SAN FRANCISCO HEALTH PLAN
Here for you

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Dear Providers,

San Francisco Health Plan (SFHP) in the Spring 2014 released a plan for improving chronic non-cancer pain management. This comprehensive pain program proposed dose ceilings and tapering targets on an aggressive timeline. Based upon the thoughtful feedback from many of you, SFHP is revising the plan and focusing on working with clinicians in preparation for implementation of dosing limits for SFHP members.

SFHP is grateful for your long history of dedication to our community's underserved members. We recognize that care strategies for chronic pain management have rapidly evolved over the last 10 years. We continue to seek your partnership in delivering safe, compassionate, effective pain management.

Our plan to work with providers to taper SFHP members to 400 mg MED and then to 200 mg MED is forthcoming. We will release a new timeline of PA requirements for the phased implementation of dose limits. Please see Attachment A for an overview of the program.

What follows are the key changes:

Policy for Refills, Short-Acting Opioids, and Multiple Opioids

Effective 3/1/14, SFHP has limited fills for all opioid medications to a 30 day supply. This means that pharmacies will not dispense more than a 30 day supply of an opioid medication at one time. Providers may continue to indicate refills on the prescription for Schedule III-V medications (i.e. hydrocodone/acetaminophen or acetaminophen/codeine). The pharmacies will still honor refills for schedule III-V medications, but will only fill a 30 day supply at one time.

Effective 6/1/14, SFHP has limited refills to no sooner than 90% of the expected duration. This means that a 30-day supply cannot be filled sooner than 27 days. This is to allow fills prior to weekends. Providers can enforce 30-day windows, if desired, by writing "do not fill sooner than 30 days" on prescriptions.

Effective 9/1/14, SFHP will limit short-acting opioids to a maximum of 120 tablets every 30 days. Short-acting opioids should be used for breakthrough pain, not for ongoing daily routine use. If a short-acting medication is prescribed more frequently than 4 times a day, SFHP will work with the prescriber on potential simplification of the regimen. Caution should be used when transitioning from one opioid to another, with consideration of starting the new regimen on 30% less than the calculated equivalent dose.

We recognize that this work is extremely challenging and that these patients have complex lives and many comorbid conditions. We know that altering a medication plan for patients on high-dose can be very difficult. SFHP would like to support providers in any way possible. Please send your questions to Mimi Zou, Project Manager of Clinical Improvement Programs, mzou@sfhp.org.

Best regards,

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Executive Overview

Attachment A

The highlighted areas indicate a change from the original release of the program. The new implementation timeline for these areas is forthcoming.

Page	Topic	Highlights
1	**Background about epidemic; SFHP priorities**	SFHP's top priorities: 1. Avoiding opioids in the presence of active substance use 2. Avoiding high-dose opioids (>200 mg Morphine Equivalents or >50 mg methadone daily) 3. Avoiding simultaneous opioids and benzodiazepines 4. Avoiding opioids for pain while receiving opioid-replacement therapy for addiction
1-2	**SFHP's approach to pain management**	1. Incentive bonuses supporting protocols and best practices 2. Promoting integrated approaches to pain 3. Supporting care coordination and information exchange between systems of care 4. Educational and training opportunities for providers, staff and patients
2-3	**Best practices**	Best practices based on evidence and national guidelines, with supporting references.
4	**Substance Use Policy**	Prescribing in the face of active substance use increases the risk of overdose and death for the patient, and puts the community at risk.
4-5	**High-Dose Opioid Policy**	High-dose opioid ceilings, with exceptions made for medical necessity, staged incrementally. SFHP will work with providers on appropriate (3-12 month) tapering regimens. The following dates are target dates and may be adjusted if needed: 1. **Timeline TBD: Dose freeze**: SFHP will not approve dose increases or new starts for members receiving >200 mg Morphine Equivalents Daily (MED) or >50 mg methadone daily unless medical necessity requirements met. 2. **Timeline TBD: Dose ceiling of 400 mg MED*:*** SFHP will work with providers to taper members on >400 mg MED or >100 mg methadone, unless medical necessity requirements met. Goal: <200 mg MED or <50 mg methadone daily, tapered over 3-12 months. 3. **Timeline TBD: Dose ceiling of 200 mg MED:** SFHP will work with providers to taper members receiving >200 mg MED or >50 mg methadone, unless medical necessity requirements met. Goal: <200 mg MED or <50 mg methadone daily.
6	**Opioid and Benzo Policy**	Recommendation against prescribing opioids and benzodiazepines concurrently, due to increased risk of overdose and death. No authorization requirements at this time.
6	**Refill and short-acting medications policies**	**1. 6/1/14: refill only allowed at 90% (e.g. 27 days of 30 day Rx)** **2. 9/1/14: limit short-acting opioids to 120 per month** ***3.*** **Timeline TBD: limitation to one short-acting and one long-acting opioid prescription**
7	**Medical and Pharmacy Homes**	**Timeline TBD:** At SFHP or provider request, members may be limited to controlled prescriptions from one practice site, and/or to one pharmacy
11	**Discontinuation of opioid therapy**	SFHP strongly discourages firing patients from the practice for any reason short of physical safety (e.g. violent threat). If opioids are discontinued, PCPs should continue the therapeutic relationship and help patients receive needed services, including substance use treatment if needed.
8 – 28	**Pain management resources**	• References supporting the policies • Table listing maximum daily recommended doses • **Timeline TBD** for SFHP PA policy implementation • Literature review and talking points for providers with patients • Draft prior authorization form (subject to change) • Example of one practice's urine drug screen protocol, for reference only • Draft peer review charter and referral forms

SFHP PAIN MANAGEMENT PROGRAM:
GUIDELINES FOR USE OF OPIOIDS IN CHRONIC NON-CANCER PAIN

GOAL

San Francisco Health Plan (SFHP) ensures that our members with chronic non-cancer pain are treated effectively and compassionately, in accordance with medical evidence, national guidelines and Medical Board of California requirements. SFHP is committed to working with our provider network to prevent opioid overuse, and identify system-wide solutions for prevention of overdose and harm from opioid medications.

This program outlines SFHP's approach to the treatment of chronic nonmalignant pain. The guidelines do not apply to patients with terminal illness.

1) **Background:** While opioids are an important tool in the treatment of chronic pain, the US has recently experienced an epidemic of overdose deaths, diversion, and addiction from prescribed opioid medications. The following section provides background for the need for pain management guidelines.

   a) **Numerous reports from the literature** identify situations that increase risk for overdose, substance use, and diversion. SFHP is prioritizing the following situations for intervention *(see references, page 11):*
      i. Prescribing opioids in the presence of signs of active substance use
      ii. High-dose opioids, defined as more than 200 mg of oral morphine equivalents daily (MED) or more than 50 mg methadone daily. MED calculators are easily available on-line, such as http://www.globalrph.com/narcotic.cgi.
      iii. Combination of opioids and benzodiazepines
      iv. Combination of methadone with other opioids

   b) **SFHP is committed to supporting evidence-based, compassionate, effective, and safe pain management for our members and the community.**

      i. SFHP has co-led the SF Safety Net Pain Management Workgroup since 2012 with the Department of Public Health. The workgroup focused on the following improvement areas, with examples of SFHP's approach in each area listed below.

         (1) ***Promoting protocols and best practices in primary care***
            a) SFHP's incentive bonus program, the Practice Improvement Program, incorporated measures and financial incentives for clinics and medical groups supporting the use of best-practice protocols, pain management agreements, urine drug screens, peer review committees, and use of Patient Activity Reports.
            b) SFHP supported technical assistance and coaching for clinics implementing registries and setting up pain management peer review committees.

(2) ***Promoting integrated nonpharmacologic options for chronic pain***

a) SFHP developed a reference guide for complementary therapy options in San Francisco, at http://www.sfhp.org/files/providers/community_resources/SFIntegrativeMed_Resources.pdf

b) SFHP partnered with the California Health Care Foundation to develop a computer-based cognitive behavioral therapy and health education intervention to support patients with chronic pain.

c) SFHP supported development of curricula for pain management groups.

(3) ***Improved information exchange and care coordination***

a) SFHP and community medical leaders attended physician meetings at multiple emergency departments, advocating for best practices in opioid prescribing.

b) SFHP met with the Hospital Council of Northern and Central California, advocating for consistent pain management guidelines in local emergency departments.

(4) ***Developing educational opportunities for providers, staff and patients.***

a) SFHP sponsored several CME events from 2012 to present, focused on pain management best practices, management of substance use, difficult conversations, and orthopedic approaches to musculoskeletal pain.

b) SFHP developed a patient education pamphlet at the request of providers.

c) SFHP sponsored training for behavioral health providers on difficult conversations in pain management.

c) **The provider community is requesting that SFHP provide clear criteria and guidance, including dose ceilings.** SFHP has received input from providers through the SF Safety Net Pain Management Workgroup, two annual all-day medical education events on chronic pain, and through direct requests. Providers are looking for the assistance of SFHP to support safe prescribing with guidelines and prior authorization policies, to ensure consistent practice across our network, and to take the burden of the provider of having to make hard decisions alone.

d) **SFHP developed these pain management guidelines** with the aim of supporting our providers to ensure safe, compassionate, cost-effective care for SFHP members with chronic non-cancer pain, while minimizing the risk of abuse or diversion. This program has been reviewed and supported by the SF Safety Net Pain Management Workgroup, the SFHP Quality Improvement Committee, the SFHP Physician Advisory Committee, and the SFHP Pharmacy and Therapeutics Committee.

2) **<u>Goals:</u>**

This program was developed as an essential tool for SFHP to support providers in treating chronic pain safely and compassionately. Goals of the program:

a) Promote best practices through incentive payments (Practice Improvement Program), technical assistance (coaching), and consistent prior authorization policies.

b) Ensure compliance with CMS Fraud, Waste, and Abuse policy, and with DEA guidelines

c) Provide pharmacy utilization reporting (lists of clinic and medical group members on chronic opioids, with calculations of MED) to support panel management.

d) Implement prior authorization policies to support safe prescribing.

e) Implement a process by which, over time, SFHP members on high-dose opioids can be transitioned to safer doses, in cooperation with the primary care provider (PCP).

3) **Expectations for providers: Routine monitoring and management of patients on chronic opioids**

The following best practices are recommended by national pain management guidelines[30] and by the Medical Board of California:

a) Every patient should review and sign a **pain management agreement and informed consent** document annually. This document should outline clinic or practice policies, and inform the patient of risks and side effects of opioid treatment.

b) Clinicians should define **clear goals of opioid therapy**, and document progress against those goals. Opioid therapy should be discontinued if it is not improving functional status and helping patients achieve activity goals.[30] **Consider use of validated screening tools to assess effectiveness of opioid therapy and objectively assess risk.** The PEG tool is simple, quick and easily administered, and consists of three questions related to Pain, Enjoyment of Activies, and General Functioning[65]. The Opioid Risk Tool is a validated self-assessment tool,[63] and the DIRE tool is a validated clinician assessment.[64]

c) Clinicians should **screen all chronic patients for depression and other mental illness**, and refer for cognititive behavioral therapy and other appropriate behavioral health interventions. CBT has been proven to be effective in improving pain and function for patients with chronic noncancer pain.[61] In one study, 40% of fatal opioid overdoses were in patients with mental illness[62].

d) Clinicians should order a **random urine drug screen** for all patients at initiation of treatment, and at least once a year, to detect prescribed and non-prescribed opioids and other controlled or illicit drugs. Monitoring should increase in frequency in the presence of behaviors concerning for substance abuse. Rationale: physicians are extremely inaccurate in predicting substance use based on clinical judgment alone.[24]

e) Clinicians should regularly check the **CURES database** in all patients being prescribed opioids, at minimum when assuming care of a new patient, then annually moving forward; more frequently in the presence of concerning behaviors. Rationale: the CURES database provides record of all dispensed controlled substance, regardless of payer source. It is a reliable method to detect patients who are receiving opioids from multiple prescribers.

f) Practices should develop standardized policies **ensuring consistent practices by prescribers for common challenges in pain management**: new patients, early refill requests, management of unexpected urine drug screens, and management of concerning behaviors, including guidelines on when discontinuation or weaning of opioids is required. Practices could consider a tiered approach, depending on the behavior. Examples of successive tiers include: warning/concerned discussion, increased monitoring, decreased dosage of medication, or cessation of medication. Rationale: wide variation in the management of concerning behaviors by prescribers at a clinic or practice site contributes to doctor-shopping and has a negative impact on patient safety, provider morale and staff morale.

g) SFHP strongly **recommends against discharging patients from primary care** for concerning behaviors; rather, we encourage the provider to work closely with the patient to ensure referral to appropriate treatment, even when opioids are no longer prescribed.

h) Practices should implement **peer review or medical director review** for concerning behaviors and for high-dose patients. Ideally, this structure is multi-disciplinary. See appendix G for sample charter for peer review committees, and sample referral forms.

i) Patients should be informed that it is not recommended to **drive under the influence** of any medication that can impair ability to operate a vehicle. **Monitor for sedation** that would make driving motor vehicles unsafe, particularly if opioids are combined with other sedating medications, alcohol, or other substances. If the patient is potentially unsafe to drive a motor vehicle, recommend to the patient they not drive if impaired and consider reporting the patient to the Department of Motor Vehicles (DMV) for evaluation.

j) **Prescribe naloxone to patients at risk of overdose.** California law permits prescribing naloxone to patients taking opioids (legal or illegal) for use in an emergency to prevent accidental death, for the safety of the patient, and for those in the household who might inadvertently take the medications. See www.prescribetoprevent.com for details.

k) **SFHP recommends against the combined use of opioids, stimulants, alcohol, and/or marijuana**. Combining these substances increases the risk of overdose and death. Increasingly, many pain specialists and clinics are asking patients to choose which treatment they want to use for pain, and not prescribe opioids if marijuana is consistently used. SFHP will leave this decision to provider discretion.

l) **SFHP has the capacity to restrict an individual patient to using a single pharmacy and a single prescriber or practice for controlled medication** (excluding substance use treatment programs). This is done at the request of the prescriber, or when a patient is identified to be using multiple prescribers. If you have a patient on whom you would like to request restricted status, call the SFHP pharmacy department at 415-547-7817, ext. 7085, and we will initiate the process.

4) **SFHP Substance Use and Opioid Prescription Policy**

a) **Continuing to prescribe opioids (other than buprenorphine/naloxone) in the face of evidence of active substance use or excessive alcohol intake is outside the standard of care, and puts the patient and the community at risk[42, 44]**. Per American Pain Society 2009 Guidelines[43], "*Clinicians should taper or wean patients off of COT who engage in repeated aberrant drug-related behaviors or drug abuse/diversion, experience no progress toward meeting therapeutic goals, or experience intolerable adverse effects.*" In one study, 75% of fatal overdoses were in patients with histories of substance use.[62]

b) Addiction is more common than currently claimed, affecting 30% of chronic pain patients on opioids.[60]

c) SFHP believes one instance of an abnormal urine drug screen merits a compassionate conversation, with an opportunity for the patient to commit to following the pain management agreement, and subsequent closer monitoring. If the behavior continues after this conversation, then it shows a pattern, and should result in referral to substance use treatment, consideration for buprenorphine/naloxone replacement therapy, and discontinuation of prescribed opioids.

d) Continuing to prescribe opioids in the face of repeated signs of substance use or diversion can result in the following negative outcomes:

i. Risk to the patient, including overdose and death
ii. Risk to the community due to diversion, crime, or motor vehicle accidents.
iii. Risk to the provider's DEA license (see reference 41 for examples).

e) If SFHP identifies a member with repeated urine drug screens showing unprescribed opioids or illicit substances, SFHP will refer that member to the practice's peer review committee, or call the prescriber. The goal of the conversation is to determine a safe treatment plan for the patient, which may include a pharmacy or medical home lock, or PA requirement for future opioid prescriptions, to allow SFHP the opportunity to review the safety of the treatment plan with any new prescribers.

5) **SFHP High-Dose Opioid Policy: Recommendation for dose limit of 200 mg MED or 50 mg methadone, with prior authorization requirement.**

a) **Rationale:** Current national consensus is that high opioid doses increase morbidity and mortality, and lowering doses decreases mortality and can improve function. Relevant literature is summarized below:

1. Two studies showing that dosages over 100 mg MED daily have up to a 9-fold increase in overdose, and a 1.8% annual death rate.[6,7]
2. Patients receiving very high doses (>400 mg MED) had a much higher overdose death rate (9.94 per 1000) than those receiving lower doses (7.92 per 1000 for 200mg – 400 mg, and 1.63 per 1000 for <200mg MED).[52]
3. Patients receiving 120mg MED or more were more likely to have drug-related emergency department encounters than those getting lower doses.[51]
4. Dose limitation is associated with reduction in death rate by 50% (see reference for impact of Washington State 120 mg MED dose limit).[50]
5. Patients tapered off of high-dose opioids reported significant pain reduction and improved mood.[57]
6. Long-term studies showing the safety and efficacy of high dose opioid therapy are not available.[4,5]
7. High dose opioids over time can increase pain (hyperalgesic effect).[38,39]
8. Higher doses are associated with increased risk of abuse.[40]
9. Attention deficit is more common during morphine treatment compared to placebo, which is more pronounced at higher dose.[54]
10. High-dose opioids are associated with sleep disorders.[55, 56]
11. A Massachusetts Medicaid plan implementing dose limits lowered overall opioid usage of long-acting medications by 20%.[53]
12. A Denmark study demonstrated that in patients receiving opioids, pain was worse, health care utilization was higher, and activity levels were lower compared to a matched cohort of chronic pain patients not using opioids.
13. A randomized trial of opioid treatment strategies showed that pain scores did not change with steadily increasing doses of opioids.[66]
14. Methadone mixed with other opioids greatly increased the risk of death by overdose.[48]

b) **SFHP Prior Authorization Policy for Opioids**

(1) Based on current evidence, SFHP considers that ongoing treatment of non-cancer pain with high-dose opioids creates an unacceptable risk of overdose or functional impairment. We will work with providers and members on an individual basis to support a transition to a safer opioid regimen.

(2) SFHP recognizes that reducing the opioid dose to a safer range can be time-consuming, and we are committed to staging the intervention incrementally, and providing resources to help providers identify appropriate tapering regimens. In addition, SFHP is working with the substance use treatment community to ensure adequate access to opioid

treatment options, given the current expansion of the Medi-Cal benefit (as of 1/1/2014) to include inpatient and outpatient substance use treatment.

(3) SFHP's goal is to only approve high-dose opioid therapy (>200mg MED) for members with specific medical contraindication to tapering to a safer dose. Due to the high volume of SFHP members on high-dose regimens, SFHP will stage our approach incrementally. Exceptions to the policy must meet the prior authorization criteria listed in (h) below.

(4) Timeline of phased implementation of dose limits:

a) **2012 – Ongoing**: education of providers regarding risks of high-dose opioids and management best practices (multiple CME events ongoing).

b) ***Timeline TBD: Dose limitation of 200 mg MED (OR 50 mg methadone) for new starts.*** SFHP will not approve new regimens > 200 mg MED or >50 mg methadone, unless the member meets medical necessity requirements, and the provider documents that all best practices have been followed; see prior authorization criteria below.

c) ***Timeline TBD: Stabilization policy. SFHP will not approve increasing the dose of opioids for members currently taking >200 mg MED (or 50 mg methadone) unless the member meets specific medical necessity criteria.*** As of 10/1/14, SFHP will ensure that members who are currently on >200 mg MED or >50 mg methadone can continue to receive refills for these doses, but requests to increase dose will trigger a requirement for prior authorization. SFHP will not approve a dose increase for members whose regimens are over 200 mg MED (or 50 mg methadone) unless the member meets the medical necessity requirements listed below.

d) ***Timeline TBD: provider outreach/referral to peer review.*** When SFHP identifies a significantly high-risk patient, a SFHP medical director will refer that patient to a clinic peer review committee, clinic medical director, or contact the prescriber directly. The goal of the referral is to evaluate the regimen for appropriateness and safety, and discuss voluntary transitions to lower dose treatment, to opioid replacement (in the presence of substance use disorder or opioid dependence), or to other substance use treatment. SFHP's goal is to work with providers to identify opportunities for transition before the authorization policy goes into place in 2015.

e) ***Timeline TBD: Dose limitation of 400 mg MED (or 100 mg methadone).*** As of January 1st, SFHP will require prior authorization for ongoing opioid treatment for any member currently receiving > 400 mg MED or >100 mg methadone. SFHP will work with the providers on a safe transition plan, with the goal of tapering the member over 3-12 months to ≤ 200 mg MED or ≤ 50 mg methadone. SFHP will not approve ongoing treatment of >400 mg MED regimens for members unless the member has a medical contraindication to tapering to a lower dose regimen, and meets prior authorization requirements listed below.

f) ***Timeline TBD: Dose limitation of 200 mg MED (or 50 mg methadone).*** As of January 1st, SFHP will require prior authorization for ongoing opioid treatment for any member currently receiving > 200 mg MED or>50 mg methadone. SFHP will work with the providers on a safe transition plan, with the goal of tapering the member over 3-12 months to 200 mg MED or less. SFHP will not approve ongoing treatment of >200 mg MED or >50 mg methadone regimens for members unless the

member has a medical contraindication to tapering to a lower dose regimen, and meets prior authorization requirements listed below.

g) **PA duration.** After review and approval of the authorization for high-dose opioids, the PA approval will be in place for 6 months (if a change of medication is expected) or 12 months (if the medication is expected to be long-term). Renewal of prior authorization will require submission of the prior authorization requests, with continuing documentation that the criteria are met. At the provider's request, SFHP will build a tapering program into the prior authorization approval, to ensure the pharmacy can follow a tapering plan without need for repeated authorizations.

h) **Criteria for approval of ongoing treatment with high-dose opioids:**

1. **The goal of the prior authorization program** is to work with prescribers to safely taper members on high-dose opioids to no more than 200 mg MED or 50 mg methadone, based on the evidence of safety and efficacy of opioids in long-term cancer pain (see references).

2. **SFHP will work with providers on a reasonable tapering timeline, over 3-12 months,** based on the needs of the member.

3. **The following documentation** is required as part of the prior authorization:
   a. All urine drug screens in the last 12 months
   b. Updated patient agreement/informed consent (signed by patient within the last 15 months)
   c. Chart notes from recent pain management visits, which include the diagnosis(es) requiring opioid treatment, the treatment plan, treatment goals, documentation of treatment efficacy (e.g. opioids are improving functional status), and assessment for concerning behaviors (ruling out substance use, medication misuse, and/or diversion)

4. **Exceptions to the tapering policy require documentation of medical necessity**, such as one of the following:
   a. Terminal illness or severe co-morbid condition with life expectancy less than 3-5 years (e.g. severe cardiac insufficiency)
   b. Severe psychiatric instability, such as delusions, uncontrolled bipolar disease, persistent psychosis despite treatment, or recent psychiatric hospitalization.

5. **To be approved for ongoing high-dose treatment,** the member must have documentation showing low risk for overdose or harm from opioids. All of the criteria below must be met:
   a. At least 2 urine drug screens in the last year show presence of prescribed opioids, and absence of illicit drugs or unprescribed opioids.
   b. No urine drug screens in last 3 months show absence of prescribed opioids, or presence of illicit drugs or unprescribed opioids.
   c. Chart notes show appropriate monitoring for concerning behaviors (see best practices on page 3), and that the member shows no signs of diversion, substance use, or inappropriate use of medications.
   d. The member is not currently receiving methadone or buprenorphine treatment from an independent substance use center. The prescriber has a signed consent from the patient allowing the provider to contact Community Behavioral Health Services and other treatment centers to confirm that the member is not actively in treatment.

e. The patient's chart has been reviewed by the practice's peer review committee, or the practice medical director, and the recommendation is to continue current treatment. *NOTE: this requirement is waived for small practices without peer review committees or medical directors.*
f. No benzodiazepines are prescribed, or there is an attached psychiatric consultation documenting that removal of benzodiazepines would put the patient at risk of destabilization and hospitalization.

6) **Policy for Combined Opioids and Benzodiazepines**
   a) Multiple studies confirm the increased overdose risk of combining long-term opioids and benzodiazepines[44, 45, 46].
   b) SFHP recommends that prescribers work with patients to either taper the benzodiazepine, or the opioid medication, and not to continue patients on combined therapy long-term.

7) **Policy for Refills, Short-Acting Opioids, and Multiple Opioids**
   a) **Effective 6/1/14, SFHP will limit refills to no sooner than 90% of the expected duration.** This means that a 30-day supply cannot be filled sooner than 27 days. This is to allow fills prior to weekends. Providers can enforce 30-day windows, if desired, by writing "do not fill sooner than 30 days" on prescriptions.

   b) **Effective 9/1/14, SFHP will limit short-acting opioids to a maximum of 120 tablets every 30 days. Short-acting opioids** should be used for breakthrough pain, not for ongoing daily routine use. If a short-acting medication is prescribed more frequently than 4 times a day, SFHP will work with the prescriber on potential simplification of the regimen. Caution should be used when transitioning from one opioid to another, with consideration of starting the new regimen on 30% less than the calculated equivalent dose.

   c) ***Timeline TBD*****, SFHP will only approve one long-acting opioid and one short-acting opioid at a time** (other than brief exceptions during transition periods from one opioid to another, and exceptions for medical necessity).

   d) **If a member is receiving methadone treatment,** SFHP strongly recommends against prescribing additional opioids from a physician who is not involved in the methadone treatment program. 30% of opioid deaths involve methadone, and having two prescribers independently prescribe high-dose opioids increases the risk of overdose.[30, 48]

8) **Prior Authorization for Nonformulary Opioids**
   a) **Generics vs. Brand Name Medications**
      i. SFHP mandates the use of generics when there is an FDA AB rated generic available.
      ii. Patient intolerance to generic drug is often more related to perception and marketing than to true biochemical difference.[35]
      iii. The FDA evaluated 2,070 human studies comparing absorption of brand name and generic drugs.[36] The average difference in absorption between the two was 3.5%, in either direction. No generic drug is approved without meeting FDA standards for bioequivalence.
      iv. Conditions such as chronic pain are known for waxing and waning symptoms, and frequent treatment flares.[37] When a flare occurs coincidentally after a switch to a generic, the generic drug is often blamed.
      v. Brand name medications will be usually be denied, with rare exceptions reviewed on a case by case basis.

   b) **SFHP requires that members have adequate trials of formulary agents** prior to approval of nonformulary agents.
      i. **Failure due to allergy or side effects.**
         (1) Because side effects from morphine and other opioids are commonly confused for allergy, and because allergy to morphine is exceedingly rare, SFHP requires

documentation of hives or anaphylaxis in a medical chart prior to approving a nonformulary alternative due to morphine allergy.

(2) Side effects such as itching and nausea can be managed through dosage adjustment, change of delivery system (patch vs. oral), adequate duration of trial, or medications for symptom management.

ii. **Failure due to inadequate pain relief**

(1) SFHP has multiple formulary agents available for the relief of pain.

(2) There is no medical evidence showing that nonformulary agents are superior for pain relief compared to formulary agents.

(3) Opioids have been shown to be ineffective for many pain diagnoses (e.g. neuropathic pain, migraines, low back pain, fibromyalgia), and may be an inappropriate choice for that patient[30].

(4) Inadequate pain relief can be delivery system (poor absorption), noncompliance, diversion, loss of placebo effect, opioid tolerance, or development of hyperalgesia. Adding non-opioid medications (e.g. membrane stabilizing agents for neuropathic pain), rotation among formulary agents, or lowering the overall dose[28] could be effective.

9) **Reporting**

As part of the Practice Improvement Program, SFHP delivers reports to clinics and medical groups listing all of the patients assigned to that practice who have received more than 20 mg of morphine equivalents daily, for three months in a row. The report is designed to assist providers in developing registries and managing the population effectively.

10) **Medical Home and Pharmacy Home Program – Timeline TBD**

When SFHP or a prescriber identifies a pattern of potential abuse or diversion, either may request that the member be enrolled in **SFHP's pharmacy home or medical home program,** where the member may be limited to either one prescriber/practice site, one pharmacy or both, when filling controlled medications. SFHP will inform the member, the prescriber, and the pharmacy when this limitation is in place.

11) **Discontinuation of Opioid Therapy**

a) If a prescriber believes ongoing opioid therapy is appropriate, SFHP strongly encourages the provider to continue the therapeutic relationship, and to promote member access to resources for substance use treatment (when indicated) or nonpharmaceutical approaches to improving function.

b) SFHP offers the following resources:

i. Pharmacy support to develop a safe weaning program from the opioid therapy.

ii. Care Support case management to help the member access available substance use treatment benefits, or behavioral health support.

iii. SFHP can work with the provider and member on an alternative treatment plan, potentially using behavioral health services, physical therapy, non-opioid medication alternatives, or other non-medical options for pain management.

12) **Opioids in Pregnancy**

Pregnant members taking opioids chronically should be referred to high-risk obstetrics to discuss the risks and benefits of tapering programs, and/or planning for the need for a neonatal weaning protocol.

13) **Pain Management Resources**

SFHP provides the following tools and resources to assist providers in managing chronic non-cancer pain:

i. Maximum daily doses chart (Appendix A)
ii. Timeline of SFHP policy implementation (Appendix B)
iii. Literature review and talking points for physicians to patients (Appendix C)
iv. Prior Authorization Form for high-dose opioids (Appendix D)
v. Urine Drug Testing References (Appendix E)
vi. Sample low-literacy pain management agreements, in English, Spanish and Chinese (Appendix F)
vii. PEG tool to assess impact of opioid therapy on function (Appendix F)
viii. Taper calculator from Washington Medicaid http://www.hca.wa.gov/medicaid/pharmacy/Documents/Forms/AllItems.aspx, See "taper schedule" on the link
ix. Resource list for low-cost and free alternative therapy http://www.sfhp.org/files/providers/community_resources/SFIntegrativeMed_Resources.pdf
x. Patient education brochure on chronic pain Website; currently under reconstruction; link will be available after July 2014.
xi. Assistance accessing the Department of Justice CURES website, including covering the one-time cost of a notary fee to obtain access (contact provider.relations@sfhp.org)

DEFINITIONS

Chronic non-cancer pain: Pain that limits function and quality of life, that is not attributable to cancer or another terminal illness

CURES reports: on-line resource available to prescribers, which lists all controlled medications filled by any provider in the State of California in the last year. This database helps providers identify the cases when a patient is using multiple prescribers for opioids, to assist in the identification of abuse and diversion.

High-dose Opioids: SFHP uses 200 mg MED as our dose threshold based on Roger Chou's 2009 Pain Management Guidelines[30], endorsed by the American Pain Society. This is higher than the CDC (100 mg), the State of Washington (120mg), and the 2012 American Society of Interventional Pain Physicians[49] (91mg), as a starting place for intervention. SFHP may choose to lower this threshold in the future, based on the impact of the initial intervention. Ballantyne and Mao[14] state that "doses above 100 mg of morphine equivalent dose per day have not been validated in clinical trials and should be considered excessive."

Opioids: Controlled medications used to treat chronic non-cancer pain, including natural and synthetic opioids. For the purposes of this policy, controlled non-opioid medications (e.g. tramadol) are not included.

Morphine Equivalents Daily: Calculation comparing different opioids to the equivalent morphine daily dose, considering chronic use. The dose SFHP uses to determine high-dose methadone is based on the prevalence of high-dose methadone use in our membership, and should not be considered an equivalent to high-dose morphine therapy. Extreme caution should be used in transitioning patients to and from methadone, due to long half-life and differences in metabolism.
http://www.globalrph.com/opioidconverter2.htm

Pain Management Agreements: Agreements between the prescriber and the patient, that typically cover the topics listed below. The purpose of the agreement is to avoid misunderstandings, ensure the prescriber can treat the patient and minimize the risk of harm, abuse, diversion, office disruption and misunderstandings, and to ensure the patient has full informed consent about the risks of long-term opiate treatment.

1) Side effects, risk when driving and operating machinery, risk of tolerance or addiction
2) Expectations of treatment: chronic opioid treatment will not cure pain; it may minimize but not eliminate pain
3) Practice policies: including annual random drug screens, CURES screening, refill policies (standing refills, early refills)
4) Expectations for the patients: avoiding abusive behavior, avoiding illicit drugs, requirements to follow up with appointments and treatment recommendations, , behavior expectations in terms of treatment of staff

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Appendix A: Maximum Daily Recommended Oral Doses of Opioids (200mg MED) (For chronic, non-cancer pain)

Note: to allow for incremental change, given that transitions take time, SFHP will stage in the requirements over time.

Table for 200 mg MED requirement[†] (effective 10/1/14 for new starts; 7/1/15 for grandfathered members)

Drug (Generic Name)	**Morphine Equivalent Dose**	**Quantity requiring PA** (note, dose limit appies to combination of short- and long-acting medications)
Morphine (PO)	30 mg	MSIR: >120 tablets/30 days MSER: >100 mg bid, or >60 mg tid
Codeine (PO)	200 mg	>120 tablets/30 days
Fentanyl Transdermal	See chart	PA required for all doses High dose: >75 mcg every 3 days
Hydrocodone (PO)	30 mg	> 120 tablets/30 days
Hydromorphone (PO)	7.5 mg	> 120 tablets/30 days
Methadone (PO)	7.5 mg	High dose[‡]: > 50 mg per day (NOT equivalent to 400mg; see footnote) 5 mg: > 300 tablets/30 days 10 mg: > 150 tablets/30 days
Oxycodone (PO)	20 mg	Oxycodone IR: >120/30d Oxycodone ER: all doses require PA High-dose: >40 mg tid or 60 mg bid
Oxymorphone (PO)	10 mg	>6 10 mg tablets daily

Table for 400 mg MED requirement (effective 10/1/14 for new starts; 1/1/15 for grandfathered members)

Drug (Generic Name)	**Morphine Equivalent Dose**	**Quantity requiring PA** (note, dose limit appies to combination of short- and long-acting medications)
Morphine (PO)	30 mg	MSIR: >120 tablets/30 days MSER: >200 mg bid
Codeine (PO)	200 mg	>120 tablets/30 days
Fentanyl Transdermal	See chart	PA required for all doses High dose: >150 mcg every 3 days
Hydrocodone (PO)	30 mg	>120 tablets/30 days
Hydromorphone (PO)	7.5 mg	> 120 tablets/30 days
Methadone (PO)	7.5 mg	High dose: > 100 mg per day (NOT equivalent to 400mg; see footnote) 10 mg: > 300 tablets/30 days
Oxycodone (PO)	20 mg	Oxycodone IR: >120/30d Oxycodone ER: all doses require PA High-dose: >80 mg tid
Oxymorphone (PO)	10 mg	>6 10 mg tablets daily

Source: **http://www.globalrph.com/opioidconverter2.htm**

[†] Dates are subject to change.

[‡] Methadone doses are NOT equivalent to morphine doses in this table; they only reflect the upper limit requiring PA review, based on recommendations from local experts about a reasonable starting place for weaning goals.

Appendix B: Timeline

DATE	INITIATIVE *(the following initiatives do not apply to members on hospice or with terminal conditions. Medical necessity exceptions apply)*
6/1/14	Implement 90% refill rule (can fill no sooner than day 27 of 30-day prescription)
9/1/14	Implement 120 tabs/30 day max for short-acting opioids
10/1/14	Implement dose freeze (no increases of dose) for all SFHP members on >200 mg morphine equivalents daily (MED) Implement dose ceiling of 200 mg MED for new starts
1/1/15	Implement dose ceiling of 400 mg MED; work with providers on 6 month weans if appropriate, to <=400 mg MED
7/1/15	Implement dose ceiling of 200 mg MED; work with providers on 6 month weans if appropriate, to <=200 mg MED
7/1/15	Implement policy to limit members to one short-acting and one long-acting opioid medication

Appendix C: Literature review and draft patient talking points

Recommendation	Rationale	Supporting Evidence	Sample talking points for prescribers
Physicians should not prescribe opiates in the face of signs of diversion or substance use. Continuing to prescribe puts the patient and the community at risk.	In one study, 75% of fatal overdoses were in patients with histories of substance use.[62] Addiction is more common than currently claimed, affecting 30% of chronic pain patients on opioids.[60]	Chou, et al, Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer pain, American Pain Society 2009. Heavily referenced guidelines reflecting expert panel consensus: *"COT must be discontinued in patients who are known to be diverting opioids or in those engaging in seriously aberrant behaviors"*	*I see that Dr. ____ took you off pain medications because he was concerned about safety. I will work with you to try again, but I need to let you know I will be closely checking for signs that these medicines are doing harm – which means I will ask you to bring in your medicines for random pill counts, leave urine every visit for occasional random drug screens, and sign an agreement to only receive opiates from me. If I see a sign that these are harming you, I will stop them and strongly recommend you get treatment.* *I am concerned about your safety. I cannot continue to prescribe opiates. I would like to help support you in getting into treatment.* *I know you have ongoing pain. Buprenorphine can control pain, and is a safer choice in this situation. I am happy to help you access this treatment, and can only prescribe opiates for (1-4) weeks to give you time to get treated.*
	Physicians are extremely inaccurate in their assessment of diversion and opiate misuse. 53% of cohort in SFGH clinic reported misuse of opiates; clinicians are poor judges of who is misusing meds	Vijayaraghavan M, Penko J, Guzman D, Miaskowski C, Kushel MB. Primary Care Providers' Judgments of Opioid Analgesic Misuse in a Community-Based Cohort of HIV-Infected Indigent Adults. J Gen Intern Med. 2011;26(4):412–8.	*I am not judging or accusing. I realize I could be wrong. However, given the information I have, I don't think these medications are safe. I would like to still be your physician and take care of you.* *I think the opiates aren't helping you and may be hurting you. I need to stick to this decision, and I would like to see you in ___ weeks to see how you are.* *Let's talk about other ways to manage your pain. There are low-cost resources for alternative treatments. Sometimes physical therapy can help. Buprenorphine and methadone can help pain, and treatment centers can talk to you about how to make sure your pain and substance use are both treated.*
	Physicians have lost their DEA license for ignoring signs of diversion and substance use	Examples with detailed reasons why DEA license was revoked: http://www.deadiversion.usdoj.gov/fed_regs/actions/2013/index.html	*There are rules I have to follow as a doctor to keep my license. In situations like this, I can't continue to prescribe opiates – the Medical Board of California has clear guideline that I need to follow.* *I know you would like me to continue to prescribing. The law says I can't prescribe opiates to patients who are using street drugs, even if I would like to help. Are you open to getting treatment? Let's work on this together.*
Prescribers need to increase vigilance if the patient has a history of misuse; if misuse recurs, opiates should be discontinued. 1) Receiving multiple prescriptions from multiple providers;	Substance use disorder means a pattern of use. One sign of misuse should lead to increased vigilance; a recurrent sign should lead to action (wean, discontinuation, and/or referral)	Chou, et al, Clinical Guidelines: "In some patients, such as those actively using illicit drugs, potential benefits are outweighed by potential risks, and Chronic Opiate Therapy should not be prescribed outside of highly controlled and specialized settings (such as an opioid treatment program with directly observed therapy)".	*I am in a group practice, and have to follow our practice rules. The (peer review committee, medical director, health plan) reviewed your situation, and our practice can no longer prescribe opiates. I would like to stay as your doctor, and help you with your care.* *You are telling me that you only used once; I hear you. Using opiates with cocaine can kill you, and I do not think it is safe to prescribe until you can show me you have been sober for at least ___ months. And if we try again, and I see that you use again, it will be a sign that you don't have control over your use, which means it is not safe to be on opiates.* *This information is in your record, and the information is available to all doctors and nurses in the system. I know you are angry, but I hope you consider not leaving the clinic and allowing me to continue to care for you. I think we can work together to improve your quality of life.*

Recommendation	Rationale	Supporting Evidence	Sample talking points for prescribers
2) Increased ER use for obtaining narcotics; 3) Previous dismissal and/or opiate agreement violation with another system, clinic, provider	"For every unintentional overdose death related to an opioid analgesic, 9 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."	Morbidity and Mortality Weekly Report; JAMA. 2012;307(8):774-776.	*I see you have been in the emergency department for opiates. We reviewed a pain management agreement and agreed that I would be the only person prescribing opiates. At this point, I do not feel comfortable with the treatment plan.* *The opiates do not seem to be helping your pain, since you continue to use the ER for pain, even on very high dose opiates. I would like to refer you to (____) and I will work with you on a tapering program so that you don't suffer withdrawal while we wean you off.*
	4 or more previous aberrant drug-related behaviors were a strong predictor of a current substance use disorder.	Feming, et al: Substance use disorders in a primary care sample receiving daily opioid therapy. J Pain 8:573-582, 2007	*I am concerned that these opiates are not helping you, and that you are showing signs of a substance use disorder. I think your life would be better if you were in treatment, which can include opiate replacement, or they can help you wean off opiates.*
	Addiction is more common than previously claimed, affecting 30% of chronic pain patients. 30% of SF opiate deaths involve cocaine (Medical Examiner data)	Boscarino et al. Prevalence of prescription opioid-use disorder among chronic pain patients: comparison of the DSM-5 vs. DSM-4 diagnostic criteria. J Addict Dis. 2011;30:185-94. [PMID: 21745041]	*You are not alone. One-third of people who go on these medications become addicted. I can help you get off the medications, and many people tell me they feel better – with less pain – when they are off of them.* *Buprenorphine has been life-changing for many of my patients. People have told me it saved their life – they got "sick and tired of being sick and tired" and made a change. This medicine can help take away cravings, and it gives you a steady dose of medicine throughout the day that can both keep you from relapsing, and help with pain.*
Prescribers should use tools to screen for risk, and act on identified issues. Opiate Risk Tool high risk score, or DIRE score 7-13: >90% chance of developing problematic behaviors	Self-assessment through the Opiate Risk Tool and clinician assessment through the Diagnosis, Intractability, Risk, Efficacy (DIRE) tool are validated instruments that predict risk of addictive behaviors or poor outcomes with opiates. Screener and Opioid Assessment for Patients with Pain (SOAPP) is also a validated self-assessment tool.	Webster, et al, Predicting aberrant behaviors in opioid-treated patients; Preliminary validation of the Opioid Risk Tool. Pain Med 6:432-442, 2005	*I use a tool called the opioid risk tool to help me make the decision about whether opiates are safe. Your score was very high, and I believe opiates would be too high risk a treatment. Let's talk about other options for you.*
		Belgrade et al: The DIRE score: Predicting outcomes of opioid prescribing for chronic pain. J Pain 7:671-681, 2006	*Opiates don't help many kinds of pain, and many people have been harmed by them, including from accidental overdoses. I don't think they are safe for you.*
All chronic pain patients should be screened for behavioral health conditions, referred	Undiagnosed or undertreated depression is one of the most common reasons for escalating opiate doses.	Chou, et al. Clinical Guidelines	*Depression can cause pain, and it can make it hard to cope with pain. Part of treating your pain is treating your depression. Treatments like CBT have been shown to improve pain, even better than pain meds. If you were to break a leg, I couldn't prescribe crutches without a cast. Likewise, I can't keep prescribing opiates if you are not getting treatment for your depression. I would like to see you in a month, and a condition of my continuing to prescribe is that you follow through with this referral.*

Recommendation	Rationale	Supporting Evidence	Sample talking points for prescribers
for treatment, and the outcome of treatment should be documented. PHQ2 or 9 is helpful for screening. PHQ score over 15 should lead to treatment. The provider should respond with a plan when treatment is refused.	Chou: "Cognitive-behavioral therapy is the best-studied psychological therapy and is consistently shown to be effective for CNCP [chronic non-cancer pain]."	Ostelo et al: Behavioral treatment for chronic low-back pain. Cochrane Database of Systematic Reviews: Article No.: CD002014, 2005	*The mind is an amazing thing – and a technique called CBT helps you use your mind to decrease your pain and manage flares. You can get CBT in person at a group or individual or appointment, or on your own through a computer program. Which will work best for you?*
	Halle showed that over 75% of overdoses (ODs) were in people with a history of substance abuse, and about 40% were in people with mental illness -- compelling reason to exclude untreated mental illness and h/o substance abuse. 60% of ODs were for meds that hadn't been prescribed to the decedent, highlighting the importance of avoiding diversion.	Hall et al. Patterns of Abuse Among Unintentional Pharmaceutical Overdose Fatalities, JAMA 2008; 300 (22); 2613-2620	*We work as a team, and Dr. X has a lot of experience helping people in your situation. I would like you to see her, and we can talk next month about the appointment.* *Last month we talked about how your ____ was affecting your pain. I do think Dr. X will help you and I would like you to follow through. I do need you to know that I won't feel comfortable continuing the opiate part of your treatment if you don't follow through with other parts of your treatment for pain.* *There is a group education class that can help you take charge of your pain and help you have a better quality of life. We talked about setting goals to see if the treatment is helping, and that I can only continue to prescribe if we are making progress on the goals. Would you like to set a goal about how many classes you can attend in the next three months?*
Opiates should be avoided with history of suicide attempt or overdose.	Increased risk of deliberate opiate overdose and death.		*More people die from overdoses from opiates than from car crashes. I do not think these pills are safe for you. Let's talk about other ways to manage your pain.* *You were in the hospital because these pills stopped your breathing. We can't risk that happening again.*
Patients receiving methadone or suboxone in SU treatment settings should not be receiving opiate Rxs from their PCP.	Overdose risk dramatically increases with concurrent methadone use; 30% of opiate deaths included methadone. Suboxone and methadone can be dosed to also treat pain. Lack of communication btwn SU treatment and PCPs can lead to dose escalation and overdose.	Chou, et al. Clinical Guidelines MMWR 7/6/12/Vol 61 No 26	*Methadone and opiates together increase the chance of accidental overdose. I do not think it is safe to be on these two medications. Let's talk about how to manage your pain with fewer medications, or on burprenorphine.* *Sometimes methadone clinics will split your doses to help your pain. Would you sign a release so I can talk to your methadone clinic? I am not comfortable continuing to prescribe, but we could work together on the best plan for your situation.* *I ask all of my patients to sign a release so I can talk with other prescribers, such as emergency departments, or substance use treatment. I am only comfortable prescribing if I am the only one prescribing controlled medications. It is better if we talk openly about this, rather than me discovering through a urine screen or a CURES report.*
Prescribers should document goals of opiate treatment, track progress, and discontinue opiates if there is no sign of functional improvement. (This is a requirement of the medical board	There is no evidence that long-term opiates improve function and improve non-cancer pain long-term. "Clinicians should taper or wean patients off of COT who…experience no progress toward meeting therapeutic goals."	Chou, et al, Clinical Guidelines	*Pain meds don't cure pain. Their only role is to increase activity and quality of life. We need to set goals about increased activity and function – if you don't improve on these goals, it is a sign that the pain meds aren't working.* *Your pain continues to be 8 out of 10, even as we have increased the dose, and it doesn't seem to help you get out of the house and have a good quality of life. For many people, pain meds can make things worse – make you tired, or less motivated. Since they are not working for you, I will work with you to wean them off over the next 3 months. There are some medications that can help your symptoms. I can offer this list of resources for low-cost alternative therapies. CBT has been shown to help pain, and I am happy to refer you, which can also help improve quality of life.* *I know it feels like the meds help your pain – but that may be just the relief of withdrawal as they are wearing off. In all the time you have been my patient, you have always been in pain, and you are*
	Systematic review concluded that there is only poor to fair evidence to support long-term pain control or improved function from opioid	Manchikanti et al. A systematic review of randomized trials of long-term opioid management for chronic	

Recommendation	Rationale	Supporting Evidence	Sample talking points for prescribers
of California, and is part of the audit during investigations)	analgesics.	noncancer pain. Pain Physician 2011;14:91-121.	*showing signs of harm from the opiates – you have fallen asleep in the waiting room, you were in a car accident, and you had to go to the ER because you were so constipated. Let's work together, and I think you will feel better over time as we get you to a lower dose/off the meds.*
	Poor outcomes are associated with secondary gain (disability payments or workers' comp dependent on ongoing pain and disability).	Franklin et al. Opioid use for chronic low back pain: a prospective, population-based study among injured workers in WA State. Clin J Pain 2009;25:743–51. Rohling et al, A meta-analytic review of the assoc. btwn financial comp and the experience and tx of chronic back pain. Health Psych 14:537-547, 1995	*Opioids have been shown not to help low back pain, and they can even make it worse (by decreasing activity, or by creating bowel pain which can refer to the back.) I would like to work with you on other ways to manage your back pain, and we will wean your medications over the next three months.* *We started opiates after the car accident three months ago; at this point, staying on opiates is likely to do you more harm than good. People on opiates are more likely to have trouble going back to work, and have difficulty getting their life back. Let's work on other ways to get you active again – walking group, pain group, physical therapy, acupuncture (low-cost resource list).*
The PEG tool is a quick, simple way to track progress on pain level, quality of life (enjoyment) and activity	The PEG tool can be used as a way to measure function, measuring pain, enjoyment, and general activity (see appendix F)	Medical Board of CA guidelines: requires treatment plan and documentation of goals, functional improvement. "Continuation or modification of controlled substances for pain management therapy depends on the physicians evaluation of progress towards treatment objectives"	*I know it is hard to set goals, but otherwise we won't know if the meds are working. Here are some examples of reasonable goals:* *4) Increase walking from ½ block to 4 blocks per day* *5) Be able to shop for my own groceries* *6) Be able to ride my bike again* *7) Sleep 8 hours a night* *8) Not go to the emergency room more than once every 3 months* *We set a goal last time I saw you; how is it going?* *With your diabetes, we see how well the treatment is working based on your sugars. This is how we know how well the pain meds are working.*
Prescribers should have a clear diagnosis. **Opiates should not be used for conditions that have been shown not to benefit from chronic opiate treatment** (low back pain, fibromyalgia, chronic headache)	Poorly defined pain conditions, somatoform disorder, or unresolved legal issues predict poorer response to opiate therapy There is no evidence supporting the efficacy of opiates for low back pain, fibromyalgia, or migraines.	Pincus et al, A systematic review of psychological factors as predictors of chronicity/disability in prospective cohorts of low back pain. Spine 27: E109-E120, 2002 Chou, et al, Clinical Guidelines Martell B: Systematic review: Opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction. Ann Intern Med 146: 116-127, 2007.	*Fibromyalgia hurts, I know that. But there have been studies showing that opiates don't help fibromyalgia pain, and may even make it worse. Sometimes when you take pain meds, your body no longer is able to make chemicals to help you deal with pain.* *I know you suffer from migraines. I am worried about rebound headaches – these are when migraines turn into chronic daily headache from daily use of opiates, Tylenol, or Motrin. I will work with you on a slow wean of these medicines, since they haven't helped your headaches, and they may be making them worse.* *Opiates haven't been shown to help chronic low back pain. The main things that have been proven to help are daily walking, staying active, and learning how to strengthen your core so you can protect your spine. I know you have been on these meds for a long time – I would like to work with you to wean down on them slowly, and we can work on other ways of coping with pain (CBT, PT, alternative meds, walking program, etc)*
Chronic opiates should not be combined with long-	Increased risk of OD with combo benzo/opiates.	Caplehorn: Fatal methad toxicity:Austr & NZ J of PH 2002; 26(4):358-62	*I am concerned about the side-effects of these medications when used together. They both can stop breathing in high doses; when used together, people have accidentally died of overdose at lower doses.*

Recommendation	Rationale	Supporting Evidence	Sample talking points for prescribers
term benzo treatment. (exceptions should require psych eval)	Chronic benzo use is associated with depression, which is associated with dose escalation and poor functional outcomes. SF Medical Examiner found that 25% of SF opiate overdoses involved benzodiazepines; 30% involve cocaine.	Bleich, et al: Benzo abuse in a methadone maintenance treatment clinic…Israel J of Psych 2002; 39(2)104-12	*Benzos can cause depression, which can make your pain worse. I have been concerned about your depression, and would like to work with you to slowly wean off your benzo.*
		Backmund, et al: Co-consumption of benzodiazepines in heroin users, methadone-substituted and codeine-substituted patients. Journal of Addictive Diseases 2005; 24(4):17-29	*¼ of opiate deaths in SF involve benzos; and many of these were accidental. I do not want that to happen to you.*
	Showed that depression, h/o substance abuse, current substance abuse, and recent/concurrent use of sedative hypnotics were all associated with OD risk.	Dunn et. Al. Opioid Prescriptions for Chronic Pain and Overdose. Annals of Internal Medicine 2010; 152; 85-92	*The medicines you are using put you at risk of accidental overdose. I would like to prescribe you naloxone, which friends or family members can use in case of emergency. I would also like to work with you to be on a safer dose of your meds.*
High-dose opiates increase the risk of overdose. (200 mg as defined by national guidelines) SFHP will be staging our outreach, and initially working with >400 mg, or >200 mg with risk factors.	Mortality increases with high-dose treatment; see CDC Figure 3 below showing association with overdose and doses above 100 mg morphine equivalents. 10% of patients on 100 mg or more from 1 prescriber account for 40% of deaths; another 10% receive 100 mg or more from multiple prescribers, and represent another 40% of deaths. Medicaid patients have 6 times the death risk that other patients have when prescribed opiates.	http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6101a3.htm MMWR **January 13, 2012 / 61(01);10-13**	*High-dose opiates can do you harm and I am concerned about you. You are taking the equivalent of 80 Vicodin a day, and I have had patients die accidentally from doses like this, especially if combined with alcohol or other drugs.* *Studies have shown some patients actually get WORSE pain on high doses. Their bodies no longer make endorphins, or natural pain-killers. When the medicines are weaned down, they do better.* *Your condition (asthma or emphysema, sleep apnea, insomnia, chronic abdominal pain, fatigue, depression) can be caused or made much worse with opiates. I have had patients who were able to get off oxygen, or whose sleep and pain got much better after they were weaned. It will take time, and we will do it slowly. But I am convinced you will be healthier and happier on lower doses.* *Your pain is still uncontrolled after all of these years, even on these doses. I don't think the meds are helping you.* *Because of safety concerns, I can no longer get this dose on your health plan. They are willing to work with us over the next 3-6 months to wean your meds down to a safer level.*
	Decreasing doses reduces mortality. An analysis of WA workers' comp patients over a 10 year period showed a reduction in average morphine-equivalent dose per day and a reduction in mortality.	Franklin, et al: Bending the prescription opioid dosing and mortality curves: impact of the Washington State opioid dosing guideline, Am J Ind Med. 2012 Apr;55(4):325-31.	*In Washington, the entire state worked together to help patients get on lower doses. They saw that fewer people died of accidental overdoses. I know you think this will never happen to you, but many people think it will never happen to them. Yet more people die from overdoses than car crashes.* *Your pain is real, but opiates will only help your pain by 20-30%. Our goal will be to get you down to 120mg (the maximum safe dose for our clinic) and to work together to help you stay active with a good quality of life.*
	Higher doses do not improve pain scores; higher doses are associated with opioid misuse. Increased opiate doses did not change self-reported pain scores.	Naliboff, et al, A randomized trial of 2 prescription strategies for opioid treatment of chronic nonmalignant pain, J Pain, 2011. Vol 12(2): 288.	*There was a study showing that as people's doses increased over time, their pain did not improve. Sometimes we think the higher doses are helping us because it takes us out of withdrawal, since our bodies become dependent on the meds. Our bodies are able to recover though, and if we wean you down slowly, you will be able to manage without significant withdrawal.*

Recommendation	Rationale	Supporting Evidence	Sample talking points for prescribers
	High-dose opioids may contribute to pain sensitization via opioid induced hyperalgesia, decreasing patient pain threshold, and potentially masking resolution of a pre-existing pain condition. Hyperalgesia is associated with higher opiate doses; pain scores improved after doses were decreased Opioids do NOT have proven efficacy or safety for treating chronic pain long-term. Opioid replacement with buprenorphine can decrease risk of overdose and improve pain control and functioning.	Angst, et al: Opioid-induced hyperalgesia: a quantitative systematic review. Anesthesiology 104:570-587, 2006 Baron, et al: Significant pain reduction in chronic pain patients after detoxification from high-dose opioids. J Opioid Manag 2:277-282, 2006. Chu, et al: Opioid tolerance and hyperalgesia in chronic pain patients after one month of oral morphine therapy. J Pain 7:43-48, 2006. Blondell et al, A Clinical Trial Comparing Tapering Doses of Buprenorphine with Steady Doses for Chronic Pain and Co-existent Opioid Addiction	*Hyperalgesia means that pain can get worse on higher dose opiates. There were some studies showing that patients pain scores got BETTER when they were weaned down off of high-dose opiates. I know this is hard to believe, and it won't happen right away. But if we work together closely, we will be able to get you on a lower dose of meds and we may find that your pain is actually better controlled.* *I know you are frustrated and feel that your pain is worse on the lower dose. I know the weaning transition is hard. What would work better for you – we could do the wean faster, so your body could adjust faster to the lower dose. There are medications that can help withdrawal (kick-pack).* *However, as we discussed, I am not comfortable prescribing a higher dose for you than ____. This is our goal dose, and I am happy to work with you to get there between 3-6 months, depending on how quickly you would like to move through the doses.* *Buprenorphine can control your pain, and treat symptoms of craving. I am happy to refer you to a program to transition you to buprenorphine, which is a safer treatment plan for you.*
Avoid opiates for dental pain.	Opiates are less effective than NSAIDS for acute dental pain; Portland clinics standard of care is not to use opiates for dental pain	Hersch et al: Prescribing Recommendations for the Treatment of Acute Pain in Dentistry, April 2011; Copendum; ADA, CERP	*I see you were in the emergency room for dental pain. Remember, your pain agreement means that you and I agreed that you would not get opiates from another provider, unless there was a true emergency (like a broken leg). Opiates do not work that well for dental pain. If this happens again, I will not be comfortable continuing to prescribe opiates. Let's work on getting you into dental care, and I will prescribe ibuprofen to help.*

Sample talking points: how to address unexpected urine drug screens:

1) I was expecting to see your medicine in the urine, and it was not there. Let's talk about this. (CAUTION – make sure that the urine has a low enough threshold for detection, or that you confirmed with gas chromatography. A high detection threshold without confirmation can still be consistent with a patient who is taking meds as prescribed.)
2) You left a urine sample last week. Can you let me know what you expected it to show?
3) I am concerned about this result. It is the first time I have seen something that could mean you are having difficulty with drug use. Let's talk about it. In order to make sure you are safe, we are going to have to do more monitoring (pill counts, frequent urine drug screens, etc).
4) It is the second time we have found this result, even after our conversation last month. I am concerned this means you are not in control of your use. I am not comfortable continuing to prescribe opiates, and let's talk about what we can do to get you the help you need (taper vs discontinue, refer to suboxone, refer to SU counseling, case management, alternative therapies, behaviorist, PT, etc)
5) The urine showed that it was too dilute – meaning we couldn't test it. Can we talk about what happened?
6) When we get a result like this (dilute urine, missing opiates, unexpected opiates, refused urine), I get concerned about your safety. Let's get real – I think there is a good chance there are things that you aren't comfortable telling me. Can we talk about what is going on?
7) Refused urine. Let's talk – is there something in your urine you don't want in your record? I would like us to trust each other and have an open conversation.

Appendix D. DRAFT Prior Authorization form for Opiates >200 mg Morphine Equivalent Daily (MED) ***Timeline of implementation TBD***
Confidential Information

Patient Name

Patient ID Number

Patient DOB

Specialty

Prescriber Name
Prescriber Phone | Prescriber Fax | NPI#

Prescriber Address
City | State | Zip
Pharmacy Name | Pharmacy Phone | Pharmacy Fax

Medication Name and Strength Requested:

Directions and Quantity Requested:

Prior Authorization requirements:

1) Please submit the following with your prior authorization request:
   - ☐ A copy of all urine drug screens performed in last 12 months
   - ☐ A copy of a patient agreement/informed consent signed in the last 15 months
   - ☐ A CURES report run in the last 3 months *(SFHP notes the CA DOJ has been experiencing administrative difficulties with CURES account support)*

2) SFHP expects providers to taper patients to no more than 200 mg MED, based on published medical guidelines. Exceptions to this policy require ALL of the following to be true. SFHP is happy to work with providers to provide bridge therapy for up to 12 months to allow providers time to taper patients:

   a. The patient has a medical contraindication* to tapering the opiate regimen below 200 mg MED. (Examples include life expectancy less than 5 years, recent psychiatric hospitalization, etc). Please document details below:

      **Note: If there is no medical contraindication to a taper, SFHP will assist the provider in developing a taper schedule over 3-12 months, and will provide authorization for high-dose treatment during that taper. After a maximum of 12 months, SFHP will only authorize up to 200 mg MED, in the absence of medical contraindications.*

   b. There is no sign of substance use, diversion, or inappropriate use of medications.

   c. At least 2 urine drug screens in the last year show presence of prescribed opiates, and absence of illicit drugs or unprescribed opiates (attach results)

   d. No urine drug screens in last 3 months show absence of prescribed opiates, or presence of illicit drugs or unprescribed opiates

   e. The member is not currently receiving methadone or buprenorphine treatment from an independent substance use center, and the physician has a signed consent from the patient allowing the provider to contact Community Behavioral Health Services and confirm that the member is not actively in treatment.

   f. The patient's chart has been reviewed by our practice's peer review committee, or the practice medical director, and the recommendation is to continue current treatment. NOTE: this requirement is waived for small practices without peer review committees or medical directors.

   g. No benzodiazepines are prescribed, or there is an attached psychiatric consultation documenting that removal of benzodiazepines would put the patient at risk of destabilization and hospitalization. If that is true, please document why opiates could not be reduced to under 200 mg to decrease risk of overdose.

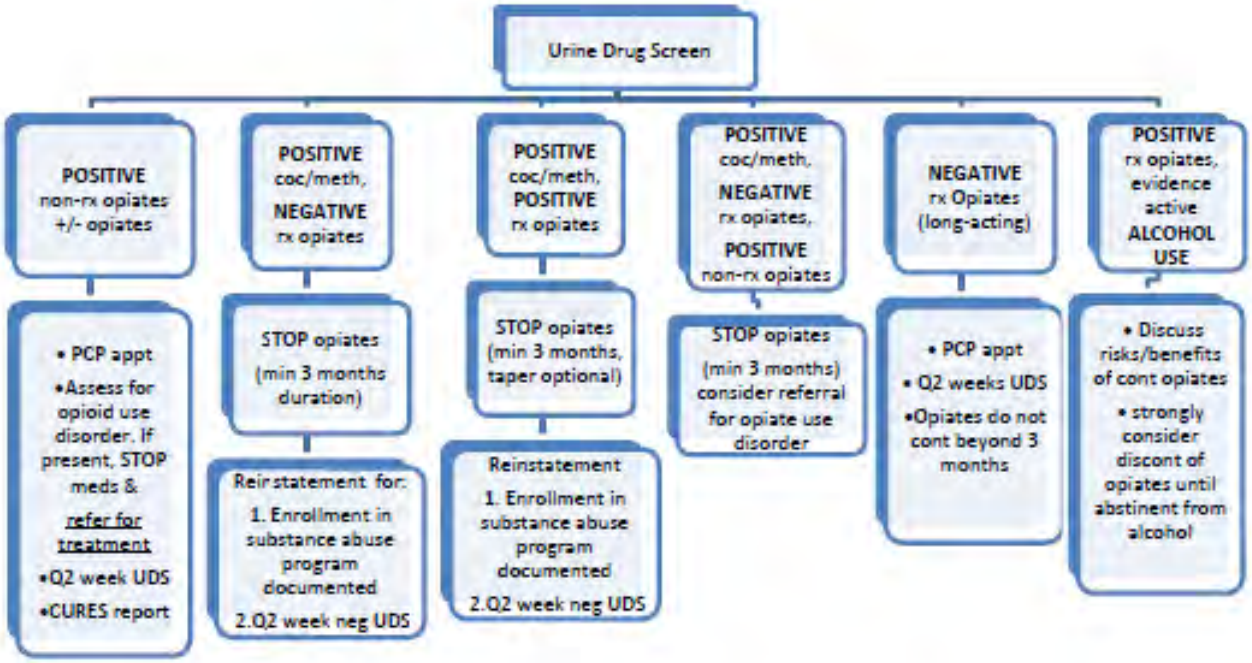
Provider signature: Date:

Appendix E: DRAFT Urine Drug Testing Quick Reference
(SAMPLE algorithm for the management of Urine Drug Screens, from a local DPH clinic)
The following algorithm is presented as a reference and tool, not as SFHP policy.

Management of Abnormal Urine Drug Reports

Rationale: inconsistent approaches leave providers struggling to balance the role of patient advocate with the need to ensure safe prescribing.

- **All patients receive a Urine Drug Screen (UDS)** within 1-3 months of starting opiates, and at least once a year (more frequently with concerning behaviors)
- USD screens should be standardized for the clinic for specific indications
- Clear guidelines should be available to interpret positive or negative results
- The clinic should have a clear policy about how to act on unexpected results – especially the presence of prescribed substance.
- Any exemptions need to be documented on the flow sheet and explained



Abnormal Utox Algorithm Key:
coc/meth = cocaine and/or methamphetamine positive urine drug screen
Rx opiates = prescribed opiates
Non-rx opiates= non-prescribed opiates
*it is not recommended to reinstate opiate therapy if the patient is receiving opiate replacement therapy for substance use treatment; this puts the patient at risk of overdose

Appendix F:
Sample low-literacy Pain Management Agreement (from DPH Community Oriented Primary Care) in three languages

Please visit the SFHP Pain Management website for sample chronic pain informed consent and agreements: http://www.sfhp.org/providers/improving-quality/pain-management/

Pain Management Patient Agreements and Informed Consent

- Chronic Pain Informed Consent-CHINESE
- Chronic Pain Patient-Provider Agreement-CHINESE
- Chronic Pain Informed Consent-ENGLISH
- Chronic Pain Patient-Provider Agreement-ENGLISH
- Chronic Pain Informed Consent-SPANISH
- Chronic Pain Patient-Provider Agreement-SPANISH

PEG tool to assess impact of opioid therapy on pain, enjoyment, and function.

1. What number best describes your pain on average in the past week:

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

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

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

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

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Appendix G:
Sample charter for peer review committees, and sample referral forms (DRAFT; for use as a tool if helpful)

Controlled Substances Review Committee (CSRC) Charter

Goal: Every clinic with a chronic pain population has a controlled substances review committee (CSRC) to support rational, effective and safe chronic pain treatment.

Potential Measures of Success

- Numbers of patients reviewed per month
- Tracking of committee recommendations; % of recommendations followed within 3 months;
- Potential other measures: avg opiate dose for pain management population; # of patients on high-dose (>120 mg morphine equivalents)

Tools:

- Urine Drug Screen interpretation guide (example: p 5 of this document)
- Weaning calculators
  http://www.globalrph.com/opioidconverter2.htm
  http://www.globalrph.com/narcotic.cgi
- Free and low-cost complementary therapy resources
  http://www.sfhp.org/files/providers/community_resources/SFIntegrativeMed_Resources.pdf

- Controlled substances committee referral form (example: p 10 of this document)
- Chronic pain protocols/guidelines
- SFHP Practice Improvement Program Pain Management measure (see p 19 of this document)

Scope of CSRCs

Within the scope of the committee:

- Focused review of the medication regimen
- Focused review of risk factors for overuse, misuse, or diversion
- Recommendation a treatment plan, based on evidence-based guidelines
- Recommendations for alternatives to controlled substances, or for substance use treatment when needed

Recommendation

The following is NOT within the scope of the committee:

- Complete review of the patient's medical history and problem list
- Review and recommendations on issues on the problem list not directly related to pain management
- Opportunity for the provider or patient to vent or make a case for ongoing therapy
- Comprehensive psychosocial evaluation of the patient
- Case management
- Writing prescriptions or otherwise providing medical care

Committee members

The goal of the committee is to have a multi-disciplinary approach. Committees can include some of the following (depending on availability):

- Medical Director or clinical champion
- QI lead
- Primary care provider
- Physician with special expertise in addiction
- Behavioral Health specialist or social worker
- Pharmacist
- RN or MA

A minimum of __ committee members is required for a quorum.

Potential Sources of Referrals:

- High-dose patients (above 120 mg morphine equivalents); SFHP will provide this report
- New patients requesting treatment with controlled medications for chronic pain
- Existing patients who are requesting a new start of daily opiate treatment for chronic pain
- Patients with "yellow-flag" or concerning behaviors for diversion, misuse or abuse of controlled substances
- Potentially all patients, for annual review

Referrals can come from providers, staff, or the health plan.

Red flag behaviors (behaviors mandating discontinuation of therapy by clinic policy) do not require review, unless the provider is not following clinic policies.

Referral form

The best review will require information from the medical chart (in particular, details about dates, results, and context for urine drug screens and "yellow flag" behaviors). The comprehensive referral form can be filled out by the prescriber or a committee member with access to the chart.

Decision-making process

The committee will aim for consensus, but if consensus is not reached, a two-thirds majority is sufficient to finalize a recommendation. Clinic medical directors should support the decisions of the CSRC, and work with the provider to either implement the recommendations, or negotiate a compromise.

Committee meetings

Following a defined structure will increase the productivity and sustainability of the committee:

1. Preparation – by local clinic champion, or staff champion (e.g. MA)
    a. For each hour of committee meeting, prep 5-6 cases in advance. Ensure that all comprehensive referral forms are complete – if needed, remind prescriber or clinician champion. Incomplete referrals should not be brought to committee.
    b. Conduct a brief chart review of last month's cases – were recommendations implemented? (e.g. MA could review current dose with recommended dose). If discordant, alert medical director or clinic champion.

2. Meeting structure:
    a. First 5 minutes: any issues with last month's cases? Were all recommendations followed?
    b. Time-keeper: ensure no more than 10 -12 minutes per case. (e.g. 2 minutes for review, 6 minutes for discussion, 3-5 minutes to finalize recommendations.)
    c. Assign note-taker: document recommendations
    d. Assign communicator: who will send recommendations to provider
    e. Assign responsible party for prep for future meeting: who will do chart review of this month's recommendations, and bring issues back to the committee?

Communication

Committee recommendations will be sent to the provider, the medical director, and (if the committee believes that continuing controlled medications are unsafe for the patient) to the health plan. The purpose of sending the recommendations to the health plan is to facilitate communication between providers if the patient changes PCPs, and to allow the health plan to enforce prescription limitations, if any.

Tools that could be sent to the prescriber:

1. Checklist of recommendations
2. Weaning template sample (if taper recommended)
3. Complementary medicine resource sheet
4. List of pain management resources (e.g. pain groups, etc)
5. Urine Drug Screen interpretation guide (if appropriate)

NOTE: Peer review is usually considered protected and some clinics therefore do NOT put it in the chart for legal reasons.

Strength of Recommendations: Committees should not be convened unless either the clinic providers have a "social contract" that recommendations are binding, or the medical director is committed to working with providers to ensure recommendations are either implemented, or a compromise is obtained. Committees that provide recommendations that are not followed put the clinic and provider at risk for bad outcomes, and medical board investigation.

Sample Committee Review Referral Form

Patient Name:_____ MRN:_____ DOB:_____

PCP:_____ Patient Provider Agreement signed: _____
Date

What is your reason for referral?

_____

_____

Aberrant medication related behaviors

Please list any aberrant medication related behaviors.
See back of referral sheet for examples.

_____

_____

Latest urine drug screening: _____ Were results congruent with prescribed medication? □Yes □No

History of prior incongruous urine drug screens? □ Yes □ No

Risk Factors for Opioid Abuse/Diversion/Overdose

	Yes	No	Unkown
History of substance abuse/addiction, including nicotine and alcohol			
Family history of ubstance abuse/addiction			
ADHD, ADD, PTSD, Schizophrenia, Bipolar disorder			
Depression			
History of oversedation with medication			
History of overdose			
History of physical or sexual abuse			

Pain Management History

Diagnosis/cause of pain:

_____

(Required) Current medication list, especially opioids, up to date in LCR? □ Yes □ No
Has pain improved with opioid therapy? □ Yes □ No □ Unknown
If unknown, please explain:

_____

Has function improved with opioid therapy? □ Yes □ No □ Unknown
If unknown, please explain:

_____

Has quality of life improved with opioid therapy? □ Yes □ No □ Unknown
If unknown, please explain:

_____

What non-opioid approaches to pain has the patient tried (eg. medications, PT, injections, massage, counterstrain, pain group, psychotherapy, surgery)?

_____

_____

_____

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
- Report of multiple medication sensitivities
- Request for specific drugs or refusal to take generic medications
- Unsanctioned dose escalation one or two times
- Aggressive complaints about the need for more drug
- Open acquisition of similar drugs from other medical sources one or two times, e.g. in the ER
- 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

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
- 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
- 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

Sample Committee Recommendation Form	
Pain	
Medication Changes	
	Opioid dose change
	Increase
	Taper
	Anti-epileptic medications
	Antidepressant
	NSAID/Tylenol
	Topical (lidocaine, capsacin)
	Withdrawal symptom pack: Clonidine 0.1mg BID PRN malaise, anxiety. Loperamide PRN diarrhea. Ondansetron 4mg q8 PRN nausea. Trazadone 50mg nightly PRN insomnia.
	Naloxone prescription
Procedures	
	Joint injection
	Trigger point injection
	Orthopedics appointment
	Specialist referral
	Ice
	Heat
Movement based	
	Physical therapy
	Supervised/graded physical activity
Behavioral and Psychological	
	Individual therapy
	Spine health group
	Chronic pain group
	Pelvic pain group
	Depression/anxiety group
	Social engagement plan
	Pacing
Complementary and Alternative	
	Counterstrain
	Massage
	Acupuncture
	Chiropractic
	Anti-inflammatory eating pattern
	Herbs or supplements
	Meditation Class
	Gratitude journal
	Joy practice
	Yoga
	Tai Chi

Diagnostics	
Substance Use Disorder	
	Taper medications
	Make prescribing contingent on entry into residential treatment
	Make prescribing contingent on entry into residential treatment or methadone clinic
	Buprenorphine treatment
	Methadone treatment
	TAP referral
	Referral to needle exchanges
	Safe injection counseling, harm reduction counseling
	Recommend naloxone training at needle exchange http://www.sfaf.org/client-services/health-services/syringe-access/site-schedule.html

NOTE: form from SFGH Family Health Center Pain Squad