Family Health Center of Worcester
Chronic Pain Program
Opioid Prescribing Protocol

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Introduction

The treatment of chronic pain is a frequent concern of both patients and medical providers alike in the primary care setting, often occupying the central focus of a patient's medical care. While non-opioid treatments for chronic pain are important and essential parts of a treatment plan, often the opioid is the most controversial element of this plan. Providers and patients must together weigh the individual risks and benefits of opioid therapy while keeping in mind the well-publicized societal risks of opioid diversion and misuse.

The Massachusetts State Medical Board Model Policy for the Use of Controlled Substances for the Treatment of Pain provides the framework for the FHCW Chronic Pain Opioid Prescribing Protocol, and is attached to this document as Appendix K. Its preamble states that "the diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic." Furthermore, "the Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins", and that "for the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments." The Board seeks to reassure providers that they will not be disciplined for proper prescribing of opioids but calls upon them to seek proper training in pain management and follow established guidelines.

This document is not meant to be a comprehensive training tool on chronic pain management or use of opioids. Rather, it is intended to provide structure and guidance to FHCW clinicians and chronic pain nurses in their roles taking care of patients in the Chronic Pain Program. It describes an outline for patient evaluation, intake, treatment, ongoing assessment and discharge in the context of a team-based approach using PCP, behavioral health, nursing and specialty care support. It includes a sample nursing progress notes which will help providers assess and monitor the progress of their patients receiving opioids in a manner consistent with the medical board's Model Policy guidelines. Ultimately, the purpose of this document and the FHCW Chronic Pain Program is to assist FHCW providers achieve the goal of appropriate, safe, and effective pain management while minimizing the risk to the community from prescription drug diversion and abuse.

Program Goals

- Appropriate evaluation of patients for pain management with opioid and non-opioid treatments.
- Effective pain management targeting improvement of function and quality of life for patients.
- Safe opioid prescribing practices with a "universal precaution" approach modified by individual patient risk.
- Prevention of prescription medication-related criminal activity and drug abuse.

Perspective and Program Overview

Chronic pain is pain which has persisted continuously or intermittently beyond the usual course of an acute disease or healing of an injury, typically at least 3 months, even in the absence of a clear pathologic basis for the pain. Over time, especially when inadequately treated at the outset, neuroplastic changes can lead to chronic pain becoming a disease itself (i.e. chronic pain syndrome, ICD-9 338.4). Pain can be somatic or visceral tissue-based (nociceptive), arise from nerve injury (neuropathic), or both. It is intimately influenced by psyschological, emotional, cognitive, and social factors. While acute pain management is outside of the scope of this document, it should be noted that opioid dependence most likely is well-established by 3 months. Therefore, while early, adequate pain relief is important to avoid neuroplastic patterning towards chronic pain, it is strongly encouraged to taper patients off acute pain opioids well before this time, and that all patients who remain on opioids for 3 or more months be enrolled in the Chronic Pain Program.

Chronic pain management has become one of the more challenging problems facing outpatient clinics and individual providers, bringing challenging time- and energy-intensive patients to our doors. Many communities, including our own, lack a comprehensive pain management clinic combining the proper interdisciplinary mix of pain specialists, primary care clinicians, psychologists, psychiatrists, complementary medicine practitioners, occupational and physical therapists, and addiction specialists. For many communities, the only available pain clinics are procedural hospital-based practices with no interest in prescribing medications, let alone any of the other non-procedural therapies (cognitive behavioral therapy, tai chi, yoga, massage, acupuncture, relaxation techniques, meditation, and support groups, to name a few).

It is widely acknowledged that there are no high-quality, long-term studies either proving or disproving the effectiveness of opioids for chronic pain, and that there are many known problematic aspects of chronic opioid use both for the patient and the community. Nevertheless, several national guidelines support their use to treat chronic pain unrelieved by other means. At FHCW management of chronic pain is managed by a team comprising the primary care provider, a behavioral health specialist, the chronic pain nurses and program director, and the medical home we create for the patient. Pain management thus occurs in the context of care patients receive for all their chronic medical conditions, which de-exceptionalizes and de-stigmatizes the use of opioids in pain management. As the MA state board writes, "appropriate pain management is the treating physician's responsibility", and thus FHCW primary care providers are expected to learn about pain management principles and standards of care through self-directed and CME activities and maintain an open mind about the use of opioids for their patients when other approaches have not been sufficiently effective. We strongly discourage moving chronic pain patients from one provider to another and ask providers to work with the Chronic Pain nurse and program director when needed for particularly challenging patients. While some patients with refractory pain syndromes will need care from outside pain specialists, the vast majority of patients may be treated safely in the community health center setting when best practices are followed.

We recommend an approach that combines the following: a rigorous, thorough assessment of the patient's complete medical history, including the following: the seven cardinal features of the patient's current symptom(s), a narrative of the patient's chronic pain evaluation and treatment from the onset to the current time; a substance abuse and social history; a complete initial physical exam; a thoughtful consideration of a treatment plan, made in collaboration with the patient and behavioral health specialist, including further workup and referrals if needed; and a "universal precautions" approach to harm reduction employing a risk-tiering system for monitoring patients. This system submits all patients receiving opioids to periodic scheduled and unscheduled drug screens and pill counts to minimize abuse and diversion, employing tighter scrutiny for higher-risk patients. Treatment plans must clearly state their goals relative to the pre-treatment baseline pain, function and quality of life assessment, and should include both opioid and non-opioid treatments. The latter comprises the following at Family Health Center: acupuncture (Dr. Rathmell), cognitive behavioral therapy and other forms of counseling (Social Services), the Living Well With Chronic Pain group visits (Joan Fleishman, PhD and the Chronic Pain nurses), and the Non-Opioid Pain Management Information Series (also by Joan Fleishman, PhD). Other resources in the community include: Interventional Pain Clinics at UMass and St.Vincent's; Physical and Occupational Therapy; Osteopathic Manipulation; Chiropractic Therapy; Tai Chi; and Yoga.

The FHCW Chronic Pain Program includes a Continuous Quality Improvement (CQI) program, which began in 2013 with a report tracking opioid prescriptions in NextGen, including the number of patients exceeding a total daily morphine equivalent opioid dose (MED) of 120mg and the number of patients on more than 25mg MED in short-acting form. Proposed QI measures include the number patients on methadone and the percentage with an EKG in the last 15 months; percentage of patients with a Opioid Medication Consent Form signed within the last 15 months; and the percentage of patients with 3 or more aberrant behaviors in the last 6 months. The CQI program provides an additional layer of surveillance and improves our ability to follow best practices in chronic pain management.

Patient Evaluation and Consideration for Opioid Therapy

- The patient must have an FHCW PCP; we will not prescribe opioids to patients with outside PCPs.
- The initial medical visit should comprise a thorough history and exam for both pain-related and other medical issues, and describe the seven cardinal features of the patient's pain. Providers should document in the medical record (from the state medical board Model Policy Appendix K) "the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance", i.e. inadequate pain control from other treatments or contraindications to their use. For guidance, providers can also consult the UMass Department of Family Medicine Pain Packet for tools on obtaining a pain history and risk assessment. These forms can also be given to the patient to take home and fill out.
- A behavioral health specialist should be involved as soon as possible to assess and engage patients with pain self-management, goal setting, cognitive behavioral therapy, exercise, meditation, or relaxation exercises.
- The PCP should also refer the patient for any necessary specialist evaluations to diagnose and treat the cause of the pain, as well as for complementary treatments such as physical and occupational therapy, yoga, tai chi, massage therapy, acupuncture, and biofeedback.
- If the PCP considers opioid therapy due to the inadequate efficacy of other treatments, **we recommend not starting opioids at the first visit**, although you may do this if you can confirm the dose, lack of aberrant behaviors, proper indication, and absence of contraindications as documented by another provider.
- **The following are required for all patients prior to opioid initiation or continuation:**
  - A urine drug screen (UDS) – this can be done by the nurse at the Nurse Intake (see page 5)
  - Opioid Risk Assessment (ORA; see Appendix A) – done by PCP
  - Massachusetts State Prescription Drug Monitoring Program check – done by PCP (http://www.mass.gov/eohhs/provider/licensing/compliance/drug-control/ma-online-prescription-monitoring-program)
  - Chronic Pain Nurse intake (see page 5)
- Higher risk patients are not necessarily precluded from receiving opioids, but should be monitored more closely to ensure safe and appropriate use (see page 8, Risk Tiering, Monitoring and Management). However, those with active or recent histories of prescription drug abuse should be referred for addiction treatment (see Appendix O), and those with histories of diversion should not be prescribed opioids.
- Together the PCP and the patient formulate a pain management plan. If it will include opioids, they must have an open, honest discussion of the potential risks and benefits of opioids (see the Opioid Medication Consent Form (Appendix E) as a guide for this discussion, as well as for the program requirements; this form will also be reviewed by the Chronic Pain nurse at the nursing intake (see page 5).
- The patient must be in stable mental health, engaged in appropriate treatment when necessary, and have no identified risk of harm to self or others before initiating or continuing opioids.
- Patients known or found to be using illicit drugs should be referred for addiction treatment and not begun on opioids (either the FHCW OBOT/Suboxone Program, or see Appendix O for other resources). Once the patient is sober, they may be carefully treated with opioids provided they are not on methadone maintenance or buprenorphine (Suboxone).
- It is recommended that contraception status be solidified prior to opioid initiation as opioids have been linked to neural tube defects (2013), and that patients who may become pregnant be weaned off opioids (5% dose reduction per week is recommended). Pregnant patients who are unable to wean off and remain on opioids may be treated in the FHCW Chronic Pain Management Program and continue to receive obstetric care at FHCW, but should be referred in the 2nd trimester to UMass MFM for a high-risk OB consult. If at that time or subsequently the PCP and MFM consult deem it necessary, the patient can be transferred to UMass OB (CWC).

- **All patients on opioids for 3 or more months at Family Health Center must be enrolled in the Chronic Pain Program.**

- **All providers are asked to read the Opioid Medication Consent Form and abide by and enforce the program requirements when prescribing opioids for chronic pain.**

Chronic Pain Nurse Intake

- If a PCP thinks they may prescribe opioids for chronic pain, the patient must be referred for a Chronic Pain nurse Intake by using the yellow checkout card to book an intake in the next available slot.
- The nurse will inform the patient of office hours and general program requirements. If these are not feasible for the patient and cannot be resolved prior to initiating treatment, the PCP will be notified that the patient is not recommended for opioid treatment of their chronic pain at FHCW.
- The nurse will review the PCP note and incorporate the PCP's opioid risk assessment and treatment plan into their note. They will also set up a table in the note for urine drug screen (UDS) results. See Appendices F and G for the nurse note template and a sample nursing note.
- When necessary, the Chronic Pain nurse will fax a signed release of information forms to prior providers. Review of this information is critical for providers assuming the care of patients either already on opioids from other clinics or with complicated pain evaluation and care histories from other providers.
- The nurse will very carefully review the FHCW Opioid Medication Consent Form (see Appendix E) with the patient in their primary language, using an interpreter if necessary, and witness the patient's signature. This form will be scanned and the nurse will record the date in their note. This will be renewed annually to refresh patient understanding of the agreement and answer any questions.
- **The patient must agree to and initial all items and sign the form to receive opioids for chronic pain.**
- The patient will then be sent for a urine drug screen at SECON of New England on 415 Main St. in Worcester. Testing is done at SECON to ensure sample integrity and acceptable specificity for tested drugs (see Appendix D for the default UDS order, which may be modified as needed by the PCP). In rare instances when a patient cannot go to SECON, if approved by the Chronic Pain Management Program Director, a patient may submit a sample at FHCW which will then be sent to SECON.
- Providers should inform patients that they will not receive a prescription for an opioid at the nurse intake visit unless they are already on an opioid and are due for a refill.
- The nurse will ensure that all patients enrolled in the Chronic Pain Management Program have the diagnosis code 338.4 (chronic pain syndrome) on their Chronic Problem List. This is used to identify patients for the Chronic Pain CQI Report.
- Patients will be encouraged to ask questions, engage with the Chronic Pain Team, and participate in their treatment.

PCP Case Review

- After completion of the nurse intake, PCP will see the patient again and do the following:
    - Review outside records and confirm the patient's history.
    - Review results of the screening UDS and the Opioid Risk Assessment (done then if not at the first visit)
    - Check to see that the signed Opioid Medication Consent Form is in the EMR and that the patient understood the risks of opioid therapy.
    - Confirm that the patient knows the clinic hours and agrees to fulfill requirements for frequent appointments, phone contact, call-backs for random pill counts and drug screens, safe medication storage and the other patient requirements.
- It is particularly essential to review prior records in patients transferring to FHCW to assess the adequacy of prior workups and potential problems the patient had with opioids in their former care setting(s), and this should be done before initiating or continuing opioids. As mentioned above, this review should include checking patient's record on the MA State Prescription Drug Monitoring Program website.
- If no contraindications are found, the PCP may initiate a trial of opioid therapy, with a focus on improvement of function and quality of life through better pain control. Functional assessment will include physical, psychological, and social realms.

Opioid Selection and Dosing Recommendations

- Many patients will already have been on opioid medications for three or more months at the time of enrollment in the Chronic Pain Management Program. However, some may be on sub-optimal regimens for chronic pain, so the following points should be reviewed for potential modification of the existing opioid regimen.
- The provider must choose an opioid, its dose, and a long- or short-acting formulation. Opiates (codeine, which is a prodrug of morphine, and morphine itself, which for convenience are grouped together with opioids in this document) may produce nausea and histamine release in some patients. Opioids (semi-synthetics such as oxycodone, hydrocodone, oxymorphone, and hydromorphone, and synthetics such as methadone and fentanyl) tend not to have these opiate-specific side effects, but can cause the other opioid side listed in Appendix E, and are potentially more euphorogenic, particularly in short-acting form or when long-acting forms are altered.
- For nociceptive pain there are no data that describe whether one opioid is more effective for treating different types of injury than another, so choice of an opioid may be driven by a patient's own idiosyncratic reaction to different opioids (which appears to be genetically determined) or the targeting of a specific dose or formulation.
- For neuropathic pain, through inhibition of NMDA receptors (in addition to regular mu and kappa opioid receptors), methadone has a theoretical and anecdotal advantage over other opioids. Methadone, however, should typically be a fourth-line choice for neuropathic pain behind other drugs such as tricyclics (TCAs) - nortriptyline and desipramine; SNRIs - duloxetine, venlafaxine; the anticonvulsants gabapentin and pregabalin; or tramadol, which is a weak opioid/TCA-like compound.
- For intermittent pain, low-dose, short-acting opioids in limited quantities are appropriate (1- 3 tabs/day).
    - Some pain guidelines for chronic non-malignant pain now endorse less use of short-acting "breakthrough" pain medication, as these are more likely to be euphorogenic than long-acting medications and hence more prone to abuse and diversion. However, they are acceptable when the total daily morphine equivalent dose (MED) is lower than that available through the lowest MED of long-acting formulations.
    - Vicodin (hydrocodone/acetaminophen), Percocet (oxycodone/acetaminophen), oxycodone (alone) and Morphine Sulfate IR are the most common short-acting opioids. Hydrocodone is equipotent to oral morphine (1:1); oxycodone is more potent (2mg oxycodone = 3mg oral morphine).
    - For patients with no cirrhosis or active alcohol abuse, use of Vicodin and Percocet <= 3 tabs/day is generally safe for the liver (< 2g acetaminophen/day). Otherwise, or if the patient gets no relief from acetaminophen, use a pure opioid (although hydrocodone is not available by itself). The FDA may soon discontinue acetaminophen/opioid combination products due to safety concerns related to liver toxicity.
    - Once the total daily dose of a short-acting opioid exceeds the minimum long-acting dose for that same opioid, that dose should be converted into the long-acting form (or another opioid in the case of hydrocodone, which does not have a long-acting form at the time of this writing, although one is pending FDA approval).
- For pain frequent enough to warrant more than 3 times daily dosing of a short-acting opioid, or for constant or more severe pain, long-acting opioids are preferred. The most common options are MS Contin (= morphine;15, 30, 60mg tabs), Oxycontin (=oxycodone;10, 15, 20, 30, 40, 60mg, 80mg tabs), fentanyl (12, 24, 50, 75, 100mcg/hr patch), and methadone (5, 10mg tabs).
    - The first-tier opioid for MA Health is MS Contin, which is typically dosed q12h but can be changed to q8h if titrating a dose up or down or if the patient has breakthrough pain nearing the end of the 12hr interval.
    - The second-tier opioid for MA Health is Oxycontin, which also is typically dosed q12h but can be dosed q8h as well. Oxycontin now is formulated in a gel matrix that prevents abuse by crushing, which was a significant problem with the initial formulation. It requires a PA explaining why MS Contin cannot be used, either due to prior adverse effect or inadequate analgesia at 360mg/day (although this dose far exceeds what is typically advised, which is <= 120mg/day).
    - Another first-tier MA Health opioid is methadone, due to its low cost. However, it can be dangerous and must be prescribed with caution:
        - Methadone accounts for 17% of opioid prescriptions but over half of opioid-related deaths.
        - Methadone's half-life is extremely long and variable (8-59hrs, avg 36), which means that dose increases should not be done more often than weekly, but preferably only monthly, and should not be more than 25% higher than the previous dose, or >15% if the dose is >90mg/d).
        - Methadone's potency relative to other opioids is not linear, and prior exposure to other opioids will paradoxically potentiate methadone's effect. While typical conversions using opioid conversion tables recommend calculating the equianalgesic dose of the new opioid and starting at half of that value, for methadone the conversion must be done with a sliding-scale table (i.e. not a fixed ratio) and then reduced by 75% (instead of 50%).

Opioid Selection and Dosing Recommendations (continued)

        - Methadone can prolong the QT interval, requiring EKGs before initiation and 30d thereafter, 30d after dose changes, and annually. For QTC 450-500ms, reconsider risk:benefit ratio; for >500ms, do not use methadone.
        - Recommended starting doses of methadone are low: 2.5-5mg q8h .
        - Methadone's analgesic half-life is only 8hrs, so methadone must be dosed q8h when used for pain. Once daily dosing is for opioid addiction only and can only be done at methadone clinics.
        - Consultation with a pain specialist is highly recommended when using methadone.
    - Fentanyl also requires a PA and should only been used in opioid tolerant patients (on >= 60mg MED) with chronic pain. Unlike the metabolites of morphine and the semi-synthetic opioids, fentanyl's metabolites are not neurotoxic and therefore can be useful for patients with renal failure. As fentanyl is a CYP3A4 substrate, caution is advised with strong inhibitors such as ketoconazole, clarithromycin, and ritonavir. It is useful for patients that cannot take oral medications as it comes in transdermal form.
- Patients should be titrated to a dose achieving an appropriate balance between harm and benefit. Attention should be paid to all potential side effects, but in particular sedation, confusion, and respiratory depression. Opioids should not be expected to completely relieve pain, but rather to provide sufficient relief to allow the patient to achieve sufficient function and quality of life in physical, psychological, and social realms. Daily doses of 5-120mg MED in combined short and long-acting forms are typically sufficient to achieve this.
- Total doses ≥ 240mg MED require review by the Chronic Pain Management Program Director, even if the patient is already on this dose, due to an increase in overdose risk. As of March 2014, MA Health requires a PA for doses exceeding 240mg MED (which is 160mg oxycodone and 60mg methadone). PA criteria include:
    - Appropriate diagnosis
    - Medical records documenting treatment plan, rationale for high dose and record of titration to this dose
    - Consultation from a pain specialist or a hematologist/oncologist addressing the high dose requested
    - Signed and dated patient-prescriber agreement for opioid use
- Doses exceeding 240mg MED for chronic non-malignant pain will be typically be discouraged due to the heightened risk of overdose and undesired effects, including opioid toxicity syndrome and hyperalgesia (increasing pain with higher doses of opioid).
- **Providers are to be particularly cautious with patients on both opioids and benzodiazepines**. It is preferable that the PCP defer benzodiazepine prescribing to a psychiatrist, avoid prescribing benzodiazepines whenever possible, and maintain vigilance for signs of sedation, confusion, abuse, or other adverse effects. Patients at added risk are those with sleep apnea, who drink alcohol, or take other sedating medications.
- To reduce the risk of diversion, we recommend that the prescriber write "must use insurance" in the comments section of the prescription. Exceptions may be made for patients known to be uninsured, although these patients will also need to pay for intermittent UDSs at SECON, which cost ~$150.
- Multiples of 7 days are used when prescribing opioids, with a maximum of 28 days, so that patients can follow up on the same day of the week when the nurse and provider are in clinic and to avoid needing refills over a weekend.
- Opioid prescriptions may only be provided at nurse or provider visits, with no refills. The PCP may grant a rare exception to allow a surrogate to pick up a prescription, but this should not occur more than twice a year.
- Senna and docusate should be prescribed at the time of opioid initiation to help prevent constipation.
- Providers are encouraged to do CME in pain management and consult web-based resources, such as this excellent free CME curriculum www.opioidprescribing.com sponsored by the Boston University School of Medicine.
- Additional information about opioids (types, schedules, formulations, relative potency, duration of effect, duration of detection in urine, and expected metabolites) are provided in Appendices L-N.

Risk Tiering, Monitoring and Management

- All patients begin at the highest Risk Tier (4) and proceed to lower levels at the minimum specified intervals provided there are no aberrant behaviors (see Appendix H, Risk Tier Management Table, which specifies Rx duration as well as visit, UDS, and random call-in frequencies.
- Appointment frequency starts at weekly then increases to biweekly and monthly according to the Risk Tier Management Table. When the lowest Tier (1) is reached, the PCP sees the patient every 3 months to assess pain regimen efficacy relative to the treatment goals. The PCP must clearly record the management plan in each note so that the nurse will be able to carry it out effectively.
- Nurses see the patient between PCP visits and send the PCP their notes. The PCP is expected to read it to ensure good communication and awareness of the patient's progress. The nurse will carry out scheduled and random UTSs and pill counts according to the Risk Tier Management Table or at the added discretion of the PCP.
- At each visit, nurses and providers will assess and document the "5 A's", Analgesia (pain level), Activities and Affect (function in the various realms – physical, emotional, social, home, work, achievement of goals), Adverse effects, and Aberrant behaviors. Visits should also be used to promote healthy behaviors and continued efforts to find non-opioid means for managing chronic pain.
- Monitoring for aberrant behaviors is important throughout all Risk Tiers. See below, as well as Appendix J, which lists aberrant behaviors per the DSM V definition of Opioid Use Disorder, for examples of this. Patients must be free of these behaviors for the minimum specified interval before moving to a lower Tier.
- As opioids can lead to relapse in patients with prior histories of addiction, or even trigger addiction in susceptible patients, patients must be monitored closely for signs of an opioid use disorder or other risky or aberrant behaviors:
    - Use of non-prescribed opioids or use of prescribed opioids exceeding specified doses.
    - Use of cocaine, heroin, alcohol, barbiturates, amphetamine, "street" benzodiazepines or other illicit drugs.
    - Problem use of prescription benzodiazepines characterized by impairment, sedation, overdose, adverse medical events or unsafe behaviors.
    - Failure to respond to telephone calls and/or adhere to the call-in policy for random pill counts and UDSs.
    - Failure to keep appointments with nurses, PCPs, physical therapists or other specialists.
    - Lost or stolen prescriptions or medication bottles.
    - Use of more than one pharmacy or obtaining opioid prescriptions from more than one provider
    - Lack of or minimal metabolite for the prescribed opioid on GC/MS UDS testing (i.e. oxymorphone for oxycodone, hydromorphone for hydrocodone, EDDP for methadone).
- Measures to be considered for patients exhibiting aberrant behavior, among others:
    - Moving the patient back up the Risk Tier for more frequent visits, UDSs and pill counts.
    - Reassessment of pain history for new problems or progression of disease and adequacy of opioid dose (i.e. to screen for "pseudo-addiction", where inadequate pain relief drives drug-seeking behavior). Collaboration with counselor and/or psychiatrist.
    - Opioid dose reduction. This may be used in certain patients displaying concerning aberrant behaviors as a motivating measure, and serves as a precursor to possible opioid discontinuation. Dose reductions are typically 10-20% mg q1-2wks until the UDS is clean or other problems are resolved, after which time the dose may be increased back to its previous level if clinically indicated.
    - Consultation with the Chronic Pain Management Program Director via email is encouraged whenever a provider would like assistance with a challenging case.
- If a patient falls out of care, they must see the PCP for a full reassessment and the nurse for an intake before resuming opioid treatment.
- If a patient's opioid prescription or medication is lost, stolen, or damaged, an early refill will generally not be given. If an exception is granted per the discretion of the PCP, only one will be allowed per year, and the patient shall be moved up at least one Risk Tier until re-stabilized. The date of this will be recorded in the nursing note.
- Patients may be maintained on a stable opioid dose for months to years, depending on the complex nature of their pain, psychological and medical comorbidities, and social environment.
- Pregnancy tests will be done as clinically indicated (i.e. depending on the patient's fertility, sexual activity, and contraceptive method). Pregnant women not choosing to taper off their opioid medication may receive obstetric care at FHCW but should be seen in their 2nd trimester by UMass MFM for a high-risk OB consult.

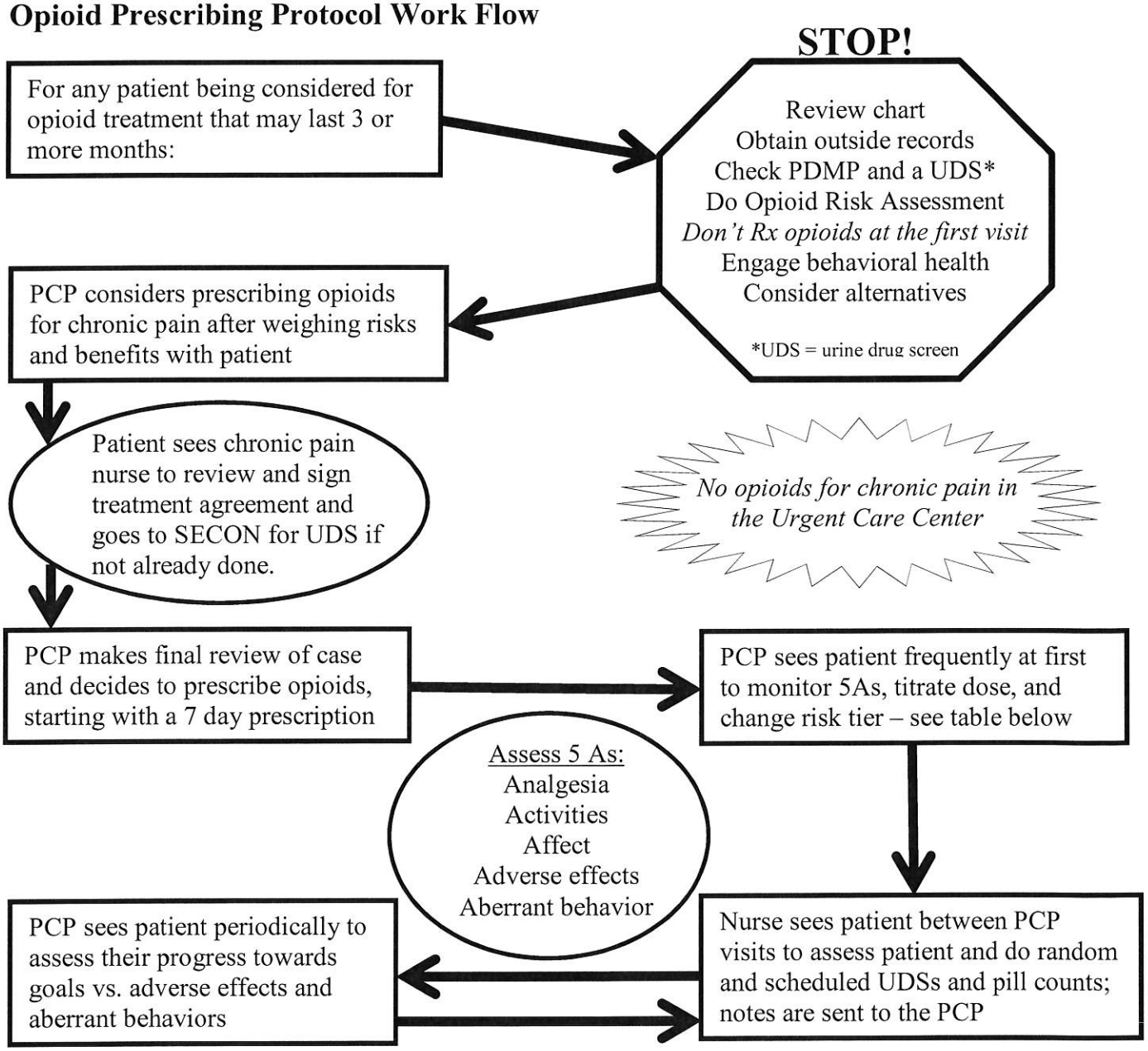
Discontinuation of Opioids

- A patient may be discontinued off opioid medications (**i.e. moved to Tier X**) at any time at the discretion of the PCP for failure to meet program requirements, such as the following:
    - use of illicit drugs, non-prescribed opioids, or problematic use of prescription benzodiazepines
    - negative urine tests for the prescribed opioid (providers are advised *not* to warn patients after the first negative sample if they suspect the patient is diverting the medication, but to repeat the test immediately)
    - missed appointments or inability to contact patient
    - failure to adhere to the call back policy and keep appointments for UDS or pill counts
    - improper follow through with recommended medical specialty or mental health care
- The number of aberrant behaviors allowed before opioid discontinuation will depend on the infraction(s) and the PCP's judgment, but in general no more than 3 aberrant behaviors in a 12 month period should be tolerated.
- The patient may also be discontinued off opioids if the PCP feels that opioid therapy is ineffective or in any other way no longer appropriate for the patient. This must be clearly documented and substantiated in the medical record.
- If the PCP and patient are in disagreement about this decision and the patient does not wish to seek care elsewhere, the PCP should present the case to the Chronic Pain Management Program Director for review, either in person or via email. PCPs should not book the patient to see the Director unless the Director has approved this.
- Grounds for immediate opioid discontinuation:
    - Patient found by other means to be diverting the opioid (e.g. police report).
    - Patient alteration of a prescription or a urine sample.
    - Patient or anyone acting on their behalf being verbally or physically abusive or threatening to any staff member or another patient at FHCW.
- When opioids are discontinued for diversion, no taper is required. Otherwise a 10% dose taper per week is reasonable to minimize withdrawal, which can also be mitigated by medications such as clonidine, dicyclomine and hydroxyzine.
- The patient will be given or mailed a Notification of Discontinuation of Opioid Treatment form (see Appendix I), moved to Tier X, and the PCP should check the "No Narcotic Prescriptions" alert box in NextGen.
- Patients may be evaluated for readmission to the Chronic Pain Management Program after six months, depending on the reason for discharge (diverters will generally not be re-accepted).
- Patients who have successfully tapered their dose down and voluntarily discharged themselves from the Chronic Pain Management Program may seek re-enrollment at any time if needed.

The Urgent Care Center and Other Non-PCP Visits

- There must be no prescription of opioids for chronic pain in the Urgent Care Center (UCC). Chronic pain syndromes require a thorough, time-consuming, multidisciplinary evaluation of the patient and the complicated, individualized balance of risks and benefits of opioids as a chronic pain treatment of final, not initial resort. Prescribing opioids for chronic pain in an urgent care setting, at FHCW or elsewhere, undermines this approach and potentially attracts patients seeking these medications for illicit use. This rule also applies to providers on the primary care floors seeing another provider's primary care patient.
- Unassigned patients with chronic pain seen in the UCC will not be given priority over other patients awaiting assignment to a FHCW PCP. Therefore there is no role for a UCC or non-PCP primary care floor provider to issue a "bridging" prescription until a patient can be set up with a new FHCW PCP, as this could take several months or more, and again might create an expectation by the patient that the PCP will prescribe opioids.
- Similarly, patients presenting to the UCC or primary care floors claiming to be running out of opioids prescribed by non-FHCW providers should not be prescribed opioids; they should be offered referral to local opioid detoxification centers (see Appendix H) and/or palliative medications for opioid withdrawal (clonidine, dicyclomine, hydroxyzine, etc.).
- A UCC provider, or a non-PCP provider on a primary care floor may refill an opioid if it is part of an established plan of care with an FHCW PCP if the PCP is unavailable when the patient's prescription is due to expire. In this setting there should be no opioid regimen change unless a clear, objective finding substantiates the need for a brief course of additional opioids.

Opioid Prescribing Protocol Work Flow



TIER X = DO NOT PRESCRIBE OPIOIDS

RISK TIER TABLE	Tier 4	Tier 3	Tier 2	Tier 1
Rx Duration	1 week	2 weeks	4 weeks	4 weeks
Scheduled UDS[1]	Weekly	Every 2 weeks	Every 4 weeks	Every 12 weeks
Random Call-In[1]	Every 2 weeks	Every 4 weeks	Every 8 weeks	Every 12 weeks
PCP Visits	Every 2 weeks	Every 4 weeks	Every 8 weeks	Every 12 weeks
Nurse Visits	Weekly, alternating with PCP	Every 2 weeks, alternating with PCP	Every 4 weeks, alternating with PCP	Every 4 weeks in between PCP visits
Minimum Time to Next Tier	2 weeks	4 weeks	12 weeks	N/A

[1] These are maximum intervals; PCP may ask for more frequent UDSs or random call-ins at their discretion

Appendix A Opioid Risk Assessment

If present, add the number shown in parentheses, which is different for males and females; if not present, add zero:

	(M/F)
Family History of Alcohol Abuse	(3/1)
Family History of Illegal Drug Abuse	(3/2)
Family History of Prescription Drug Abuse	(4/4)
Personal History of Alcohol Abuse	(3/3)
Personal History of Illegal Drug Abuse	(4/4)
Personal History of Prescription Drug Abuse	(5/5)
Age 16-45	(1/1)
History of Preadolescent Sexual Abuse	(0/3)
Psychiatric Disease (ADHD, OCD, bipolar, schizophrenia)	(2,2)
Depression	(1,1)

Total Score Risk Categories: 0-3 = Low Risk; 4-7 = Moderate Risk; ≥ 8 = High Risk (by Lynn R. Webster, MD)

Appendix B Chronic Pain Management Program Random Call-in Policy

To monitor and verify the proper use of the opioid we are prescribing, the Chronic Pain nurse will call the patient sporadically to come to the health center for a random drug test and a medication count. The patient must return this call promptly, preferably within 4 hours, and must come to the clinic within 24 hours of the initial call with the medicine bottle and all of the remaining opioid pills.

For this policy to function, the patient must ensure that we have current and accurate contact information. It is the patient's responsibility to tell the Chronic Pain nurse immediately if there are any changes to this information. If the patient fails to return for a monitoring visit we may need to decrease their medication dose, set shorter times between office visits, or stop their opioid treatment altogether.

Appendix C: Chronic Pain Management Program Verification of Mental Health Visits (not a program requirement)

Name:_____

1. Counselor/Group Name:_____
   i. Date of visit:_____
   ii. Agency name:_____
   iii. Counselor signature:_____
2. Counselor/Group Name:_____
   i. Date of visit:_____
   ii. Agency name:_____
   iii. Counselor signature:_____
3. Counselor/Group Name:_____
   i. Date of visit:_____
   ii. Agency name:_____
   iii. Counselor signature:_____

Appendix D: Chronic Pain Management Program Default SECON Urine Toxicology Screen (UTS) Order

Opiates (Morphine, Heroin (diacytlmorphine)), Opioids (Hydrocodone, Oxycodone, Oxymorphone, Methadone, Fentanyl, Tramadol), Cocaine, Benzodiazepines, Cannabinoids, Amphetamines, Barbituates, Alcohol.

Default diagnosis code: 338.4 (chronic pain syndrome, NOS; use a more specific code if there is a more specific diagnosis)

Appendix E: FHCW Opioid Medication Consent Form (two pages)

I, _____, will read (or have read to me, in my primary language) the following and will initial each line to confirm my understanding of and agreement with each item:

Goals of the FHCW Chronic Pain Management Program

I agree with the goals of the Family Health Center of Worcester Chronic Pain Management Program for the treatment of my chronic pain:

_____ Appropriate evaluation of patients for pain management with opioid and non-opioid treatments.
_____ Effective pain management targeting improvement of function and quality of life.
_____ Safe prescribing practices with "universal precaution" approach that monitors all patients closely.
_____ Prevention of prescription medication-related criminal activity and drug abuse.

Information about Opioids

_____ Opioid medications may relieve your pain effectively for the first few months, but there are no medical studies proving nor disproving that they will provide good pain relief and improvement of function beyond this early period. There are, however, several known problems with chronic (i.e. more than three month) use of opioids.

_____ After chronic use of opioids your body will get used to them such that you may no longer feel the same degree of pain relief from taking the same dose; this is called tolerance. Although increasing the dose will work for some time, there likely will be a point where your doctor judges that the benefit of further dose increases is outweighed by the harm of side effects, including a decreased pain threshold, and overdose risk. You will likely then be held at this dose and will need to work to find other ways to help relieve your pain.

_____ After chronic use of opioids your body will get used to them such that you will get sick and be in severe pain if you stop them abruptly; this is called physical dependence. Some patients have great difficulty with this even when the dose is lowered slowly. It may thus be extremely difficult for you to stop this medication after chronic use.

_____ After chronic use of opioids, some patients will develop opioid addiction, which includes tolerance and dependence, but also medication cravings and compulsive use despite negative consequences at home, work, or school, and with relationships or the law. The risk for this is difficult to estimate but is thought to be around 5%.

____ Common side effects of chronic opioid use include: constipation, sedation, confusion, nausea, dizziness, vomiting, itchiness, physical dependence , tolerance, lowered pain threshold and respiratory depression. If you have any of these side effects from the medicine, notify the doctor or nurse.

_____ Less common but serious opioid side effects include delayed stomach emptying, immune system and hormonal dysfunction (such as low testosterone), muscle rigidity, and muscle spasms. If you have any of these side effects from the medicine, notify the doctor or nurse.

_____ Patients on chronic doses of opioids have not been shown to be at higher risk for accidents, but because opioids can cause drowsiness and confusion, you should not drive a vehicle or operate heavy machinery for at least three days after starting or increasing the dose of opioids.

____ If you take an opioid with alcohol or any medicine or drug that causes sleepiness, you could become very sick, stop breathing, and die. Taking sedatives such as the benzodiazepines Klonopin, Valium , Xanax, Ativan, Librium or Serax can thus be very dangerous for people on opioids and will be allowed only when taken as prescribed by a physician and there are no signs of impairment, sedation, overdose, unsafe behaviors or other adverse medical events.

_____ There are most likely other medications that could be used to treat your pain. You confirm that you have discussed these other options with my doctor and that you are willingly choosing to take an opioid because these other medications have not controlled your pain well enough to achieve satisfactory function and/or that they were unsafe for you to take on a prolonged basis.

Program Requirements

____ I will not use illegal drugs, alcohol, or prescription opioids from another doctor.

____ I will not take benzodiazepines (Xanax, Klonopin, Ativan, Valium, Librium, Serax) unless prescribed by a doctor.

____ I will tell my doctor about all prescription and non-prescription medications I am taking.

____ I will seek opioid refills only during scheduled office visits and will not call at night or on the weekends for refills.

____ I share responsibility with the Chronic Pain nurse and my doctor to have an appointment for my next opioid refill before I am due to run out. If I have trouble making an appointment through the receptionist, I will call the Chronic Pain nurse at 508-860-7804 the week before I will run out to make an appointment.

____ I will bring my opioid prescription bottle to each Chronic Pain nurse visit, whether scheduled or random.

____ I will follow the policy for random medication checks and drug testing. This means that I will call the Chronic Pain nurse back within 8 hours any time they call and, if requested, come in for a medication count and a drug test within 24 hours. If I will be away it is my responsibility to let the Chronic Pain nurse know this in advance.

____ It is my responsibility to provide a working phone number at which I may be reached at any time during regular business hours (8am-5pm Monday through Friday).

____ I will keep my opioid medication safe and out of reach of children in a locked box, bag, or cabinet in a labeled prescription bottle with a child-proof cap, and will not put tablets on counters, sinks, dresser, or nightstands. I will call 911 if there is an accidental exposure.

____ I will protect my opioid prescription and medication. Aside from Chronic Pain nurse appointments, I will keep my medication locked safely at home and will not carry it in my pocket, bag, purse or backpack.

____ I understand that an early refill will not be granted if my opioid prescription or medication is lost, stolen, or destroyed, or if I take more opioid medication each day than what was prescribed.

____ I will follow through on the plan of care my doctor and I establish to manage my chronic pain, which may include appointments with specialists, physical therapists, mental health providers, or other resources.

____ If I sell my opioid medication or share it with others my treatment will be stopped.

____ I will treat all staff and fellow patients at the office with courtesy and respect at all times, and understand that behavior that is disrespectful or threatening to staff or that disrupts the care of other patients may cause immediate discharge from the Chronic Pain Management Program.

____ I understand that I may be discharged from this program if I break any part of this contract or if my doctor feels that a opioids are no longer appropriate or effective for the treatment of my chronic pain.

I have read and understand the statements on this form and have had a chance to ask questions about them. I understand that these expectations are required of all patients being treated with opioids for chronic pain. I agree to comply with all Program Requirements and give my consent to begin or continue opioid treatment. I acknowledge that I will need to review and sign this Opioid Medication Consent Form annually.

_____Patient Name

_____Patient Signature

_____Interpreter Signature (if needed)

_____Date Signed

_____Provider or Nurse Name

_____Provider or Nurse Signature

_____Date Signed

Appendix F: Chronic Pain Management Nursing Progress Note Template

HPI: yoM/F with chronic pain syndrome presents in Risk Tier # presents for a chronic pain nursing visit with the following interim history:
Analgesia (min, avg, max pain score 0-10):
Activities (home and work function and goals):
Affect (mood, psychological function):
Adverse Effects (med side effects):
Aberrant Behaviors:

Opioid Medication Regimen:
Adjunctive Medications and Therapies:

Last 12 Urine Toxicology Screens and Pill Counts

CHRONIC PAIN MANAGEMENT PROGRAM TRACKING TABLE:
Intake Date:
Last early refill (if granted; not to exceed one per year):
Last annual review and signing of FHCW Opioid Medication Consent Form:
Last PCP visit:
Contraceptive Status:

VITAL SIGNS: see elsewhere/below in note

PHYSICAL EXAM: Patient appears to be comfortable / in mild/moderate/severe pain.

ASSESSMENT: yoM/F with chronic pain syndrome with pain control that is [sufficient/partially sufficient/insufficient] to enable acceptable functioning, quality of life, and progress towards patient's goals with [no/mild/moderate/significant adverse effects] in the setting of [no/noted aberrant behaviors].

PLAN:
Will/will not refill opioid pain medication for X days, Rx signed by PCP/covering provider X.
Patient to remain in / move to Risk Tier #.
Monitoring: planned random/scheduled UTS and pill counts in X days.
Harm Reduction: Safe storage, medication directions reviewed.
Additional plan(s):

Next Visit: [X day nursing visit] / [X day PCP visit]

This note will be tasked to the PCP.

Appendix G: Sample Chronic Pain Management Nursing Progress Note

HPI: 55yoF with chronic pain syndrome presents in Risk Tier 2 presents for a chronic pain nursing visit with the following interim history:

Analgesia (min/avg/max pain score 0-10): 4/6/8

Activities (home and work function and goals): can walk, sit and lie down ok but has trouble bending over, running or doing other exercise or physical work. Goals: would like to be able to exercise and get back to work as a landscaper.

Affect (mood, psychological function): has some down days but overall is doing well, getting along with husband and son.

Adverse Effects (med side effects): denies sedation, drowsiness, or nausea; mild constipation that responds well to Senna.

Aberrant Behaviors: did not keep her PT appointment last month, but has rebooked it and will start next week.

Opioid Medication Regimen: Oxycontin 20mg q8h.
Adjunctive Medications and Therapies: nortriptyline 50mg qhs, naproxen 500mg bid prn.

Last 12 months' Urine Toxicology Screens and Pill Counts
4/5/13 (scheduled) - Proper
5/2/12 (scheduled) - Proper
6/1/12 (random) - IMPROPER – cannabinoids, clonazepam; pill count correct.
6/15/12 (scheduled) - Proper.
6/29/12 (scheduled) - Proper.
7/27/13 (scheduled) - Proper.

CHRONIC PAIN MANAGEMENT PROGRAM TRACKING TABLE:

Intake Date: 5/6/09.

Last early refill (if granted; not to exceed one per year): 11/5/11.

Last annual review and signing of FHCW Opioid Medication Consent Form: 5/2/12.

Last PCP visit: 4/5/12

Contraceptive Status: post-menopausal

VITAL SIGNS: see elsewhere/below in note

PHYSICAL EXAM: Patient appears to be comfortable.

ASSESSMENT: 55yoF with chronic pain syndrome with pain control that is sufficient to enable acceptable functioning, quality of life, and progress towards goals with well-controlled adverse effects in the setting of an aberrant behavior 6/12 (+benzos, missed PT appointment). Patient was moved from Risk Tier 2 to 3, did well, and moved back to Tier 2.

PLAN:
Will refill opioid pain medication for 28 days, Rx signed by PCP Dr. Bolduc.
Patient to remain in Risk Tier 2 until next PCP visit.
Monitoring: planned random UTS and pill counts in 7 days.
Harm Reduction: Safe storage, medication directions reviewed.
Additional plan(s): Patient is going to look into yoga classes at the YWCA.

Next Visit: 28 day nursing visit; will then see Dr. Bolduc in 8 weeks.

This note will be tasked to the PCP.

Appendix H: Risk Tier Table (Tier X = do not prescribe opioids; note this in ALERT table in EMR)

	Tier 4	Tier 3	Tier 2	Tier 1
Rx Duration	1 week	2 weeks	4 weeks	4 weeks
Scheduled UTS[1]	Weekly	Every 2 weeks	Every 4 weeks	Every 12 weeks
Random Call-In[1]	Every 2 weeks	Every 4 weeks	Every 8 weeks	Every 12 weeks
PCP Visits	Every 2 weeks	Every 4 weeks	Every 8 weeks	Every 12 weeks
Nurse Visits	Weekly, alternating with PCP	Every 2 weeks, alternating with PCP	Every 4 weeks, alternating with PCP	Every 4 weeks in between PCP visits
Minimum Time to Next Tier	2 weeks	4 weeks	12 weeks	N/A

[1] These are maximum intervals; the PCP may ask for more frequent UTSs or random call-ins at their discretion

Appendix I: Notification of Discontinuation of Opioid Treatment

Date

Dear _____,

We regret that we will no longer be able to provide pain treatment with opioid medications for you at the Family Health Center of Worcester due to the following:

1._____

2._____

3._____

4._____

You may be at risk for experiencing withdrawal symptoms. If you are interested in seeking detoxification services, please call:

Community Health Link, Worcester	508-860-1200
Spectrum Health Systems, Westborough	508-898-1570

If you feel you have opioid addiction and are interested in methadone maintenance, please contact

Spectrum Health Systems, Worcester 508-854-3320

Spectrum allows people to come in for same day admissions on Thursdays—you will need to arrive there on Thursday before 5:30 AM to sign up for this option. Alternatively, it may be easier to get into methadone treatment by going to detox first, and asking for a referral to methadone maintenance.

We are happy to continue to provide you comprehensive medical care and non-opioid pain management. You may request copies of your medical record if you choose to seek treatment elsewhere.

Sincerely,

Appendix J: Diagnosis of Opioid Use Disorder (DSM V - 304.00)

A maladaptive pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period: (includes both opioids and opiates)

1. the opioid is often taken in larger amounts or over a longer period than was intended
2. there is a persistent desire or unsuccessful efforts to cut down or control opioid use
3. a great deal of time is spent in activities necessary to obtain, use, or recover from the opioid's effects
4. recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household)
5. continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights)
6. important social, occupational, or recreational activities are given up or reduced because of opioid use
7. recurrent opioid use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use)
8. the opioid use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the opioid
9. tolerance, as defined by either of the following:
   a. a need for markedly increased amounts of opioid to achieve intoxication or desired effect
   b. markedly diminished effect with continued use of the same amount of opioid
   (Note: Tolerance is not counted for those taking medications under medical supervision)
10. withdrawal, as manifested by either of the following:
    a. the characteristic withdrawal syndrome for opioids (see Appendix F: Clinical Opiate Withdrawal Scale)
    b. the same (or a closely related) opioid is taken to relieve or avoid withdrawal symptoms
    (Note: Withdrawal is not counted for those taking medications under medical supervision such as analgesics)
11. Craving or a strong desire or urge to use the opioid

Specify the Following:

Early Remission. This specifier is used if, for at least 3 months, but for less than 12 months, the individual does not meet any of the criteria 1-10 for a Substance Use Disorder (i.e. none of the criteria except for Criterion 11, "Craving or a strong desire or urge to use a specific substance").

Sustained Remission. This specifier is used if none of the criteria 1-10 for a Substance Use Disorder have been met at any time during a period of 12 months or longer (i.e. none of the criteria met except for Criterion 11, "Craving or a strong desire or urge to use a specific substance").

The following specifiers apply as further specifiers of remission (e.g. "early remission on maintenance therapy", "early remission in a controlled environment", "sustained remission on maintenance therapy", and "sustained remission in a controlled environment") if the individual is in remission and on maintenance therapy or in a controlled environment:

On Maintenance Therapy. This additional specifier is used if the individual is on a prescribed agonist medication such as methadone or buprenorphine and no criteria for a Substance Use Disorder have been met for that class of medication (except tolerance to, or withdrawal from, the agonist). This category also applies to those being maintained on a partial agonist, an agonist/antagonist or a full antagonist such as oral naltrexone or depot naltrexone.

In a Controlled Environment. This additional specifier is used if the individual is in an environment where access to alcohol and controlled substances is restricted, and no criteria for a Substance Use Disorder have been met. Examples of these environments are closely supervised and substance-free jails, therapeutic communities, and locked hospital units.

Appendix K: Model Policy for the Use of Controlled Substances for the Treatment of Pain (3 pages)
Adopted by the Massachusetts Board of Registration in Medicine December 15, 2004

Section I: Preamble

The Massachusetts Board of Registration in Medicine recognizes that principles of quality medical practice dictate that the people of the Commonwealth of Massachusetts have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The Massachusetts Board of Registration in Medicine is obligated under the laws of the Commonwealth to protect the public health and safety. The Board recognizes that the use of opioid analgesics for other than legitimate medical purposes pose a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines
The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

Evaluation of the Patient—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

Treatment Plan—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

Informed Consent and Agreement for Treatment—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including o urine/serum medication levels screening when requested; o number and frequency of all prescription refills; and o reasons for which drug therapy may be discontinued (e.g., violation of agreement).

Periodic Review—The physician should periodically review the course of pain treatment 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

Medical Records—The physician should keep accurate and complete records to include
1. the medical history and physical examination,
2. diagnostic, therapeutic and laboratory results,
3. evaluations and consultations,
4. treatment objectives,
5. discussion of risks and benefits,
6. informed consent,
7. treatments,
8. medications (including date, type, dosage and quantity prescribed),
9. instructions and agreements and
10. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

Compliance With Controlled Substances Laws and Regulations—To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions
For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

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

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief Seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction

Appendix L: Opioid Types and Controlled Substance Schedule

	Schedule	Notes
Opiate		
Morphine	II	
Codeine	II (III with APAP)	
Opioid (Semi-Synthetic)		
Oxycodone	II	
Hydrocodone	II	
Oxymorphone	II	
Hydromorphone	II	
Heroin	I	
Opioid (Synthetic)		
Fentanyl	II	Lack of toxic metabolites = useful in renal failure.
Tramadol	N/A	
Meperidine	II	Use is widely discouraged due to toxic metabolites.
Buprenorphine	III	μ-opioid agonist with ceiling effect and blockade of other opiates and opioids; also inhibits norepinephrine and serotonin reuptake
Methadone	II	Also blocks NMDA receptors and therefore can be useful for neuropathic pain. **Use with caution for chronic pain.** Can prolong QT interval.

Appendix M: Opioid Formulations and Equivalency/Duration

Drug	Formulation	Trade Names	MED[§]	Duration (h)
Morphine				
	PO Morphine		1	3-6
	IV Morphine		3	3-4
	Controlled-Release Morphine	MS Contin, Oramorph	1	8-12
	Sustained-Release Morphine	Kadian	1	12-24
	Extended-Release Morphine	Avinza	1	24
Hydromorphone				
	PO Hydromorphone	Dilaudid	4	3-6
	IV Hydromorphone	Dilaudid	20	3-4
Codeine				
	PO Codeine	Tylenol #3 (w/ APAP)	0.2	4-6
Oxycodone				
	PO Oxycodone	Oxy IR, Percocet (w/ APAP)	1.4	3-6
	Controlled-Release Oxycodone	Oxycontin	1.4	8-12
Hydrocodone				
	PO Hydrocodone	Vicodin (w/ APAP)	1	4-8
Oxymorphone				
	Extended-Release Oxymorphone	Opana ER	7	12
Methadone				
	PO Methadone		†	†
Fentanyl				
	Transdermal Fentanyl		‡	48-72h/patch
Tramadol				
	PO Tramadol	Ultram		4-6 (initial use) 3-11 (chronic use)

§ MED: Morphine-equivalent dose is the number of milligrams of PO morphine required for equianalgesia for 1mg of the conversion opioid (e.g. 20mg of PO morphine equals 1mg IV hydromorphone); all equianalgesic ratios/formulas are **approximations**; clinical judgment is needed when making dose or drug conversions

† Non-linear conversion from other opioids, and variable duration with long half-life

‡ 1mg/day of morphine is roughly ~0.42μg/hr of TD Fentanyl; refer to conversion tables and follow recommended guidelines for use

Appendix N: Toxicology Detection Times and Expected Metabolites

Toxicology Detection Times

Drug	Detection	Exceptions	Drugs Causing False ⊕
Amphetamines	2-3 days		
Cocaine	2-3 days		
Marijuana	1-7 days	Heavy use detectable for up to 1 month	
Opiates/Opioids	1-3 days		Poppy seeds
Phencyclidine	7-14 days		Ketamine
Benzodiazepines	5-7 days	Flunitrazepam (i.e. "Roofies") detectable for <3 days	
Barbiturates	2 days	Phenobarbital detectable for 1-2 weeks	

Expected Metabolites

Drug	Major Metabolites	Minor Metabolites	Notes
Codeine	Morphine	Hydrocodone	
Hydrocodone		Hydromorphone	
Oxycodone	Oxymorphone		
Morphine		Hydromorphone	
Hydromorphone			No metabolites
Heroin	6-MAM, morphine	Codeine†	Heroin not detectable (rapidly metabolized)

† Codeine is not a metabolite of heroin but is listed as such for simplicity; codeine is frequently seen with heroin ingestions as it is the metabolite of acetylcodeine which is an impurity found in illicitly synthesized heroin.

- Opioids have both major and minor metabolites.
- After a drug is used, appropriate patterns include:
  - Only the parent drug itself
  - Parent drug PLUS metabolites
  - Only the metabolites
- Minor metabolites are not always seen, even in appropriate use.

Resources:

Test metabolite patterns, and detection times were provided by UMass Hospital Labs.

Appendix O: Addiction Treatment Services in Worcester, MA

- Community Health Link
  - 508-860-1200
- Spectrum Health Systems
  - 508-854-3320
- AdCare
  - 508-799-9000
- Addiction Wellness Centers
  - 508-890-0990