0 1 2 3 4 5 6 7 8 9 10
Does not Completely
Interfere Interferes

APPENDIX D

Expected Urine Toxicology Screen Results

DRUG	POSITIVE TEST	DURATION POSITIVE	COMMENT
Amphetamine Methamphetamine MDMA	Amphetamine	1-2 days	
Barbiturates	Barbiturates	Up to 6 wks	
Benzodiazepines	Benzodiazepines	1-3 days up to 6 wks with heavy use	False negatives with low doses. Clonazepam is positive 2-4 days.
Cocaine	Cocaine	2-4 days 10-22 days with heavy use	
Codeine	Morphine Codeine High dose hydrocodone	1-2 days	
Fentanyl			Not detected
Heroin	Morphine Codeine	1-2 days	
Hydrocodone (Vicodin)	Hydrocodone Hydromorphone	2 days	
Hydromorphone (Dilaudid)	May not be detected	1-2 days	May not be detected
Methadone	Methadone	2-11 days	
Morphine	Morphine Hydromorphone	1-2 days	
Oxycodone (Percocet)	Not reliably positive, but may show Opiates Oxycodone Oxymorphone	1-1.5 days	

DRAFT

Potrero Hill Health Center Pain Management Policy and Procedure

Purpose: To establish SMHC's approach to pain management and to ensure appropriate assessment, management and monitoring of patients with acute and chronic pain. To establish guidelines on the use of pharmacologic agents in the management of pain syndromes.

Policy: It is the goal of SMHC to relieve patients' pain and suffering. The management of patients with pain includes: (1) use of a standardized tool to measure the intensity of pain and its affect on activities of daily living, (2) development of an individualized treatment plan, (3) patient education relating to the cause of pain, expectations of pain management, treatment modalities and adverse effects; (4) use of a stepped-care approach for treating pain, (5) use of multi-modal strategies for pain management, including complementary therapies, (6) reassessment of pain on an ongoing basis, utilizing a standard tool; (7) use of interdisciplinary teams or pain centers for management of patients with chronic pain syndromes.

The following guidelines apply to patients who require long term controlled substances: (1) one provider takes responsibility for prescribing; (2) a Treatment Agreement is signed by patient and provider and filed in the medical record; (3) failure of the patient to abide by this contract may result in the termination of controlled substances prescriptions; (4) patients may be asked by the provider to undergo random urine drug screening to monitor their controlled substance usage; (5) all such patients are considered for referral to a pain center for guidance in pain management; (6) patients may be referred to substance abuse treatment; (7) patients may be referred for psychiatric/psychological evaluation and treatment

Procedures:

I. SMHC pain management philosophy statement:

SMHC is committed to the holistic treatment of patients and to upholding their dignity. We attempt, to the best of our abilities, to follow the goals of Medicine and Nursing, which includes the relief of pain and suffering. Such relief may include effective symptom management such as pain relief, and management of other symptoms associated with illness, including (but not limited to) nausea, shortness of breath, depression and social isolation.

SMHC believes that effective pain management is that therapy which allows the patient to live as fully as possible and be as comfortable as possible in the setting of acute or chronic pain. Pain management at SMHC will:

- Adhere to the highest technical standards, making use of both traditional and alternative modalities known to be effective for pain relief.
- Integrate the psychosocial and physical aspects of patient care to more effectively address patients'

- needs and concerns.
- Offer a support system to help the patient’s family and personal community to cope with the patient’s illness and suffering.

II. Pain assessment

All patients are assessed at each visit (on a regular basis) for acute or persistent pain.

The assessment of pain focuses on the events that led to the present pain complaint and on establishing a diagnosis, a plan of care, and likely prognosis

History

1. The evaluation of the present pain complaint includes the following pain characteristics: intensity, character, frequency (or pattern, or both), location, duration, and precipitating and relieving factors. A numeric pain scale will be used with 0 being no pain, 1-3 mild, 4-6 moderate, and 7-10 severe pain. A “visual” pain scale will be made available to patients, if needed.
2. Pain is assessed as to its impact on physical and social function (e.g., activities of daily living [ADLs], instrumental activities of daily living [IADLS], sleep, appetite, energy, exercise, mood, cognitive function, interpersonal and intimacy issues, social and leisure activities, and overall quality of life).
3. A thorough treatment history, including current and previously used prescription medications, over-the-counter medications, complementary or alternative remedies, and illicit drug or alcohol use/abuse, is obtained. The efficacy and adverse effects of currently and previously used medications or other treatment modalities are recorded.
4. The patient’s attitudes and beliefs regarding pain and its management, as well as knowledge of pain management strategies are addressed. The patient’s satisfaction with current pain treatment is determined and concerns identified.
5. A quantitative assessment of pain is recorded utilizing a standard pain scale that is sensitive to cognitive, language, and sensory impairments. Patient pain diaries may also be used to further evaluate the relationship between treatment modalities, pain, and functional abilities.
6. For the adult with moderate to severe dementia or who is nonverbal, the practitioner attempts to assess pain via direct observation or history from caregivers. Patients are observed for evidence of pain related behaviors during movement (e.g., walking, morning care, transfers). Unusual behavior in a patient with severe dementia may trigger assessment for pain as a potential cause.
7. For children, a comprehensive and developmentally appropriate pain assessment is used which incorporates a pain history, the child’s self-report, behavioral observations, parents’ assessment, and physiologic cues. Self-report is used as the primary source of pain assessment whenever possible; behavioral observation and physiologic cues can provide additional information. The exception is preverbal children and nonverbal or cognitively impaired individuals, for whom behavioral observations are the primary source of pain assessment, with parent or primary caregiver’s assessments providing additional information.

Back Pain Physical Exam and Diagnostics

1. The site of pain is examined; further examination may include a general physical exam, neurologic, musculoskeletal, and mental status assessments, (including an evaluation of cognitive function as well as psychological function, i.e., mood, self-efficacy, pain coping skills, feelings of helplessness, and pain related fears). The assessment also includes observation of physical function (e.g., performance of ADL's, range of motion, gait, or other measures). Pertinent laboratory and other diagnostic tests may be ordered.
2. **Expanded Physical Exam:**
- 3.

Have patient undress to expose back.

1. Record temperature and weight.

Standing Exam:

1. Have patient stand and point to area of maximal pain.
2. Observe for sciatic scoliosis, masses, asymmetry.
3. Forward flexion and extension.
4. Palpate L1-S1 spinous processes and paravertebrals
5. View from front, heel walk (L4 and L5 nerve roots).
6. Raise up onto toes (S1), unilateral, 5 times each side.

Supine Exam:

7. Test range of motion of hips in internal and external rotation (excludes serious hip pathology).
8. Neural tension signs (SLR—Straight Leg Raising):*
 - ipsilateral SLR (0-60 degrees)
 - contralateral SLR (0-60 degrees)
 - record the angle that reproduces sciatica and whether ipsi/contralateral
 -

Supine or Sitting Exam:

9. Reflexes: ankles (S1) and knee (L4)
10. . Motor (strength graded 0-5, 5 = normal):
 - knee extension (L2, L3, L4 nerve roots)
 - ankle dorsiflexion (L4 and L5 nerve roots)
 - great toe dorsiflexion (L5 nerve root)
11. Sensory:
 - foot and ankle (L5 and S1). Pinprick 1st web space (L5) and lateral foot (S1).
12. Pulses (if claudication present)
13. If anterior thigh pain, numbness, or quadricep weakness is present, assess sensation of anterior thigh (L1 – L4).
14. Chest Expansion (< 4 cm = abnormal) (if ankylosing spondylitis suspected)
15. Check abdomen for aneurysm if claudication is present.
16. If symptoms/signs of cauda equina syndrome check anal sphincter tone, perianal sensation and palpate bladder checking for distention
17. Check Waddell's Signs (see below) if psychosocial screening causes concern.

Waddell's Signs

Waddell's signs consist of five tests designed to assess the non-organic nature of back pain. These tests have been shown to be of value in pointing towards psychological causes of low back pain. Three or more positive tests often predict failure of medical and surgical treatments. The following mnemonic may be useful in remembering these tests: "DR. STOP."*

D = Distraction test. Straight-leg raising may be either diminished or the test negative when the patient is distracted, such as testing when the patient is sitting.

R = Regional. Regional strength test: When testing muscle strength, there is evidence of cogwheeling or giving way. Regional sensory test: Diminished sensation fits a stocking rather than a dermatomal pattern.

S = Simulation test. Axial loading: When the examiner presses his or her palms on the standing patient's head, the patient complains of low back pain. Simulated rotation: Back pain is reported in the standing patient when shoulder and pelvis are passively rotated in the same plane by the examiner.

T = Tenderness. Superficial: The skin is tender to a light pinch over a larger than dermatomal area in the lower back. Nonanatomic: Deep tenderness is reported that involves several unrelated structures or areas.

O = Overreaction. Excessive dramatization of the usual expression of pain, like grimacing or moaning, is present.

P = Physician reaction. The physician may begin to feel frustrated or angry with the patient.

Remember to have **HEART**:

Hurt does not equal harm.

Empathy. Listen and reassure.

Attend to the psychological issues of fear of harm, depression, family and work stress.

Recovery plan developed with patient to resume ongoing activities.

Time contingent (not prn) medications and activities. (PRN orders reinforce dependency.)

TESTING

Plain x-rays are not recommended for routine evaluation of patients with acute low back problems within the first month of symptoms unless a red flag is noted. Bony spondylitic changes correlate poorly with patient's symptoms and may be seen in asymptomatic individuals. Plain films do not diagnose acute disc abnormalities and result in relatively high gonadal irradiation.

Plain x-rays may be useful to identify tumor, fracture, or infection in patients with acute low back problems when any of the following **red flags** are present: **prior cancer or recent infection, immunocompromised, fever over 100° F, IV drug use, prolonged steroid use, low back pain unimproved with rest, progressive neurologic deficit, minor trauma in elderly patients, urinary retention or control loss, or unexplained weight loss.**

Prompt advanced imaging and consultation with a spine specialist is recommended if there is progressive motor deficit or strong suspicion of tumor or infection. In the absence of red flags for serious abnormalities, routine

advanced imaging in the first four to six weeks of symptoms is NOT recommended. Eighty to ninety percent of patients will improve within one month with conservative care. A significant percentage (30 % – 50%) of healthy asymptomatic subjects will have abnormal imaging tests. Abnormal imaging findings may not correlate with patient's symptoms.

After 4 to 6 weeks of symptoms, advanced imaging may be appropriate for situations which suggest surgical intervention:

1. patients with back-related leg symptoms and clinically specific detectable nerve root compromise;
2. a history of neurogenic claudication and other findings suggesting spinal stenosis with symptoms.

When detailed imaging is needed, MRI is encouraged as imaging test of first choice, and should be ordered in consultation with an appropriate spine specialist. MRI has advantages compared with CT and CT-myelography including the following: no ionizing radiation, non-invasive, increased soft tissue contrast, multiplanar imaging, larger field of view.

Bone scan is rarely useful in the evaluation of acute low back pain. It may be used when occult fracture, infection, or bone tumor is suspected on the basis of "red flags." Although moderately sensitive, it is non-specific. Bone scans are contraindicated in pregnancy (strength of evidence = B).

Electrophysiological Testing

EMG's are not recommended for the evaluation of acute low back pain and sciatica, but may have a role in the evaluation of chronic back pain.

III. Development of pain management plan

The risks and benefits of various pain management options are discussed with patients (and families/caregivers when appropriate), with consideration for patient and family preferences in the design of any treatment strategy. An individualized pain management plan is developed.

IV. Reassessment

Patients with persistent pain are reassessed regularly for improvement, deterioration, or complications. Reassessment may include the use of a patient pain log or diary with regular entries for pain intensity, medication use, mood, response to treatment, and impact on activities. The same quantitative assessment scales are used for initial and follow-up assessments.

Reassessment also includes evaluation of analgesic and non-pharmacologic interventions, side effects, and adherence issues.

Patient preferences in assessment and treatment revisions are considered upon re-evaluation.

V. Strategies for managing pain:

A. Approach to pain management:

SMHC uses a multi-modal approach to the management of pain, which may include ice, rest, pharmacologic therapy, physical therapy, behavioral health counseling and/or complementary therapies. If pharmacologic therapy is deemed necessary, the following guidelines are used. The strategy for pharmacologic management of chronic pain stresses the importance of **around the clock (atc)** administration of medications.

B. Guidelines for the pharmacologic management of pain:

1. Follow the analgesic ladder adapted from the WHO Three –Step analgesic Ladder and American Pain Society Guidelines:
 - a. Step 1 – Mild to Moderate Pain
 - Non-opioid
 - Acetaminophen or an NSAID is used unless contraindicated
 - Tricycles Antidepressants (TCAs) are first line medications for neuropathic conditions (diabetic neuropathy, post-herpetic neuralgia)
 - Use secondary amines (nortriptyline and desipramine) versus tertiary amines because of fewer side effects.
 - Consider using in patients with sleeping problems
 - Tertiary amine should not be used in older adults, due to strong sedative and anticholinergic effects and orthostatic hypotension.
 - Start at low doses in patients with know cardiac conditions
 - Anti-convulsants (gabapentin, carbamazepine) are second line medications for neuropathic pain. Instruct patients on common side effects and that they lessen with time
 - Drowsiness
 - Dizziness
 - Nausea
 - Gait disturbances
 - Constipation
 - Muscle relaxants such as baclofen, soma, and flexeril may help some people but there is insufficient evidence to recommend them for the treatment of chronic low back pain.
 - Capsaicin is a comparable alternative to TCAs, with the primary side effect being burning at the application site, which lessens after several days.
 - In elderly, it is best to start with a low dose codeine with Tylenol (i.e. Tylenol #3) as first line treatment, as opposed to a NSAID (risk of GI disease and vascular disease)
 - Lidocaine gel and lidocaine patch are additional options for patients with post-herpetic neuralgia and intolerant to other medications. The main side effect is reddening and rash at the affected site.
 - b. Step 2 – Mild to Moderate Pain uncontrolled after Step 1
 - Short acting PRN opioid + non-opioid around the clock, unless contraindicated
 - Ultram may be used as a second line alternative to non-opioid therapy.
 - c. Step 3- Moderate to Severe Pain

- Sustained release opioid around the clock + short acting opioid PRN +non-opioid, (unless contraindicated)
 - Long acting morphine or fentanyl is indicated
 - When possible, the same opioid is used in the short acting and sustained release formulations
2. Principles of use of pharmacologic agents:
- a. Individualize each patient’s regimen
 - b. The oral or transdermal route is the preferred route of analgesic administration.
 - c. Medications for persistent or chronic pain should be administered on an around the clock basis with a long acting opioid. Use short acting opioids for titration until stable analgesia is reached and as needed for breakthrough pain for patients who are on long-standing opioids. Pain prevention is easier than relieving already established pain.
 - d. Demerol and Darvon should not be prescribed for long-term use.
 - e. Ultram, although not physiologically addictive, can be psychologically addictive.
 - f. Fiorinal/Fioricet are not recommended as first line agents for the treatment of migraines due to their rebound effect and potential for addiction.
 - g. Constipation is a preventable yet common problem associated with long-term opioid use. It should be treated prophylactically and monitored carefully. Refer to section VII for pharmacologic strategies.
 - h. Patients with chronic or persistent pain are given a written pain management plan.
 - i. The maximum daily dose of acetaminophen is 4 grams/day. This dose should be used with caution and adjusted in patients with reduced hepatic function.
 - j. Dosages of NSAIDs should be modified given renal and hepatic function.

C. Use of complementary therapies in the management of pain

1. Consider the use of the following, as indicated for the type of pain and or associated symptoms:
 - a. Physical Therapy, Occupational therapy
 - b. Thermotherapy (application of heat or cold), chiropractic care, acupuncture, massage therapy, relaxation techniques, biofeedback, psychotherapy, meditation, nerve block, nerve stimulators, osteopathic manipulative therapy.
 - c. Patients with chronic pain syndromes should be referred to pain management clinics or programs to access such therapies and to optimize their pharmacologic management.

D. Cognitive Behavioral Therapy

1. This involves the use of several different techniques in psychotherapy (utilizing discovery, imaging, and self-instruction) to focus on the way a patient thinks. The idea is that patients have learned a particular maladaptive behavior or set of behaviors and that the same process of learning a new behavior can be used to “improve” a particular maladaptive behavior.

E. Guidelines for the short-term prescription (< 4 weeks) of controlled substances (narcotics or medications with addictive potential, including, but not limited to, benzodiazepenes, muscle relaxants, tramadol)

1. A pain assessment is performed as described above.

2. The plan of care is developed and discussed with the patient.
3. When controlled substances are prescribed, whether for short or long term, the provider documents this on the medication flow sheet.
4. Adequate pain control during this period of time is vital to prevent this acute pain from becoming a chronic pain syndrome

F. Guidelines for management of patients on long-term (>4 weeks) controlled substances (narcotics or medications with addictive potential, as defined above). (Long-term = patients requiring such medications for more than 4 weeks without an immediate plan to taper from use.)

1. The initial pain assessment noted above (Section II) is used to determine whether the long-term prescription of controlled substances is indicated.
2. If a new patient requests the continuation of a controlled substance prescription that had been prescribed by prior providers, an investigation of the pain management history and a prescription review are required before the provider can prescribe the medication. This may involve requesting prior medical records, calling prior providers, contacting pharmacies that the patient has used, all done with the patient's consent. In general, providers do not prescribe controlled substances to new patients until the necessary information is available and has been reviewed. However, if in the provider's judgment, immediate prescription of a controlled substance is warranted, no more than 7-14 days of the medication is given. Requisite documentation of the pain management history is best sent directly to the treating provider and received before the time of the next visit, otherwise further prescription may be delayed, pending this information. Patients are educated that these procedures are required under SMHC's pain management policy.
3. A review of the SMHC medical record is performed to determine if other providers are prescribing such medications and if there is a current Treatment Agreement. **One** provider takes the responsibility for prescribing controlled substances. If the primary care provider is on vacation or at a conference, then he/she will assign a covering provider to prescribe routine controlled substance prescriptions.
4. If the primary care provider is unable to prescribe the routine prescription due to illness or unavailability, then a covering primary care provider can prescribe the routine refill of medication at a scheduled appointment. These refills cannot be prescribed by telephone. If the patient misses his or her appointment with his provider, then the patient needs to reschedule the appointment in order to get the routine renewal of the prescription. If the provider deems that there is a risk to the patient to be without this medication for the time period until the next available appointment, then the provider (via a Same Day Visit) can prescribe a quantity of medication sufficient to cover the patient until the earliest available appointment.
5. Prior to prescribing controlled substances, the provider verbally reviews and signs (with the patient) a Patient Care Agreement. This document confirms that the patient has received informed consent about the treatment plan
6. The original signed form is filed in the medical record, in front of the immunization flow sheet) and a copy is given to the patient.
7. A plan for pain management is developed with the patient and documented in the progress note section of the medical record. This plan is updated on a periodic basis.
8. Lost or stolen medications or prescriptions will not, in general, be replaced and shall be recorded as a

major contract break (see section K 1). At provider discretion, a one-time only exception may be made (i.e. when the patient presents a police report describing the incident). In this case, the patient must be “red-flagged” and discussed at the next provider meeting. A second incident is **automatic cause to discontinue opioid therapy.**

9. If a provider and a patient are in disagreement about the appropriate management, the provider may refer the chart to the medical director. If the patient is still unhappy with the treatment plan, he/she may choose care at another facility.

Definitions

1. **Federal Narcotics Law:** The Federal Controlled Substances Act of 1970 recognized five schedules of drugs based upon their relative abuse potential.

Class 1: Drugs with no current medical application and maximum abuse potential. Examples include heroin, LSD,MDMAA

Class 2: Opioid analgesics (i.e. morphine, methadone, oxycodone, hydrocodone), stimulants (dextroamphetamine, cocaine) and depressants (pentobarbital). Verbal prescriptions limited to amount needed for acute emergency and provider must supply a written prescription to pharmacy in 72 hours. No refills are allowed

Class 3: codeine, hydrocodone, and other opioids in lower doses, in combinations products such as vicodin, Tylenol #3.

Class 4: Propoxyphene combination products in low dose, benzodiazepines (Valium, ativan), stimulants such as phenteramine. Written prescription required and up to 5 refills are allowed within 6 months of issuance for this class

Class 5: Cough medicines with codeine in low dose (Robitussin-AC)

2. **Addiction** is a behavioral pattern of compulsive substance use for non-medical purposes despite their harmful effects. Addiction is characterized by psychological dependence and aberrant drug related behaviors. Addicts compulsively use drugs, are obsessive about securing their supply and have a high tendency to relapse after withdrawal. Compulsive use of controlled substances results in physical, psychological and social harm to the user. The addict seeks continued use despite that harm. The chronic pain patient addicted to prescription opioids has an intense desire for their drug and concern over its continued availability.
3. **Physical Dependence and Tolerance** may be normal physiologic consequences of extended opioid therapy and are not the same as addiction
4. **Substance Abuse** is the use of an agent outside the social or medical norms approved by a given culture. It can include prescription drugs, which may result in physical, psychological, economic, legal, or social harm to the individual or others.
5. **Pseudoaddiction** is an iatrogenic syndrome cause by poorly treated pain. The patient displays behaviors (moaning, increased requests for pain medications) wrongly interpreted by the provider as signs of addiction, rather than inadequately treated pain

H. Signs of Opioid Addiction:

1. Manipulative or abusive behavior directed at caregivers, including intimidation or coercion, and aimed at acquisition and continuance of the substance abuse.
2. Evidence of compulsive drug use, such as unsanctioned dose increases or unapproved uses despite side effects
3. Chaotic psychosocial behavior
4. Involvement with the law
5. Diversion for sale or misuse of controlled substances
6. Signs of poor personal habits, activities of independent living, or social dysfunction
7. Physical or emotional deterioration and de-conditioning

I. “Red flags” for Substance Abuse

1. Patient is more concerned about the drug than the problem
2. Patient reports multiple medication sensitivities
3. Patient cannot take generics
4. Refuses diagnostic workup or consultation
5. Has sophisticated knowledge of drugs
6. Says “you are the only one who can help me”
7. Says they have lost their prescription

J. Guidelines for Urine Drug Screening

1. Periodic random urine drug screens are ordered to ensure that patients are using the prescribed controlled substances and not using any illicit drugs. This is done at baseline, after 1 to 2 months of prescriptions, and 2-4 times per year thereafter. More frequent testing can be done at the provider’s discretion. Patients provide the urine specimen unsupervised. **All patients will be required to give a urine sample at every visit.** The sample will be sent to the lab at the provider discretion.
2. A negative random drug screen may indicate the absence of the prescribed medication and may be cause for tapering off controlled substances. (See procedure for tapering, below). This can be clarified with a more sensitive test such as a urine GCMS for the medication (on that same urine). The lab medical resident at SFGH will need to be notified. The approximate date and time of the last dose should be documented in the progress note.
3. A negative urine drug screen may mean that the sample was diluted. If the specific gravity is less than 1.003 and the creatinine is less than 20 mg/dl, this is considered a dilute urine and is likely an altered specimen. This may be viewed as a major contract break
4. If the patient’s urine drug screen is positive for illegal substances, the provider will make a referral for substance abuse treatment and possible taper the medication. The presence of an illegal substance is not necessarily cause neither for discontinuation nor for automatic tapering of the prescribed medication. However, there must be a treatment plan to address the substance usage (i.e. a treatment facility, narcotic anonymous) with documentation of attendance. Total abstinence initially is not an absolute requirement. Ideally, there should be a goal of a urine sample without illegal substances.

5. If a patient fails to comply with the Treatment Agreement or if the results of random drug screens are consistent with non-use of prescribed controlled substances or substance abuse, then a decision may be made to taper off controlled substances. A discussion with the patient about potential treatment options is provided and documented. Patients have the right to review this decision with the Medical Director.
6. Failure to submit a urine drug test is considered a positive test for a non-prescribed or illicit substance.
- K. **In cases of serious violation of the treatment agreement, or the violation of the law** (such as altering prescriptions) the prescribing provider may want to terminate care for the patient at SMHC. Such a decision must be reviewed and finalized by the Medical Director. Termination of care is considered and performed in accordance with the SMHC policy and procedure for patient termination of care. In cases of violation of the law, the police department is notified.
- L. **If a patient who has had controlled substances terminated walks in and is confrontational**, then the usual procedure is followed for managing the angry, confrontational patient. A supervisor is called, the patient is asked to leave and if he/she refuses, the police are notified
- M. **In the setting of end of life/hospice care**, providers may choose to waive the above requirements.
- N. **Discontinuation of Opioid Therapy**
- 1. Medication Management Agreement: Noncompliance (Contract Breaks)**
- Provider shall document contract breaks in the problem list (with the date). Cases with one serious contract break or more than one minor contract break will be discussed at the next provider meeting
 - **MINOR CONTRACT BREAKS** include:
 - a. Patient requests appointment with a provider other than their PCP, unless PCP is unavailable (as in the case of a vacation)
 - b. Patient fills prescriptions at more than one pharmacy, unless SMHC is notified prior to the change in pharmacy and as to the reason
 - c. Opioid refill is requested early (Potential minor break—assessed by provider—i.e. patient may simply have increasing pain)
 - d. Patient is not adhering to the treatment plan, including non-opioid therapies or is missing/not scheduling appointments.
 - **MAJOR CONTRACT BREAKS** include:
 - e. Urine or serum drug screen is refused
 - f. Lost or stolen medications or prescriptions
 - g. Drug screening indicates that prescribed medications are absent

- h. Request for pill count is refused or there is a pill count discrepancy
- i. Patient is abusive to staff
- j. Patient obtains narcotics from a provider other than the PCP

2. Two major contract breaks are grounds for discontinuation of opioid therapy (via a taper), either immediately by the provider, or with the final dispensation of the medications to be decided at the next provider meeting.

3. Opioid therapy may be discontinued for patients with multiple minor contract breaks at the provider's discretion. Otherwise, the provider will evaluate these patients every 1-2 weeks until adherence problems have resolved.
4. Opioid therapy shall be discontinued when the therapy or side effects are a greater detriment than benefit, as determined by consultation with the patient and family.
5. Opioid therapy shall be discontinued when there are serious safety issues as a result of treatment, such as the patient being a danger to themselves or others.
6. Opioid therapy may be discontinued if evaluation demonstrates lack of efficacy of therapy, the patient desires to discontinue therapy, or if the cause of the pain is resolved.
7. Opioid therapy will be tapered for all patients when therapy is to be discontinued, except as discussed below.
8. Opioid therapy shall be discontinued immediately if any dangerous, illegal, or criminal behaviors, including diversion of prescription medication, or alteration or forgery of prescriptions. Provider will treat potential withdrawal symptoms appropriately, or refer to addiction counseling immediately.
9. When opioid therapy is discontinued for a patient, the reason shall be written in both the progress note and the problem list and dated.
10. Patients that have been declined for treatment with controlled substances may not receive prescriptions for controlled substances from other providers at SMHC unless the patient is first discussed at the provider meeting and the provider consensus is that the patient is an appropriate candidate for such treatment.

O. Contraindications to Opioid Therapy

Absolute Contraindications to opioid therapy

- Allergy to opioid agents
- Co-administration of drug capable inducing life-threatening drug-drug interaction
- Active diversion of controlled substances
- Unwillingness or inability to comply with the treatment plan
- Unwillingness to adjust at-risk activities resulting in serious re-injury

Relative Contraindications/Cautions to Opioid Therapy

- Acute Psychiatric instability or high suicide risk
- History of intolerance, serious adverse effects, or lack of efficacy of opioid therapy
- Instability to manage opioid therapy responsibly (i.e. cognitively impaired)

- Social Instability
- Patient with sleep apnea not on Continuous Positive Airway Pressure (CPAP)
- Elderly patients
- Chronic obstructive pulmonary disease (COPD)
- Meets DSM-IV criteria for current substance use disorder

P. Guide to Tapering of Opioid Therapy

If there is concern that the patient has an active substance addiction, it may be best to consult with an addiction specialist prior to tapering the patient. It is difficult for addicted outpatients to comply with tapering schedule, since loss of control is part of the illness.

- For a fast taper: Taper 25% of the original dose every 2-3 days over a total period of 10-14 days. Rapid detoxification literature indicates that a patient needs 25% of the previous day's dose to prevent withdrawal.
- For a slow taper: Taper 25% of the original dose every week over a period of 1 month.
- Remain engaged with the patient during the tapering process and provide support.
- Consult with a pain specialist if the patient is on high dose opioids (>500mg morphine equivalent/day) or co-morbidities need to be addressed in relation to the taper.
- Patients who disagree with the treatment decision to stop opioids and drop out of treatment are encouraged to remain involved in comprehensive treatment.

Q. Educate on Withdrawal Symptoms

- Opiate withdrawal is not life threatening but can be quite uncomfortable.
- Signs and symptoms include gastrointestinal symptoms (such as abdominal cramping, nausea, vomiting, and diarrhea) anorexia, rhinorrhea, insomnia, anxiety, irritability, dysphoria, and increased sympathetic activity such as diaphoresis, tachycardia, fever, or mildly elevated blood pressures.
- Clonidine can be effective in suppressing symptoms of opiate withdrawal. Initial doses of 0.1mg bid to qid are used.
- Consider symptomatic treatment for GI symptoms
 - i. Loperamide 4mg po after the first loose stool, then 2mg po each additional loose stool, up to 16mg/24 hours
 - ii. Dicyclomine 20mg po q 6 hours prn stomach cramps
 - iii. Prochlorperazine 10mg po or 25mg suppository q 6 hours prn nausea or vomiting

O. Patients that have been dismissed from opiate treatment for contract breaks may not

Receive prescriptions for controlled substances from other providers, unless reviewed by the medical director.

P. Patients may not change primary care providers without the approval of the medical director

VI. Educating patients about pain

All patients with chronic pain or significant pain that is expected to last more than a few days receive health

education as part of their treatment plan. This may include the following topics:

1. **What to expect: goals/limitations of treatment; focus on quality-of-life outcomes.**
 - a. **DEFINED GOALS:** concrete goals should be set at the start of treatment and periodically thereafter—i.e.
 - i. Walk 2 blocks at a time
 - ii. Tie shoes
 - iii. Work 2 hours/day
 - iv. Shop
 2. Type of pain the patient has.
 3. Cause/mechanism of the patient's pain.
 4. Expected course of the pain.
 5. Treatment options, including medications and non-pharmacologic treatments. The risks and benefits of opioid treatment should be discussed
 6. Importance of overall well-being and of psychosocial factors in pain management.
- Education is tailored to the age, educational level and cognitive capacity of the patient. It may include information presented verbally, via written materials or in other modes as determined by the provider or care team. In the case of children or patients with cognitive impairments, the parent(s) or caregiver(s) also receive pain management education.
7. The definition of addiction, tolerance, physical dependency, and withdrawal should be discussed
 8. Patient responsibilities including keeping appointments, adherence to the treatment plan, obtaining medications from a single provider and pharmacy, feedback to the provider, and legal issues around diversion should be discussed.
 9. The importance of properly taking the medications should be discussed, including the dosing and timing and interactions with other medications.
 10. Adverse effects of treatment with opioid medications, including prophylactic treatment of adverse effects and management of constipation should be discussed.

VII. Common Adverse effects of Opioid Medications and Possible Interventions:

- **Constipation:** Can be managed with a stepwise approach that includes an increase in fiber and fluids, osmotic agents, a stool softener, or a mild peristaltic stimulant laxative, as needed. Treatment should be used not as a prn but prophylactically.
- **Nausea and Vomiting**—Consider prophylactic anti-emetic therapy
- **Itching**—Rule out an allergic reaction; consider treatment with antihistamines
- **Sweating**—Consider dose reduction or change of opioid
- **Peripheral Edema**—Consider dose reduction or change of opioid
- **Urinary Retention**—Consider dose reduction or change of opioid. Assess for cauda equina syndrome
- **Myoclonus**-- Consider dose reduction or change of opioid.
- **Hyperalgesia**-- Consider dose reduction or change of opioid.
- **Dyspepsia**-- Consider dose reduction or change of opioid; Add a PPI or H2 Blocker
- **Cognitive adverse effects**—Sedation, confusion, or deterioration of cognitive function. Consider referral to behavioral health, dosage reduction, change of opioid agent, or elimination of other drugs that may contribute to adverse effects. Concurrent sedative use may cause cognitive deficits in patients on chronic

opioid therapy

- **Perceptual or affective adverse effects**—Hallucinations, depression. All nonessential central nervous system acting medications (i.e. steroids) should be eliminated
- **Sexual dysfunction**—Hypogonadism may occur with chronic opioid therapy. Further evaluation and treatment should be considered

VIII. Provider competency in pain management

Providers who manage patients with pain are expected to keep up to date on current pain management strategies. Providers and clinical staff will be trained on the SMHC pain management policy and procedure upon hire and with each update of the policy/procedure.

IX. Pain management performance monitoring and quality improvement

An assessment of adherence to these guidelines and patient outcomes in acute/chronic pain management will be implemented.

X. Appendices

1. Medication list for controlled substances and treatment agreement for prescribing controlled substances
2. Flow diagram for ordering urine drug screen.

APPENDIX 1.

CONTROLLED SUBSTANCES POLICY

Medications requiring a controlled substance agreement if used >4 weeks:

Barbiturates

Benzodiazepines

Tylenol with codeine

Hydrocodone (vicodin etc.)

Oxycodone (oxycontin, percocet etc.)

Morphine (Ms Contin, Kadian)

Methadone

Hydromorphone (Dilaudid)

Fentanyl (Duragesic)

Meperidine (Demerol)

Propoxyphene (Darvocet, Darvon)

Methylphenidate (Ritalin, Concerta)

Amphetamine/dextroamphetamine (Adderal)

Carisoprodol (Soma)

Tramadol (Ultram)

PATIENT CARE AGREEMENT

This patient care agreement is between _____ and _____

for the condition of _____. The medications are: _____.

- I will see **only this provider for this medical condition**, unless the provider refers me to another or is ill/away. (Changing primary care providers for this condition can only be made with the approval of the medical director). I will make and keep my appointments with my provider. Missed appointments may result in the **complete stoppage** of this medication. Same day visits for issuing controlled medications are at the discretion of the provider. The prescription for the controlled medication is not guaranteed.
- I will use only one pharmacy for this medication: _____
- I will not share this medication
- Lost or stolen medications or prescriptions will not be replaced.
- Pharmacy records may be reviewed to confirm prescriptions
- Urine samples will be required at **every visit**. If it is felt that the urine is diluted or tampered with, my provider may chose to stop prescribing my controlled medications.
- I will have a "pill count" if my provider feels that it is necessary
- I will have an "observed urine" and/or observed taking of a medication if my provider feels that it is important
- I will not drink any alcohol, take any street drugs, or use any non-prescribed controlled substances while I am on this medication. If I have used or am using any of these substances, I will go to _____ program _____ times weekly monthly and give **written proof** to my provider
- Medications will only be refilled during office hours, by appointment with your provider
- Disruptive behavior or threats (or the appearance of this) toward staff and/or clients will result in discontinuation of the medication
- I understand that if I break this agreement, my provider may stop prescribing these medications. No other provider at south of market health center will prescribe this medication.
- My provider has the right to stop prescribing this medicine if he/she decides that it is not helpful for my problem or is harming me.
- Controlled Medications have side effects such as sleepiness, poor concentration, and constipation and may be addictive
- My goal (regarding my pain) is _____

Additional Comments _____

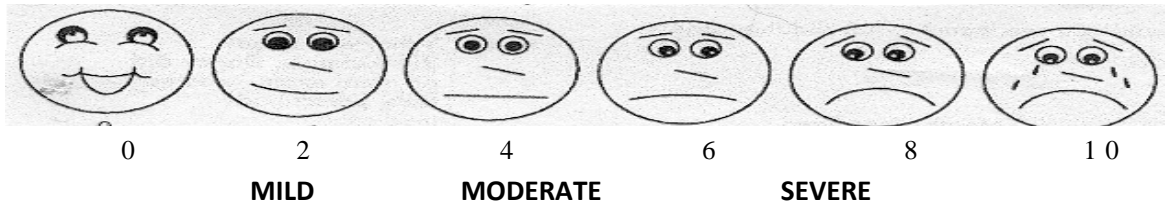
Pt signature _____ Date ____/____/0____

Prov. Signature _____ Date ____/____/0____

Revised 12/22/07

URINE TOXICOLOGY TESTING OVERVIEW draft (10.26.09)

DRUG	+ TEST	DURATION +	COMMENT
Alcohol	Alcohol	3-10 hours	Must order separately
Amphetamine	Amphetamine	1-2 days	Amphetamine, Methamphetamine, MDMA is tested
Barbiturates	Barbiturates	Up to 6 wks	
Benzodiazepines	Benzodiazepines	1-3 days, up to 6 wks with heavy use	False negative with "low" dosages, Klonopin is + for 2-4 days
Cocaine	Cocaine	2-4 days, 10-22 days with heavy use	
Codeine	Morphine, Codeine	1-2 days	
Heroin	Morphine, possibly Codeine	1-2 days	
Hydrocodone (Vicodin)	Vicodin, Hydromorphone	2 days	Urine should be neg for morphine
Hydromorphone (Dilaudid)	Hydromorphone	1-2 days	Urine should be neg for morphine
Methadone	Methadone	2-11 days	
Morphine	Morphine	1-2 days	
Oxycodone (Percocet)	Oxycodone, but not reliably	1-1 ½ days	Can use urine GC/MS for oxycodone, Urine should be neg for morphine
Phencyclidine (PCP)		1-8 days	
Propoxyphene (Darvon)		¼-2 days	Urine should be neg for morphine
Tetrahydrocannabinol (THC)		1-2 days, up to 1 month with chronic usage	



Credit to:

Harbor Health Center

Seattle Pain Clinic

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Hamakua Health Center, Inc

Petaluma Health Center

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DRAFT

Central City Concern Health Services

Old Town Clinic

PRESCRIBING OF OPIOIDS/CHRONIC PAIN POLICY

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Table of Contents

- 1. Background**
- 2. General Principals of Pain Management at Old Town Clinic**
- 3. Initiating Chronic Opioid Therapy in New Patients**
- 4. Management of Established Chronic Opioid Therapy Patients**
- 5. Maximum Dose of Chronic Opioids at Old Town Clinic**
- 6. Weaning Opioids**
- 7. Terminating Opioid Therapy**
- 8. CSRC- Controlled Substances Review Committee**
- 9. Using Opioids in Patients on Methadone Maintenance Therapy (MMT)**
- 10. Using Opioids in Patients in the CCC Recovery Center**
- 11. Prescribing Issues/Guidelines**
- 12. Management of Specific Contract/Agreement Violations**
- 13. Concomitant Prescriptions/Over The Counter Drugs in Patients on Chronic Opioid Therapy**
- 14. Recommendations for Analgesic Prescribing for Dental Pain**
- 15. Bibliography**
- 16. Appendix A: Methadone Interactions**

Abbreviations Used:

CSRC: Controlled Substances Review Committee

UDS: Urine Drug Screen

PCP: Primary Care Provider

MH: Mental Health

ROI: Release of Information

OD: Overdose

MMT: Methadone Maintenance Therapy

1. Background

Chronic, non-cancer pain, defined as pain of greater than 3 months duration, has a prevalence in the US Population of 20-60% (1). Despite its high prevalence, the optimal approach to treating chronic pain remains controversial. A paucity of clinical practice guidelines, controversy over the effectiveness of opioids on chronic non-malignant pain, and concern about potential legal and regulatory mechanisms, make caring for chronic pain patients extremely complex (2).

Several key developments in the past 12 months have caused some change in the way the medical community views chronic pain and its treatment. These include:

- A growing awareness of the hazards of chronic opioid therapy (especially at high dosages). Between 1999 and 2007, the rate of unintentional overdose death in the United States increased by 124% (3), largely because of increases in prescription opioid overdoses (4). Prescription drug abuse is the fastest growing drug problem in the United States (5).

Several recently published studies have demonstrated significant risk of harm (death, OD) in patients receiving high dose opioid therapy (6,7,8).

- A growing awareness of the public health impact of chronic opioids in the community (OD's/deaths, diversion, and a significant increase in the number of high school students who have tried prescription opioids). A recent report from the CDC/MMWR outlines the scope of the problem: "Since 2003, more overdose deaths have involved opioid analgesics than heroin and cocaine combined. In addition, for every unintentional overdose death related to an opioid analgesic, nine persons are admitted for substance abuse treatment, 35 visit emergency departments, 161 report drug abuse or dependence, and 461 report nonmedical uses of opioid analgesics (5).

- Increased appreciation for the myriad side effects associated with chronic opioid therapy.

- The adoption of "ceiling limits" of opiates (Washington State, Multnomah County Health Clinics).

The Old Town Clinic's view of long-term opioid therapy is perhaps best summarized by the following quote from a recent Annals of Internal Medicine editorial: "Given the warning signs and knowledge gaps, greater caution and selectivity are needed in prescribing long-term opioid therapy. Until stronger evidence becomes available, clinicians should err on the side of caution when considering this treatment" (9).

Given all of the complexities listed above, the high prevalence of patients seeking chronic pain medication at Old Town Clinic, and the significant rate of addiction and/or a history of addiction among our patient population, the clinic has adopted a thoughtful and holistic approach to the management of chronic pain which we believes incorporates the best available evidence to safely treat our patients.

2. General Principles of Pain Management at Old Town Clinic

Old Town Clinic patients with will receive a compressive and holistic approach to their chronic pain that that will include the following

- Complete evaluation of the pain complaint with appropriate workup and documentation.

- MH evaluation if indicated
- Participation in a chronic pain program entitled RENEW. Each patient with chronic pain will have a full pain intake assessment by our Occupational Therapist to help determine how the clinic can best treat the patient's pain. Most patients will participate in regular group sessions that will deal with alternative ways to deal with and alleviate pain.

3. Initiating Chronic Opioid Therapy in New Patients

All new patients at Old Town Clinic will sign a document acknowledging their understanding of opioid prescribing policies at the clinic during their intake appointment.

No opioids will be prescribed at the first visit. New patients will be told that it may take up to 1 month before they can receive opioids at Old Town Clinic.

Before a provider initiates opioid therapy at Old Town Clinic the following referrals/evaluation will be done

- Appointments with the patient's PCP to fully evaluate and document the cause of the patient's pain.
- OT chronic pain evaluation
- MH referral if indicated (low threshold for referral)
- full review of ROI's from previous providers/clinics
- UDS with documentation of results
- The provider will run a query through the Oregon Prescription Drug Monitoring Program and document the results of this query.
- If a patient transfers from another clinic and is on chronic opioid therapy, there will be no dose escalation of their chronic opioid dose.
- After all of the above has been done, the provider will submit a request to the Controlled Substances Review Committee (CSRC).

If approved by CSRC for chronic opioid therapy:

- The patient will have an appointment with their PCP to sign the Material Risk Notice and the Chronic Opiate Contract.
- Note that the maximum ceiling limit for chronic opioids is 120 mg morphine equivalent (see below)
- All written prescriptions for chronic opiates will be written for 28 days (or less); PCP's will make a clear designation on the prescription with the phrase "to last until (date)"
- Patients will have regular follow-up appointments with the PCP to assess the benefits of therapy and monitor opiate use; all patients must be seen at a minimum of every three months by their provider. Patients may need to be seen more often initially and/or if adjusting medications.
- Patients will have UDS's done at a minimum of every 3 months (more if necessary)
- patients will have random pill counts done at a minimum of once/year. This is done in an effort to monitor appropriate usage and assess for diversion. This process involves a call by a Panel Manager at any time during the month instructing the patient to come into the clinic within 24 hours of the call. The patient is to bring their pills into

the clinic for a pill count. The count will be recorded in the patients chart with the number of pills remaining and a report on any variance from the expected number.

-No use of illicit substance or alcohol is allowed

-No use of THC (even with a medical marijuana card) is allowed if a patient wants to be on chronic opioids.

-The concomitant use of benzodiazepines is strongly discouraged; if a patient is on benzodiazepines and opiates, a mental health provider must be involved in the care of the patient.

-If patient is on methadone for their chronic pain, a baseline, and annual, EKG, will be performed.

-Patients must engage in the clinic and participate in RENEW (if deemed appropriate by OT and the Provider)

-Patients should have their Chronic Opiate Contract reviewed and “re-signed” on a yearly basis. This should be recorded in the Problem List in the chart.

4. Follow-up of Established Chronic Pain Patients

-All written prescriptions for chronic opiates will be written for 28 days (or less); PCP’s make a clear designation on the prescription with the phrase “to last until (date)”

-Patients will have regular follow-up appointments with the PCP to assess the benefits of therapy and monitor opiate use; all patients must be seen at a minimum of every three months. Patients may need to be seen more often initially and/or if adjusting medications.

-Patients will have UDS’s done at a minimum of every 3 months (more if necessary)

-Patients will have pill counts (call by Panel Manger at any time during the month instructing patients to bring their pills into the clinic for a pill count; must come into the clinic within 24 hours of the call) done at a minimum of once/year. This is done in an effort to monitor and assess for diversion.

-No use of illicit substance or alcohol is allowed

-No use of THC (even with a medical marijuana card) is allowed if a patient wants to be on chronic opiates.

-Encourage smoking cessation (quitting smoking decreases pain)

-The concomitant use of benzodiazepines is strongly discouraged; if a patient is on benzodiazepines and opiates, a mental health provider must be involved in the care of the patient.

-If patient is on methadone for their chronic pain, a baseline, and annual, EKG will be performed.

-Patients must engage in the clinic and participate in RENEW (if deemed appropriate by OT and the Provider)

-If an existing Old Town Clinic patient is on a dose of opiates that exceeds the ceiling limit (120 mg of morphine oral equivalents), the provider will initiate a taper of the patient’s opioid medications by 10-15%/month until the patient’s dose of opioids is at the maximum opioid dosage.

-Any inappropriate behavior (missed appointments, abnormal UDS’s, failure to appear for pill counts, etc) will be submitted to CSRC for review

5. Maximum dose of Chronic Opioids at Old Town Clinic

The maximum ceiling dose of chronic opiate therapy at Old Town Clinic is 120 mg morphine equivalent (see equivalency table) Again, the total opiate dose, long-acting plus short-acting medications, should not exceed 120 mg morphine oral equivalents/day.

Drug	Equianalgesic Dose	Adult Starting Dose/Day	Ceiling Dose/Day
Morphine	30 mg	30 mg	120 mg
Codeine	200 mg	60-120 mg	800 mg
Hydrocodone	30 mg	10-20 mg	120 mg
Hydromorphone	7.5 mg	6-8 mg	30 mg
Oxycodone	20 mg	10-20 mg	80 mg
Methadone	10 mg (chronic)	5-15 mg	40 mg

The maximum dose of Fentanyl Transdermal is 25 mcg/hr (72 hrs)

OTC fully acknowledges that there may be some potential negative consequences to ceiling limits including:

- Patients leaving OTC and seeking care elsewhere.
- Patient anger.
- The increased use of illicit drugs.
- The unmasking of addiction.
- The under treatment of pain.

Again, given recent information that has come out in the past year, the clinic feels strongly that the ceiling limit of opiates currently represents the “best practice” regarding opioid dosing.

6. Weaning Opioids

A. Weaning existing patients who are on opioid doses above our ceiling limit.

The ceiling limit with opiate therapy was just initiated at OTC in December of 2011. As there are a substantial number of existing patients that are currently over the ceiling limit, these patients will need to be weaned down to the ceiling limit.

The rationale for the ceiling limit will be explained by the provider to the patient.

This discussion should be done with an emphasis on the context of “support” (not “abandonment”) and patient safety and well-being. The provider will discuss the rationale for a ceiling limit, discuss recent evidence linking potential hazards to high-dose chronic opioid therapy, the increased awareness of side effects of chronic opioid therapy, and the growing public health risk associated with opioid use. The provider will review recent ceiling limits imposed by the State of Washington and Multnomah County Clinics. Again, an emphasis will be placed on “being there” with the patient during this difficult process. Additional services will be offered to all patients including RENEW (see below) and MH services if indicated.

It is expected that existing patients will have their monthly dose decreased by 10-15%/month until they are at the ceiling limit.

B. Other Instances

In other situations where a more rapid weaning is desired, the provider may decrease the dose by 10% per week for long-acting opiates and 15% per week for short acting opiates.

A Provider may consider the use of Clonidine (0.1 mg-0.2 mg q 6 hrs) to minimize side effects.

Opiate withdrawal symptoms are uncomfortable but not dangerous.

The Provider should provide careful written instructions, documented in the record, as to how to wean down on opiates.

7. Terminating Chronic Opioid Therapy

The CSRC defines serious misuse or misconduct with regard to opiate medications as any of the following:

- 1) Forgery of alteration of prescriptions
- 2) Use of illicit substances (e.g. cocaine, methamphetamines, heroin, THC) and/or etoh, concurrently with prescribed opioids and their detection on urine toxicological testing.
- 3) Diversion of opioids.
- 4) Patient obtaining opioids, or controlled substances from multiple providers.
- 5) Negative or “clean” UDS’s. This is defined as the absence of prescribed opioids on at least two occasions in the context of a history that the patient is taking the medication as prescribed.
- 6) Inappropriate or inconsistent UDS’s. The presence on urine toxicology screens of opioids or other controlled substances not prescribed by OTC on at least two occasions without a reasonable explanation. This finding suggests polysubstance abuse, doctor shopping, or drug bartering.

Note that all violations of the Chronic Opiate Contract are to be reported to CSRC (see below). While it would be preferable for the patient’s PCP to submit the referral to the CSRC, any provider who is aware of a violation of the Chronic Opiate Agreement, may refer the patient to the CSRC. In an instance of serious misuse or misconduct, the prescribing of the controlled substance should be terminated immediately. The Provider should document the misuse/misconduct in the patient’s medical record and a referral should be made to the CSRC. If a Provider has a question that warrants immediate attention they should seek out the Medical Director of OTC or the Medical Director of CCC.

Note that not all of the above “violations” of the Chronic Opiate Agreement will necessarily result in termination of chronic opioid therapy. In many instances, the clinic will make every effort to deal with the problem and work with the patient to prevent further problems. This is contingent upon the patient fully engaging with all of the recommendations made by the clinic (CSRC).

8. Controlled Substances Review Committee (CSRC)

The purpose of the CSRC is to review cases and make recommendations for clinical management of chronic pain patients taking opioid pain medications or who wish to take opioids. All new patients who wish to receive chronic opioid therapy must be approved for this therapy by the CSRC. All violations of the Chronic Opiate Contract are to be submitted to the CSRC for evaluation and recommendations.

Appropriate referrals to the CSRC include:

- All “new starts” for patients who wish to receive chronic opiates.
- Questions arising re pain management issues or interpretation of UDS findings
- Instances in which a patient disputes provider judgment
- Violations of the Chronic Opiate Contract

Providers will submit an “Internal Referral” on Centricity to the CSRC.

For new patients, the provider will:

- have provided appropriate documentation of the patient’s chronic pain and evaluation.
- have a completed UDS with results noted in the chart
- have reviewed outside records
- have run a query with the Oregon Prescription Drug Monitoring Program with the results of this query noted.
- have made referrals to Occupational Therapy and Mental Health (if indicated).

For existing patients where there has been a misuse/misconduct issue, or if the provider has a clinical question, the provider will:

- submit a referral outlining the issue or question at hand.

If the provider disagrees with the CSRC’s recommendation, the provider may appeal the CSRC recommendation by notifying the Medical Director. The provider will submit relevant information, and a proposed plan to the Medical Director. The Medical Director will then bring the case back to CSRC for another review.

This committee is composed of the following members: Medical Director of CCC or OTC, Psychiatric Nurse Practitioner, Addictions Specialist, Occupational Therapist, and the CSRC logistics coordinator (prints up documents for members, drafts letters to patients, etc.). OTC Providers will also be asked to serve on the committee at various times.

The CSRC will meet on a weekly basis to review all submissions made during the previous week. The CCC Medical Director or OTC Medical director will be responsible for documenting the CSRC recommendations and getting these results back to the Provider in a timely fashion. All patients submitted to the CSRC will be considered for enrollment in our RENEW program (see below) which is designed to help our patients with chronic pain.

In an instance where a patient is being discontinued on his/her opioids, the PCP (or an appropriate designee) should notify the patient verbally. This communication should be documented in the chart. Additionally, the Medical Director will draft a letter which will be sent to the patient notifying them of the discontinuation of the medication. The Medical Director will also place a “Care Alert” in the chart stating: “No Controlled Substances per CSRC”.

Other Programs for Patients with Chronic Pain at OTC

RENEW

This program is run by our Occupational Therapy Department.

Patients participate in an activity-focused group model, with topics related to relaxation, leisure, nutrition and exercise. Each patient attends a group where they will participate in a wellness-related topic and then see their provider after the group to discuss pain-related issues. Clients are also required to attend an additional wellness-related activity at the clinic (e.g. RENEW activity groups, acupuncture, yoga, etc.) or participate in a health-promoting activity in their community (e.g. going to the gym, participating at a community center, etc.).

Two additional programs exist at OTC to help patients with chronic pain that have had, or are having difficulties with their addiction. The CSRC may elect to refer a patient to one of these programs (note that a patient may continue to be on their chronic opiates if they participate appropriately in these programs):

Hot Sauce

This is an A & D group run by an Addictions Specialist at OTC (Level 1 Outpatient Treatment).

For a 1st violation of the Chronic Opiate Contract or for a patient felt to be at “high risk” for chronic opiate therapy, the CSRC may elect to refer a patient to this group.

This group meets weekly for 12 weeks.

There is a zero tolerance policy in this group for further contract violations.

These groups focus on addictions and pain management

Recovery with Chronic Pain

This is an A & D group run by an Addictions Specialist at CCCRC (meets criteria for Level 2 Intensive Outpatient Treatment).

This is for patients who need full outpatient A & D treatment and are on chronic opiates.

The group focuses on treating addiction, stabilizing/tapering dose of opiates, and improving trust and relationships with PCPs.

This group is for patients that are felt to be too “high risk” for Hot Sauce (e.g. patients actively using drugs and on opiates)

9. Using Opiates in Patients on Methadone Maintenance Therapy (MMT)

-In the event of an acute injury, short-acting narcotics may be prescribed to patients on MMT. In such a case, the Medical Director at the patient’s methadone clinic must be contacted. Short-acting opiates should be prescribed at the shortest treatment duration possible (not to exceed 2 weeks’ worth of medication).

-Do not prescribe extra doses of methadone or any other long-acting opiate to supplement the methadone maintenance dose.

-In a patient on MMT who has chronic pain, consult the Medical director at the patient's methadone clinic to consider split-dosing of the patient's methadone (for better pain control).

-In any instance where a patient on MMT is receiving (or the PCP is considering) chronic opiate therapy (short-acting opiates), there must be a full discussion, and approval from the Medical Director at the methadone clinic and the CSRC.

-If a patient is fired from a methadone clinic, the PCP may not assume prescribing of methadone for that patient even if the patient has issues of chronic pain. The patient must establish care at another methadone clinic.

-Patients with chronic non-malignant pain who are on methadone maintenance present a particularly vexing problem to the clinician. It is well recognized that once daily dosing of methadone is not optimal for pain control (and methadone maintenance programs are not designed to provide adequate analgesia for chronic pain). If it is deemed medically necessary that a patient on MMT requires long-acting or chronic opioids for chronic non-malignant pain, the following protocol must be carefully articulated and carried out in partnership with the Medical Director at the patient's methadone clinic. The patient must establish a minimum of 6 take-outs per week at his/her methadone clinic. Per discussion with the methadone clinic Medical Director (and approval of the CSRC), transition to PCP prescribing may

require up to one month's worth of take-outs. Once that has been established, the PCP may assume prescribing of methadone with split dosing (a regimen for appropriate for treatment of chronic pain) (10). If it is felt that the patient must continue to receive daily dosing of methadone at the methadone clinic, an alternative is for the methadone clinic to apply for a variance and give split dosing to the patient at the methadone clinic. Under no circumstances may a PCP assume methadone prescribing for a patient currently in a methadone clinic without following the procedure outlined above.

-Safety and Monitoring for Patients on Methadone. For patients on MMT, and those on methadone for chronic pain, monitoring for interactions with other medications is vital. See below (Appendix A) re common medications and their interaction with methadone.

-Additionally, methadone in combination with other medications may cause a prolonged QT interval. While there is no definitive evidence to suggest that obtaining a baseline EKG is necessary or prevents episodes of Torsades de Pointes (a possible complication of prolonged QT interval), the clinic recommends checking a baseline EKG and yearly EKG's to monitor for QTc. More importantly, the PCP is to obtain a careful medical history screening for known cardiac risk factors, as well as to carefully monitor all prescribed, over-the-counter and illicit medications that the patient is taking. It is prudent not to co-prescribe medications known to prolong the QT interval, or to co-prescribe medications that might produce elevations of serum methadone levels (possibly contributing to dysrhythmias) without carefully considering the risks and benefits (11).

10. Using Opioids in Patients in the CCC Recovery Center (and in recovery elsewhere)

-For patients receiving short-acting opiates for acute pain, the PCP should contact the patient's counselor at CCRC to alert him/her of the prescription.

-Initiating chronic opiate therapy on patients at CCCRC should be avoided. Patients are in early stages of recovery, and initiation of such substances complicates, and may jeopardize, recovery. Additionally, the patient may jeopardize the recovery of other patients/clients in CCCRC. The chances of successful management of pain with opiates increases the more remote the history of addiction. Chronic opiate therapy should only be considered if the patient continues to have pain despite an adequate therapeutic trial of non-pharmacologic modalities including MH referral, acupuncture, and the full range of RENEW offerings (movement classes, mindfulness, Yoga, Qi-Gong, nutrition, etc). Additionally, the patient must have had an adequate therapeutic trial of non-narcotic medications. If the patient is subsequently approved for chronic opiate therapy by the CSRC, a multi-disciplinary staffing should occur between the patient's PCP, counselor, sponsor (if available), housing case manager, and other providers as necessary.

Ongoing management requires maximal structure with frequent visits (weekly or bi-weekly), frequent UDS's, and careful monitoring for misuse/abuse.

As different programs within the Recovery Center (especially the Mentor Program) have different policies regarding client use of controlled substances, both the client and PCP must abide by the standards and guidelines of the particular CCCRC program in which the client is enrolled.

For patients with chronic pain who are in other recovery programs (not CCCRC), employ similar practices as noted above.

11. Prescribing Issues/Guidelines

All prescriptions for controlled substances are written for 28 days cycles and the refills should fall on a day when the PCP is normally in the clinic.

Lost or stolen prescriptions will not be refilled.

Refills will not be given after clinic hours, on weekends, or holidays.

All refills will be obtained through a single designated pharmacy.

Early refills should be avoided, but may be given at PCP discretion for compelling reasons. The PCP should document the reason for the early refill and document on the prescription the appropriate date for the next refill. The PCP should advise the patients that early refills will not be done a regular basis.

All refills must be obtained through the PCP, or in his/her absence, another provider in the clinic.

Dosage adjustments will only be made by the PCP unless she/he is on a prolonged leave of absence (> 4 wks).

Authorize no more than 2 (original plus 2) refills for Schedule III narcotics and only for low-risk patients.

All patients receiving chronic opioids must be seen by their PCP at least every 3 months.

12. Management of Specific Contract/Agreement Violations

1) Early refill request or running out and getting supply from outside provider

- Evaluate patient for appropriate level of pain control; patient may need dose escalation.
- Evaluate for narcotic abuse and discontinue if appropriate.
- Consider Mental Health evaluation; patient may be abusing medication to relieve psychiatric symptoms.
- Counsel patient that repeated, abrupt withdrawal from pain medication which results from early exhaustion of drug supply can compromise good pain management.
- Patients with genuine pain issues and intractable abuse of prescription opiates are sometimes effectively managed through methadone maintenance (at a methadone clinic); consult the medical director of a methadone clinic.

2. Presence of drugs of abuse in urine

- A positive screen for drugs of abuse is rarely a false positive.
- Patient is to be referred to CSRC for further evaluation/recommendations

3. Absence of prescribed drug in urine

- Absence of short-acting opiates in urine does not necessarily mean the patient is not taking the medication, especially with oxycodone, or when the patient uses low dose or takes the medication intermittently; if diversion is a concern, see below.
- Absence of long-acting opiates in the urine is presumptive evidence that the patient has not taken the drug.
 - *patient may have run out early and should be evaluated as above.
 - *patient may not be taking regularly, in which case a long-acting medication may not be appropriate.
 - *patient may be diverting medication and medication should be discontinued

4. Suspected Diversion

- Documented sale of prescription drugs should result in immediate and permanent termination of all prescriptions for scheduled drugs.
- For unsubstantiated reports or absence of drug in urine:
 - *Increase frequency of UDS's
 - *Prescribe only long-acting opiates which can be reliably monitored in the urine.
 - *Utilize random "pill-counts". Less than expected number of pills coupled with a negative UDS is presumptive evidence of diversion and medication should be discontinued.

13. Concomitant Prescription/Over the Counter Drugs in Patients on Chronic Opioid Rx

Medical Marijuana

Concomitant use of Medical Marijuana is not allowed in patients on chronic opiate therapy.
A provider may refer select cases to CSRC for review of this issue.

Benzodiazepines

-In general, the use of benzodiazepines for patients at OTC is discouraged. Any patient at OTC that is receiving benzodiazepines must be seen by a MH provider for documentation re the appropriateness of the use of benzodiazepines for the patient.

-Concomitant use of benzodiazepines in patients receiving chronic opiates is not recommended,

-Any patient on benzodiazepines who wishes to be on opiate therapy should be tapered off the benzodiazepine, or must be followed by a Mental Health Practitioner.

-Positive drug screens for benzodiazepines that are not prescribed should prompt a referral to the CSRC and prompt reconsideration of opiate prescribing because of the risk inherent in combining opiates and uncontrolled and unmonitored benzodiazepine use.

-Benzodiazepine use is strongly discouraged in patients on long-acting opioids. Benzodiazepine use, among methadone users, has the potential to cause significant morbidity and mortality (12-17). Concomitant use of a benzodiazepine in a patient on methadone mandates consultation, and ongoing visits, by a MH Provider.

Additionally, if a patient is on methadone maintenance through a Methadone Clinic, communication and consultation with the Medical Director at the patient's methadone clinic is required prior to prescribing any benzodiazepine.

Carisoprodol (Soma)

Carisoprodol is a Schedule IV drug that has, in the past, been used as a muscle relaxant. It has a high abuse potential (18) and should not be used.

Barbiturates

Avoid use due to additive sedating effects

Promethazine (Phenergan)

Concomitant use of phenergan is not recommended (a patient request for Phenergan by name should raise suspicion of opiate abuse/diversion)

New patients should not be prescribed phenergan

Existing patients should be taken off phenergan and given an alternative agent.

Quetiapine (Seroquel)

Seroquel has potential for abuse secondary to its "high street value" due to its known sedative and anxiolytic qualities.

There are also reports of intranasal pulverized pills use/abuse in the opiate addicted/abusing population. This is a very expensive drug and its it recommended that caution be used when prescribing. In patients on chronic opiates, it is recommended that MH evaluation be pursued to justify ongoing use of this medication.

Acetaminophen

Exercise caution when prescribing combination narcotic-acetaminophen drugs to insure that the total daily dose does not exceed 3 grams/day (or 2 grams/day in patients with liver disease/impairment)

Tramadol (Ultram)

Tramadol is a novel, central-acting synthetic opioid with weak mu-opioid activity. It has been approved for treatment of moderate to moderately-severe pain in adults (19,20). Although Tramadol appears to have a low potential for abuse, the literature does reveal evidence of abuse, addiction and withdrawal (21). For these reasons, Old Town Clinic treats Tramadol like an opiate and all policies that apply to opiates also apply to Tramadol (e.g. contract, CSRC referral, UDS's, etc.)

14. Recommendations for Analgesic Prescribing for Acute Dental Pain

Dental disease (and dental pain) is a common problem among clinic patients. Additionally, there is a paucity of dental services available to our patients. Using guidelines developed by the dental community (published guidelines), NSAID's are to be used to treat acute dental pain (based on evidence that optimal doses of NSAID's are superior in efficacy to single-entity- opioids, and are at least as efficacious as optimal doses of peripheral/opioid combination drugs). The addition of acetaminophen (< 3000 mg/day for patients without liver dz and < 2000 mg/day for patients with liver dz) may be helpful for patients if pain relief from NSAID's is inadequate. For patients in whom NSAID's are contraindicated, Acetaminophen is the first-line analgesic. OTC does not recommend the use of opiates for acute dental pain (22).

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Appendix A.

Table 6: QTc Interval Prolongation and Methadone

QTc prolonging medications with risk of Torsades de Pointes (www.torsades.org)	Anti-cancer	Tamoxifen	
	Anti-infective	Macrolides	Clarithromycin Erythromycin Azithromycin
		Floxins	Gatifloxin Levofloxin Moxifloxin
		Anti-virals	Amantadine Foscarnet
		Anti-malarials	Chloroquin Halofantrine
		Pneumocystis prophylaxis	Pentamidine
		Cardiac	Anti-anginal
	Anti-arrhythmics		Amiodarone Disopyramide Flecainide Ibutilide Procainamide Quinidine Sotolol
	Anti-hypertensive		Nicardipine
	Diuretic		Indapamide
	Endocrine		Somatostatin analog
	Gastrointestinal	Anti-emetic	Droperidol Ondansetron Dolasetron Granisetron
		Motility modifier	Cisapride Domperidone
	Immunosuppressants		Tacrolimus
	Neurologic	Anti-convulsants	Fosphenytoin
		Anti-migraine	Naratriptan Sumatriptan Zolmitriptan
		Anti-spastic	Tizanidine
	Psychiatric	Anti-psychotics (including atypicals)	Chlorpromazine Haloperidol Mesoridizine Pimozide Thioridizine Risperidone Quetiapine
		Anti-depressants	Fluoxetine Paroxetind Sertraline Venlafaxine
		Sedatives	Chloral Hydrate

		Mood stabilizers	Lithium
	Respiratory	Anti-asthmatic	Salmeterol/Fluticasone
	Urologic	Benign Prostatic Hypertrophy	Alfluzosin
QTc abnormal values		460 ms in women 440 ms in men Values above 500 indicate significant risk of arrhythmia	
Useful websites		www.torsades.org	Regularly updated list of drugs that may prolong QTc interval
		www.atforum.com	numerous review articles on methadone, including: methadone safety and dosing methadone-drug interactions methadone and heart health

Table 7a: Actual or Potential Methadone Drug Interactions

Medications that will increase or decrease methadone effect		MEDICATIONS THAT DECREASE METHADONE EFFECT	MEDICATIONS THAT INCREASE METHADONE EFFECT
Anti-infectives	Antibiotics	fusidic acid (Fucidin)	
	Antifungals		fluconazole (Diflucan) ketoconazole (Nizoral)
	Antimalarials	rifampin	
	Antiretrovirals	abacavir (Ziagen) amprenavir (Agenerase) efavirenze (Sustiva) lopinavir/ritonavir (Kaletra) nelfinavir (Viracept) nevirapine (Viramune)	delavirdine (Rescriptor)
	Floxins		ciprofloxacin (Cipro)
	Macrolides		azithromycin (Zithromax) clarithromycin (Biaxin) erythromycin
	Psychiatric	Antianxiety	
Antidepressants *			fluoxetine (Prozac) fluvoxamine (Luvox) moclobemide (Manerix) nefazodone (Serzone) paroxetine (Paxil) sertraline (Zoloft)
Barbiturates		amobarbital (Amytal) butalbital (in Fiorinal) pentobarbital (Nembutal) phenobarbital secobarbital (Seconal)	
Opioids		butorphanol buprenorphine naloxone naltrexone nalbuphine pentazocine	
Gastrointestinal	Acid disorders		cimetidine (Tagamet) omeprazole (Losec)
Neurologic	Anti-alcohol		disulfiram (Antabuse)
	Anti-convulsant	carbamazepine (Tegretol) phenytoin (Dilantin)	
	Anti-migraine		dihydroergotamine (Migranal)
Urologic	Diuretics	spironolactone (Aldactone)	
	Urinary	large dose vitamin C	

	acidifiers Urinary alkinizers	K-phos	sodium bicarbonate potassium citrate (K-lyte)
Cardiovascular	Calcium Channel Blocker		verapamil (Isoptin)
Corticosteroids		dexamethasone (Decadron)	
Herbal medicines		St. John's Wort	cat's claw chamomile echinacea goldenseal
Drugs of abuse		alcohol (chronic use) cocaine heroin tobacco	alcohol (acute use)
Food			grapefruit juice

* The SNRI venlafaxine has the least potential for interaction with methadone

Table 7b: Actual or Potential Methadone Drug Interactions

Medications whose serum levels are increased by methadone	Desipramine Zidovudine Dextromethorphan Codeine Hydrocodone Haloperidol Phenothiazines β-blockers
Medications with additive toxicity	Benzodiazepines** Monoamine-oxidase inhibitors
Medications associated with synergistic analgesia	Δ-9-Tetra-hydrocannabinol Ibuprofen Diclofenac

(Davis and Walsh, 2001 and Bruera and Sweeney, 2002, www.atforum.com)

** Cases of fatal drug overdose have been reported with co-administration with alprazolam due to additive toxicity

Medical Board of California

Guidelines for Prescribing Controlled Substances for Pain

Adopted Unanimously by the Board in 1994 and revised in 2007

"No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain."

Business and Professions Code section 2241.5(c)

Preamble

In 1994, the Medical Board of California formally adopted a policy statement titled, "Prescribing Controlled Substances for Pain." The statement outlined the board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement was the product of a year of research, hearings and discussions. California physicians and surgeons are encouraged to consult this policy statement and the guidelines below.

In May 2002, as a result of AB 487, a task force was established to review the 1994 Guidelines and to assist the Division of Medical Quality to "develop standards to assure the competent review in cases concerning the management, including, but not limited to, the under treatment, under medication, and over medication of a patient's pain." The task force expanded the scope of the Guidelines from intractable pain patients to all patients with pain.

Under past law, both Business and Professions Code section 2241 and Health and Safety Code section 11156 made it unprofessional conduct for a practitioner to prescribe to an addict. However, the standard of care has evolved over the past several years such that a practitioner may, under certain circumstances, appropriately prescribe to an addict. AB 2198, which became law on January 1, 2007, sought to align existing law with the current standard of care. Accordingly, a physician is permitted to prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under his or her treatment for a purpose other than maintenance on, or detoxification from, prescription drugs or controlled substances. The law, Business and Professions Code section 2241, also set forth the conditions under which such prescribing may occur. Further, Business and Professions Code 2241.5 now permits a physician to prescribe for or dispense or administer to a person under his or her treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

Inappropriate prescribing of controlled substances, including opioids, can lead to drug abuse or diversion and can also lead to ineffective management of pain, unnecessary suffering of patients, and increased health costs. The Medical Board recognized that some physicians do not treat pain appropriately due to a lack of knowledge or concern about pain, and others may fail to treat pain properly due to fear of discipline by the board. These Guidelines are intended to improve effective pain management in California, by avoiding under treatment, over treatment, or other inappropriate treatment of a patient's pain and by clarifying the principles of professional practice that are endorsed by the Medical Board so that physicians have a higher level of comfort in using controlled substances, including opioids, in the treatment of pain. These Guidelines are intended to promote improved pain management for all forms of pain and for all patients in pain.

A High Priority

The board strongly urges physicians and surgeons to view effective pain management as a high priority in all patients, including children, the elderly, and patients who are terminally ill. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain,

pain assessment and pain treatment. Pain treatment may involve the use of several medications and non-pharmacological treatment modalities, often in combination. For some types of pain, the use of medications is emphasized and should be pursued vigorously; for other types, the use of medications is better de-emphasized in favor of other therapeutic modalities. Physicians and surgeons should have sufficient knowledge or utilize consultations to make such judgments for their patients.

Medications, in particular opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, or cancer. A number of [medical organizations](#) have developed guidelines for acute and chronic pain management.

The prescribing of opioid analgesics for patients with pain may also be beneficial, especially when efforts to alleviate the pain with other modalities have been unsuccessful.

Business and Professions Code section 2241.5 provides in part: "(a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain. (b) No physician and surgeon shall be subject to disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances in accordance with this section."

However, this section does not affect the power of the board to discipline a physician and surgeon for any act that violates the law, including gross negligence, repeated negligent acts, or incompetence; violation of section 2241 regarding treatment of an addict; violation of section 2242 regarding performing an appropriate prior examination and the existence of a medical indication for prescribing, dispensing, or furnishing dangerous drugs; violation of section 2242.1 regarding prescribing on the Internet; failure to keep complete and accurate records of purchases and disposals of controlled substances; writing false or fictitious prescriptions for controlled substances; or prescribing, administering, or dispensing in violation of the pertinent sections of the Health and Safety Code.

The Medical Board expects physicians and surgeons to follow the standard of care in managing pain patients.

Guidelines

- **History/Physical Examination**

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function; a substance abuse history; history of prior pain treatment; an assessment of underlying or coexisting diseases or conditions; and documentation of the presence of a recognized medical indication for the use of a controlled substance.

- *Annotation One:* The prescribing of controlled substances for pain may require referral to one or more consulting physicians.
- *Annotation Two:* The complexity of the history and physical examination may vary based on the practice location. In the emergency department, the operating room, at night or on the weekends, the physician and surgeon may not always be able to verify the patient's history and past medical treatment. In continuing care situations for chronic pain management, the physician and surgeon should have a more extensive evaluation of the history, past treatment, diagnostic tests and physical exam.

- **Treatment Plan, Objectives**

The treatment plan should state objectives by which the treatment plan can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician and surgeon should tailor pharmacological therapy to the individual medical needs of each patient. Multiple treatment modalities and/or a rehabilitation program may be necessary if the pain is complex or is associated with physical and psychosocial impairment.

- *Annotation One:* Physicians and surgeons may use control of pain, increase in function, and improved quality of life as criteria to evaluate the treatment plan.
- *Annotation Two:* When the patient is requesting opioid medications for their pain and inconsistencies are identified in the history, presentation, behaviors to physical findings, physicians and surgeons who make a clinical decision to withhold opioid medications should document the basis for their decision.

- **Informed Consent**

The physician and surgeon should discuss the risks and benefits of the use of controlled substances and other treatment modalities with the patient, caregiver or guardian.

- *Annotation:* A written consent or pain agreement for chronic use is not required but may make it easier for the physician and surgeon to document patient education, the treatment plan, and the informed consent. Patient, guardian, and caregiver attitudes about medicines may influence the patient's use of medications for relief from pain.

- **Periodic Review**

The physician and surgeon should periodically review the course of pain treatment of the patient and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient's progress is unsatisfactory, the physician and surgeon should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

- *Annotation One:* Patients with pain who are managed with controlled substances should be seen monthly, quarterly, or semiannually as required by the standard of care.
- *Annotation Two:* Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment.

- **Consultation**

The physician and surgeon should consider referring the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Complex pain problems may require consultation with a pain medicine specialist.

In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion.

- *Annotation One:* Coordination of care in prescribing chronic analgesics is of paramount importance.
- *Annotation Two:* In situations where there is dual diagnosis of opioid dependence and intractable pain, both of which are being treated with controlled substances, protections apply to physicians and surgeons who prescribe controlled substances for intractable pain provided the physician complies with the requirements of the general standard of care and California Business and Professions Code sections 2241 and 2241.5.

- **Records**

The physician and surgeon should keep accurate and complete records according to items above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, rationale for changes in the treatment plan or medications, agreements with the patient, and periodic reviews of the treatment plan.

- *Annotation One:* Documentation of the periodic reviews should be done at least annually or more frequently as warranted.
- *Annotation Two:* Pain levels, levels of function, and quality of life should be documented. Medical documentation should include both subjective complaints of patient and caregiver, and objective findings by the physician.

- **Compliance with Controlled Substances Laws and Regulations**

To prescribe controlled substances, the physician and surgeon must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians and surgeons are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

- *Annotation One:* There is not a minimum or maximum number of medications which can be prescribed to the patient under either federal or California law.
- *Annotation Two:* Physicians and surgeons who supervise Physician Assistants (PA's) or Nurse Practitioners (NP's) should carefully review the respective supervision requirements.

Additional information on PA supervision requirements is available at www.pac.ca.gov.

PA's are able to obtain their own DEA number to use when writing prescriptions for drug orders for controlled substances. Current law permits physician assistants to write and sign prescription drug orders when authorized to do so by their supervising physician for Schedule II-IV. Further, a PA may only administer, provide or transmit a drug order for Schedule II through V controlled substances with the advanced approval by a supervising physician for a specific patient unless a physician assistant completes an approved education course in controlled substances and if delegated by the supervising physician. To ensure that a PA's actions involving the prescribing, administration, or dispensing of drugs is in strict accordance with the directions of the physician, every time a PA administers or dispenses a drug or transmits a drug order, the physician supervisor must sign and date the patient's medical record or drug chart within seven days. (Section 1399.545(f) of Title 16, California Code of Regulations)

NP's are allowed to furnish Schedule III-V controlled substances under written protocols.

Postscript

While it is lawful under both federal and California law to prescribe controlled substances for the treatment of pain - including intractable pain - there are limitations on the prescribing of controlled substances to or for patients for the treatment of chemical dependency (see Sections 11215-11222 of the California Health and Safety Code). In summary, a physician and surgeon must follow the same standard of care when prescribing and/or administering a narcotic controlled substance to a "known addict" patient as he or she would for any other patient.

The physician and surgeon must:

- perform an appropriate prior medical examination;

- identify a medical indication;
- keep accurate and complete medical records, including treatments, medications, periodic reviews of treatment plans, etc;
- provide ongoing and follow-up medical care as appropriate and necessary.

The Medical Board emphasizes the above issues, both to ensure physicians and surgeons know that a patient in pain who is also chemically dependent should not be deprived of appropriate pain relief, and to recognize the special issues and difficulties associated with patients who suffer both from drug addiction and pain. The Medical Board expects that the acute pain from trauma or surgery will be addressed regardless of the patient's current or prior history of substance abuse. This postscript should not be interpreted as a deterrent for appropriate treatment of pain.