BRIGHAM HEALTH
BRIGHAM AND WOMEN'S HOSPITAL

BRIGHAM HEALTH
BRIGHAM AND WOMEN'S Faulkner Hospital

Executive Summary: Use of Opioid Therapy for Chronic, Non-malignant Pain at Brigham Health

Purpose/Definition: The purpose of this document is to support BWH healthcare providers in delivering compassionate, evidence-based, responsible care for the patients we serve, while improving the quality and safety of care for patients treated for chronic pain. 'Chronic opioid therapy' is the continuous use of an opioid medication as prescribed for greater than 90 days.

Overall, there is little evidence to support the use of chronic opioids for non-malignant pain. The risks of opioids have been clearly documented, with rates of misuse ranging from 4-26%, a lifetime prevalence of opioid use disorder of 35%, and a risk of overdose that rises dramatically with dosages above 100 mg daily morphine equivalents

Diagnosis, Screening, and Documentation:

- **History, physical exam, diagnosis, and plan must be documented before any opioid is prescribed.**
- **All patients should be screened for risk** of opioid misuse using a validated screening tool to determine whether it is appropriate to prescribe opioids based on diagnosis and risk.
- **All patients on chronic opioid medications should receive, review, and sign an approved "Opioid Medication Management Agreement"** (Appendix B)
- **All patients receiving chronic opioid medications for pain should have 'Chronic Pain' documented as a problem in the problem list in the EMR, including indication, prescribing physician, and medication type.**

Prescribing Opioids:

- Prescribing opioids for chronic pain should only be pursued once all other options have been exhausted.
- Non-pharmacologic and non-opioid pharmacologic options should be used as a first line for chronic pain unless otherwise contraindicated.
- Providers should review side effects and **discuss the risks of addiction and overdose with all patients on chronic opioid therapy. Providers should also counsel regarding safe storage and disposal of medications.**
- **At every visit, work to taper patients on >90 morphine milligram equivalents (MME)/day to safer doses** (Appendix C)
- Providers should prescribe intranasal naloxone rescue kits to all patients on chronic opioids >50 MME/day.

Renewals:

- Patients receiving chronic opioid medications from a practice must have regular clinical reassessments in order to receive refills.
- **Patients on chronic opioid medications should be clinically reevaluated by the prescriber/surrogate at least every 4 months**. Patients should be seen at shorter intervals based upon the judgment of the prescribing clinician and care team.
- Prescriptions should be limited to 28-day supplies unless mandated otherwise by insurance.
- Renewals should not be given on evenings, holidays, or weekends.
- **The prescriber must check MassPAT prior to every schedule II or III opioid prescription, including for refills.**

Provider Monitoring: Patients receiving opioids for chronic pain should have a **regular clinical reassessment of pain, functional goals, treatment plan, and adherence, using the Opioid Documentation workflow in Epic**.

- All patients receiving chronic opioids should understand that pill counts and/or random toxicology screens (minimum yearly) are all part of a standard BWH protocol for care.
- More frequent monitoring is appropriate for monitoring of symptoms or concerns of misuse.
- Irregular findings should be addressed with the patient and documented in the EMR with the appropriate clinical and/or administrative response.

Discontinuing Opioids: Clinicians are justified in discontinuing opioids if 1) there is **evidence of harm**, 2) **risks are not outweighed** by clinical benefits, 3) **functional treatment goals are not being met**, or 4) when **there is a high level of concern for non-adherence** to mutually agreed upon treatment guidelines.

If discontinuing due to:

- *Concern about opioid use disorder*: Provide the patient with contact information for addiction treatment programs and/or provide an appropriate tapering schedule.
- *High suspicion/confirmation of diversion*: Do not taper the medication.
- *Lack of clear benefit/not meeting functional goals*: Outline taper/alternative pain plan/referral to pain program.

Special Populations: If a patient is currently on long-term opioid medications or opioid agonists/antagonists, any interruption in medications in the acute setting must be discussed with the prescribing clinician.

Clinical Strategy: Use of Opioid Therapy for Chronic, Non-malignant Pain, Updated: 6/8/2020
Brigham Health

1. Introduction: Overview and Intent

All prescribers in Brigham Health should review and adhere to the documented procedures below for the use of opioid medications in the treatment of chronic pain. This guidance does not apply to patients with active cancer and malignancy associated pain or patients receiving hospice or palliative care.

Required elements are **bolded**. Those elements which are **required** by either Massachusetts or the DEA are **bolded and underlined**.

2. Scope and Audience

Healthcare providers frequently see patients with chronic pain. These guidelines aim to support providers in delivering compassionate, evidence-based, responsible care to patients suffering from chronic pain, while reducing the number of people inappropriately prescribed opioids and those continued on opioids who are not achieving functional goals, having serious side effects, or exhibiting concerning behavior. These guidelines recognize that there are some patients who may benefit from chronic opioid therapy as a component of their management. However, there are many risks associated with opioid use, and these are heightened at higher doses. There are risks to patients of physical dependence, addiction (the behavioral syndrome of drug dependence), decreasing level of function, and overdose. Intentional or unintentional diversion is also well documented both within the Commonwealth of Massachusetts and nationally and contributes to community risk of overdose and addiction. Following consistent and clear guidelines regarding the use of opioids for chronic, non-malignant pain, and the appropriate screening and management of patients on opioid therapy has the potential to:

- Support care and quality of life for our patients
- Minimize risk to both patients and society
- Simplify and streamline clinical procedures across the Brigham Health network
- Promote stable provider-patient relationships

Definitions:

- Definition of Opioid (for this policy): 1) any drugs derived from the opium poppy (usually called opiates) such as morphine, paregoric; 2) any synthetic related drugs with similar clinical effects including but not limited to: codeine, fentanyl, hydrocodone, hydromorphone, oxycodone, methadone (for pain), and tramadol. These guidelines do not address the use of buprenorphine for the treatment of opioid use disorder.
- Unless otherwise stated, 'chronic opioid therapy' will be defined as the continuous use of an opioid medication as prescribed for greater than 90 days.
- Definition of controlled substances: (Appendix A, Section I)
- Chronic pain is defined as pain that persists beyond a timeframe of 90 days/3 months, excluding pain related to active cancer and hospice or palliative care patients.

3. Procedure

The following guidelines and recommendations are established to assist providers and their teams in the management of patients with chronic, non-malignant pain.

a. Establishing a diagnosis, screening for risk, and documenting a plan of care

- **Before any opioid is prescribed for chronic pain, a history, physical exam, diagnosis (even if provisional) and plan must be documented. Evaluate whether or not opioid therapy is still appropriate.**
- **All patients should be screened for risk of opioid misuse using a validated screening tool (See Appendix A, Section X) as well as the Prescription Monitoring Program.** The most comprehensive screening tool is the SOAPP-R, which we expect to be available in Epic soon and has been validated in Spanish. You may also use other validated tools such as Opioid Risk Tool (ORT) or Drug Abuse Screening Test (DAST), which are also in Epic. This should be documented in the patient's medical record.
- **Determine whether it is appropriate to prescribe opioids based on diagnosis and risk.** The decision to prescribe opioids for our moderate to highest risk patients (those with history of opioid overdose, active substance use disorder, known aberrant drug related behaviors, or an ORT >8 or SOAPP-R >17) should include an assessment and identification of risk factors unique to that patient. High risk patients should have close monitoring, limited quantities of medications prescribed, frequent use of toxicology screens, and multi-disciplinary care including the use of adjuvants and behavioral and rehabilitative therapies concurrently. A pain management or addiction specialist consult should be considered.
- While there are no true hard stops on prescribing, a moderate or high-risk score should be documented in the record, and the prescribing clinician should consider the following:
    - Reducing the amount of opioids initially prescribed
    - Increasing caution when prescribing refills
    - Increasing counseling (risks and overdose) and monitoring
    - Prescribing naloxone if appropriate
    - Referring to pain management specialists and substance use disorder resources
- **If appropriate, counsel regarding the risks of opioid use, overdose, and safe storage and disposal (See Appendix D).**
- For new outpatients, prior records should be requested and ideally obtained as a prerequisite to prescribing opioids. It is best practice that providers speak with the prior treating provider if possible.
- For hospitalized or emergency department patients, prescriptions should ideally be confirmed with the primary outpatient prescriber before continuing chronic opioids in the acute setting. Confirming active prescriptions in the PMP or with the pharmacy is another option, although it is best practice that providers speak with the treating provider if possible.
- All patients prescribed opioids longitudinally for pain should have 'Chronic Pain' documented as a problem in the EMR problem list. Under 'Chronic Pain' should be included nature of pain/indication for medication, medication prescribed and prescribing provider.
- **In compliance with Massachusetts law, the following must be documented for all patients prescribed opioids on a chronic basis (>90 days):**
    - Indication for an opioid prescription with a duration longer than 7 days
    - Discussion of risks associated with opioid use
    - Discussion of quantity prescribed and ability to fill the prescription for a lesser amount
    - Review of the Massachusetts Prescription Awareness Tool (MassPAT)
    - Risk assessment and completion of a pain agreement for all patients on long acting opioids.

- **MassPAT must be reviewed for all schedule II and III opioid prescriptions and for benzodiazepine prescriptions, including refills.**

b. Non-Opioid Alternatives to Pain Management

- It is recommended that non-pharmacologic and non-opioid pharmacologic options be used as a first line for chronic pain unless otherwise contraindicated. Chronic opioid therapy should only be utilized for severe pain when alternatives are inadequate. Please see Appendix A, Section XI for guidelines on the use and efficacy of non-opioid pharmacologic options for pain.
- Overall, there is little evidence to support the use of chronic opioids for non-malignant pain. Please see Appendix A, Section XII for details on the efficacy of opioids in the management of specific conditions. The risks of opioids have been clearly documented, with rates of misuse ranging from 4-26%, a lifetime prevalence of opioid use disorder of 35%, and a risk of overdose that rises dramatically with dosages above 100 mg daily morphine equivalents.

c. Prescribing

- The provider and patient should establish measurable, functional goals for chronic opioid therapy and document progression. Failure to achieve these goals may mean that opioid treatment is not effective or appropriate for this patient.
- Clinicians should consider prescribing the lowest acceptable dose and conducting time-limited trials in which functional goals are established and a plan is in place to reduce or complete therapy if goals are not achieved.
- Prescriptions should be written for generic rather than brand name medications. Rationale for any exceptions should be documented.
- **Providers must never 'postdate' a prescription** as this can result in suspension of a DEA License. Prescriptions can be written in a 'Do not fill until' format if needed (Appendix A, Section II).
- No new opioid prescriptions should be initiated after-hours unless the patient is known to the prescriber and the problem is a recurrent one or if the patient has been evaluated for a new complaint and the covering provider has access to the evaluation.
- As is the case for management of all medications at provider transition, when providers leave a given practice and have patients on controlled substances, a coverage plan for the medications prescribed must be designed to ensure a safe transition in care during interim periods.
- Providers should discuss the risk of overdose with all patients on chronic opioid therapy and prescribe intranasal naloxone (Narcan) rescue kits as appropriate (Appendix A, Section VIII).
- Patients must designate one pharmacy that will dispense the patient's prescribed controlled substance.
- **All prescriptions must state that a patient can request the prescription to be filled for a lesser quantity than prescribed.**

d. Renewals

- Avoid frequent dose escalations in the face of lack of progress and consider referral to a formal pain management program if your interventions seem ineffective.
- Appropriateness of continued use of a chronic opioid medication depends on the assessment and judgment of the treating provider.
- No opioid renewals should be given during evenings, holidays or weekends by covering clinicians, unless to correct an oversight or error.
- **In order to obtain renewals of opioid prescriptions, patients must schedule regular clinical visits at a frequency determined by the prescribing clinician, at least every 4 months.** If a patient fails to meet

the minimum requirement then the prescriber must document a clinical response.

- During regular business hours, covering providers will renew opioid prescriptions, provided that the chronic opioid management agreement (Appendix B), diagnosis, medication, dose, last toxicology screen and last prescription date are documented in the record and provided that the patient has been seen in the practice within the appropriate time frame.
- Renewals of opioid prescriptions should be prescribed electronically.
- **Unless precluded by insurance restrictions, patients should be given no more than 28-day supplies of their opioid medications and ideally not on Mondays** so as to avoid renewals due on holiday Mondays.

e. Provider Monitoring

- **All patients prescribed opioids on a chronic basis (> 90 days) to manage pain must review and sign the Partners Opioid Medication Management Agreement** (Appendix B). Patients who refuse to sign the agreement will not continue to receive opioids from clinicians after 90 days.
- This agreement may be initiated prior to 90 days based upon the clinical scenario and the judgment of the clinician.
- Content of the Partners Opioid Medication Management Agreement (Appendix B) should be reviewed on a periodic basis or whenever any significant change in medication, health status, or treatment plan occurs. Additionally, risks should be reviewed as needed (Appendix D).
- All patients on chronic opioids should have a note in the Epic Opioid Documentation workflow (Appendix E). This tool will also provide data for the Chronic Opioid Registry, which enables providers to monitor all of their patients on chronic opioids (Appendix F).
- According to the Commonwealth *of Massachusetts Board of Registration in Medicine Prescribing Practices Policy and Guidelines (Amended 11/17/10),* **patients on continuous schedule II medications should be clinically reevaluated by the prescriber/surrogate at least every 3 months.** Patients with clinical indications such as recalcitrant symptoms or a high risk of overdose, misuse, or diversion may be seen at shorter intervals based upon the judgment of the prescribing clinician and care team. At Brigham Health, we recommend that prescriptions be at the very least every 4 months.
- **Patients receiving opioids for chronic pain should have a regular clinical reassessment of their pain, functional goals, and treatment plan** (Appendix A, Section III). Reassessment can be performed by any appropriately designated member of the care team. It is recommended that this include assessment of clinical response, screening for risk of opioid misuse or current aberrant behavior, side-effects of opioids, and safe storage of medication.
- All patients receiving chronic opioids must agree to pill counts and/or random toxicology screens to receive chronic opioids as outlined in the Partners Opioid Medication Management Agreement (Appendix B). **The minimum frequency of toxicology screens should be approximately yearly. More frequent monitoring is often clinically appropriate for concerns of misuse. It is recommended that if results received appear inaccurate, care provider should confirm results with lab.**
- **Toxicology screen results, and / or unexpected results of pill counts must be acknowledged, and therapeutic or administrative response documented.** (Appendix A, Section VII)
- **The PMP must be checked prior to every schedule II and III opioid and every benzodiazepine prescription, including refills.**

f. Discontinuing Opioids

- A clinician is justified in discontinuing opioid medications when there is evidence of harm, when the high risk of the medication is not outweighed by evidence of benefit, when functional treatment goals are not being met, when patients are unable to comply with specified treatment guidelines, or when a patient outright violates the Opioid Medication Management Agreement (Appendix A, Section V)
- If a clinician is discontinuing opioid medications and there is concern about opioid use disorder, s/he

should refer the patient to the Bridge Clinic (Appendix G) and/or should outline or provide an appropriate tapering schedule. In the inpatient setting, the Psychiatry Consult/Liaison Service should be consulted for guidance. In the outpatient setting, use a psychiatry e-consult in Epic to connect with a primary care clinic's embedded psychiatrist or addiction specialists. In addition, please see Appendix A, Section XIII for a list of addiction treatment resources. Refusal of the patient to follow these recommendations or plans does not obligate the continued prescribing of opioid medications.

- If the medication is being stopped for high suspicion (e.g. positive toxicology screen, questionable pill counts, or suspect PMP record) or confirmation of diversion, the medication should not be tapered.
- If opioids are being discontinued due to a lack of clear benefit or meeting of functional goals, a taper plan and alternative pain management strategy should be outlined.
- To discuss challenging cases, the state has also provided a hotline for prescribers: MCSTAP: Massachusetts Consultation Service for Treatment of Addiction and Pain (www.mcstap.com or 1-833-724-6783).

g. Controlled Substance Agreements

- **All patients prescribed opioids on a chronic basis (>90 days) to manage pain must review and sign the established "Opioid Medication Management Agreement"** (Appendix B). The agreement will be stored in the EMR, listed on the problem list, and given to the patient for their own records.
- Patients agree in the document that failure to meet these conditions may mean that their provider will no longer provide prescriptions for chronic opioids.
- Patients acknowledge that if mutually agreed upon goals are not achieved, the agreement itself may be voided.
- Agreement may be done for other controlled substances, including schedule II, III, IV medications at the discretion of the prescribing clinician or the policy of the given practice.

h. Special Populations

- If a patient is currently on long-term opioid medications or medication for opioid use disorder, any interruption in medications in the acute setting must be discussed with the prescribing clinician.
- The initial prescribing clinician of these medications should anticipate communications from providers in the acute settings and provide the appropriate guidance and support.

Appendix A:

I. Definition of Controlled Substance Schedules (from DEA website)

II. Issuance of Multiple Prescriptions for Schedule II Controlled Substances (from DEA website)
A practitioner may provide individual patients with multiple prescriptions for the same schedule II controlled substance to be filled sequentially. The combined effect of these multiple prescriptions is to allow the patient to receive, over time, up to a 90-day supply of that controlled substance.

III. Re-assessment: What do you do at the interval appointment every 1-4 months?

Suggestions: Focus on quality of life, activities including for example:

a. 4As:

1. Analgesia- how has their pain been controlled?
2. Activity- what have they been able to do with the pain medications that they would not have been able to do otherwise? Focus on the functional treatment goals that you set.
3. Adverse Effects- Sedation, constipation, somnolence, urinary issues, depression (PCOI: Depression screening and management), sexual issues and so on.
4. Aberrant Behaviors/Addiction- ask them about impaired control over time, compulsive use, continued use despite harm, and craving.

b. PEG Score: Pain, Enjoyment, General Activity
Validated 3-question scale for monitoring chronic pain in primary care setting. Many providers find it useful to compare scores from visit to visit

c. Reassessment may include change in objective functional capacity (as reported by the patient), screens for depression and changes to treatment plan based upon evaluation.

IV. Massachusetts Online Prescription Monitoring Program:

- Drug diversion site and tool. Sign up
- Notary is no longer needed, resident physicians can sign up, and delegates can be assigned.

V. Discontinuing Opioid Medications:
You might consider when there is:

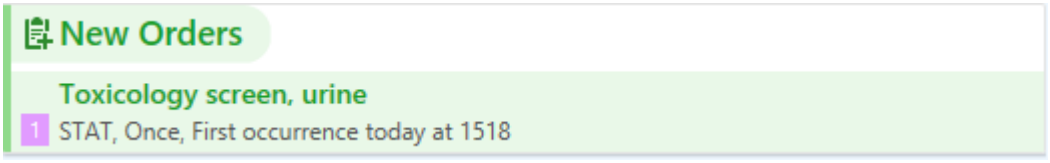
- Evidence of Harm
- High risk of the medication is not outweighed by evidence of the benefit
- For instance:
  - Failure to achieve functional treatment goals
  - Breach of opioid contract
  - Persistent presence of illicit drugs in urine toxicology screen
  - Aggressive, inappropriate or threatening behavior
  - Suspicion or confirmation that patient is diverting medications
- Violation of BWH Agreement and Informed Consent for Receiving Controlled Substances

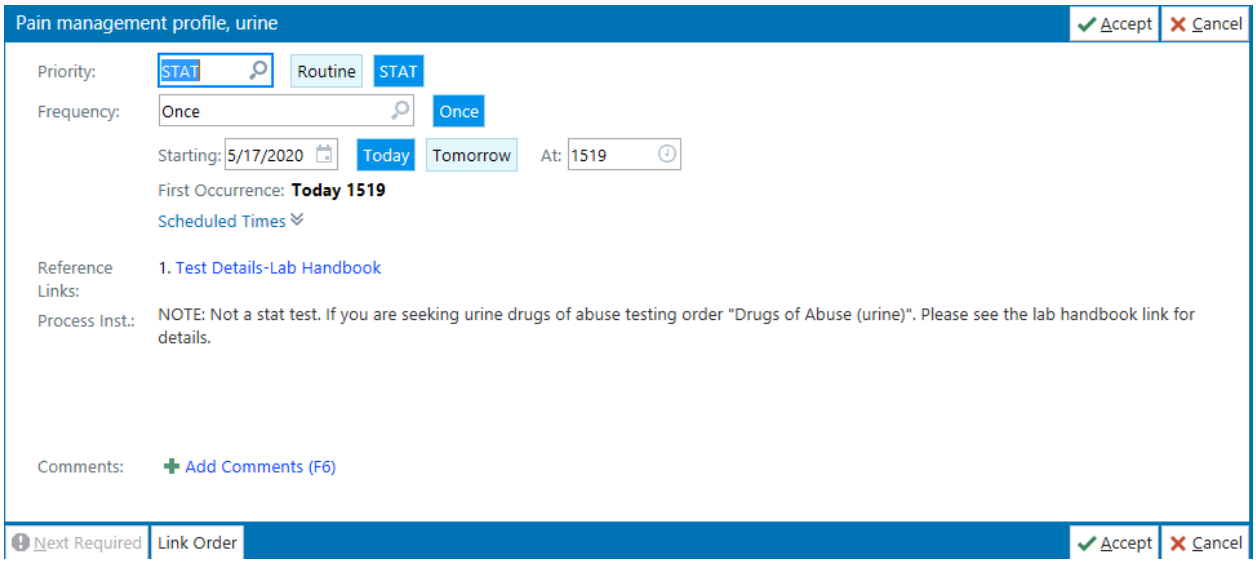
Responses to breach of agreement may depend on the reason:

- Miscommunication: Re-clarify rules once
- Pseudo-addiction: Means that patient is behaving with addictive behaviors, but it is due to pain. If you increase dose as a test then the behaviors ought to improve.
- Addiction: Stop or taper opioids and refer for treatment
- Diversion: STOP opioids

VII. Toxicology Screen Results:

- Proceed with caution since there are causes for false positives and false negatives.
- Results must be investigated and acknowledged in the medical record.
- Serum or urine can be screened for toxins at BWH, depending on clinical location. Most screening in the outpatient settings at BWH uses two urine toxin panels. The first order is for general screening. The second is much more in depth and useful for confirmation of specific substances.





- Adulteration of urine toxin screens is a common problem. The use of partially observed specimen collection with temperature monitoring cups may help reduce the risk of adulterated urine and identify patients who are falsifying their samples. Urine creatinine below 0.20 mg/ml is a marker for dilute urine and may represent an adulterated sample.
- The operating characteristics of the urine toxin screens vary from drug to drug. It is important to know that false positives and false negatives occur in many of the screens under certain circumstances. The assay sensitivity also varies by drug.
- False positive and negative results for common drugs in urine toxin screen at BWH:

BWH Toxicology Testing
Cross-Reactivities for Pain Management Profile Tests
Presumptive Testing (Immunoassay Based)

Assay	Cutoff	Detects (in order of decreasing cross-reactivity)	Poor Cross-reactivity (False Negatives)	Potential Interferences (False Positives)	Automatic Reflex to Definitive Testing?
Amphetamines DRI	1000 ng/mL	d-methamphetamine (calibrator) d-amphetamine MDA MDMA	*l*-methamphetamine *l*-amphetamine phentermine pseudoephedrine phenylpropanolamine ephedrine	9% false positive rate either pseudoephedrine or unknown	Yes Cutoff 50 ng/mL
Barbiturates DRI	200 ng/mL	Amobarbital Aprobarbital Butabarbital Butalbital Pentobarbital* (500 ng/mL) Phenobarbital* (600 ng/mL) Secobarbital (calibrator)	Barbital (1500 ng/mL)	no data on % false positive rarely confirmed	No, but can be done by request. Cutoff 100 ng/mL
*Pentobarbital and Phenobarbital may be missed due to lower cross-reactivity in the assay.					
Buprenorphine* LinZhi	5 ng/mL	Buprenorphine Norbupenorphine (calibrator)	Buprenorphine-glucuronide Norbuprenorphine-glucuronide	4% false positive Cause unknown	Yes, if ordered as part of a panel Buprenorphine - 2 ng/mL Norbuprenorphine - 2 ng/mL Buprenorphine glucuronide - 5 ng/mL Norbuprenorphine glucuronide - 5 ng/mL Naloxone - 100 ng/mL
Cocaine DRI	150 ng/mL	Benzoylecgonine	Cocaine Ecgonine Cocaethylene Ecgonine methyl ester	0% false positive Never seen a false positive with this assay	Yes Cutoff 50 ng/mL
Fentanyl Immunalysis	2 ng/mL	Fentanyl Despropionylfentanyl Acetylfentanyl	Norfentanyl Opiates Trazadone	12% false positive rate labetalol metabolite likely responsible, others	Yes Fentanyl - 0.2 ng/mL Norfentanyl - 1

		Butyrlfentanyl		unknown	ng/mL
Heroin Metabolite* LinZhi	10 ng/mL	6-AM Heroin	Opiates	0% false positive, but we get very few positive screens	Yes 5 ng/mL
Methadone DRI	300 ng/mL	Methadone Methadol	EDDP (methadone metab)	Tapentadol? Propafenone?	If discrepant with metabolite 10 ng/mL
Methadone Metabolite CEDIA	100 ng/mL	EDDP	Methadone EMDP (secondary metabolite)	Unknown, rarely confirmed	If discrepant with methadone 10 ng/mL
THC DRI	50 ng/mL	Δ9-carboxy-THC THC metabolites		1% False positive rate due to Cannabinol. Marinol Niflumic acid?	Yes 3 ng/mL
Tramadol Immunalysis	200 ng/mL	Tramadol N-desmethyl-tramadol	O-desmethyltramadol venlafaxine	no data on % false positive rarely confirmed	No, but can be done by request 50 ng/mL

***Note: This test is only run if morphine >2000 ng/mL. This is because poppy seeds can cause morphine levels to be quantifiable, but not likely to be above 2000 ng/mL**

Definitive Testing (LC-MS/MS Based)

Assay	Cutoff	Comments
Codeine	100 ng/mL	Detects: Codeine
Hydrocodone	100 ng/mL	Detects: Hydrocodone
Hydromorphone	100 ng/mL	Detects: Hydromorphone
Morphine	100 ng/mL	Detects: Morphine
Oxycodone	100 ng/mL	Detects: Oxycodone
Oxymorphone	100 ng/mL	Detects: Oxymorphone
Clonazepam	50 ng/mL	Detects: 7-aminoclonazepam
Lorazepam	50 ng/mL	Detects: Lorazepam
Nordiazepam	50 ng/mL	Detects: Nordiazepam
Alprazolam	50 ng/mL	Detects: Alpha Hydroxyalprazolam
Oxazepam	50 ng/mL	Detects: Oxazepam
Temazepam	50 ng/mL	Detects: Temazepam

For questions, contact:
Athena Petrides, PhD, Assistant Medical Directory of Chemistry/Director of Toxicology, (617) 732-6790, apetrides@partners.org

- Unexpected Positive: (presence of non-prescribed substances/illegal drug) DDX:
    a. False Positive (see above for list)
    b. Illicit drug Use
    =>Care team may decide to continue treatment based on their judgment. **Must document plan** which may include counseling or addiction treatment. Rejection of plan may result in cessation of prescribing controlled substances.
- Unexpected Negative (absence of prescribed drug) DDx:
    a. False negative (see above list)
    b. Patient not using (could be hoarding or diverting)
    c. Specimen manipulation (adulteration or dilution)
    d. Drug is present but below assay cutoff (can generally confirm with toxicology lab)
    e. Wrong assay ordered
    => **Care team must document plan**. Lack of evidence of opioid in toxicology screen without justification may lead to cessation of further prescribing of controlled substances.

VIII. Naloxone:

Consider prescribing in all patients on chronic opioid therapy. The following risk factors increase risk of overdose:

- a prior history of opioid overdose
- known addiction to heroin or other opioids
- on buprenorphine (Suboxone®, methadone, or high dose opioids (> 50mg morphine equivalent/day))
- with respiratory comorbidities such as COPD
- on opioids in combination with other sedating medications or alcohol
- requested the prescription

Other Naloxone Resources:

Nasal naloxone instructions

IX. References and Resources:

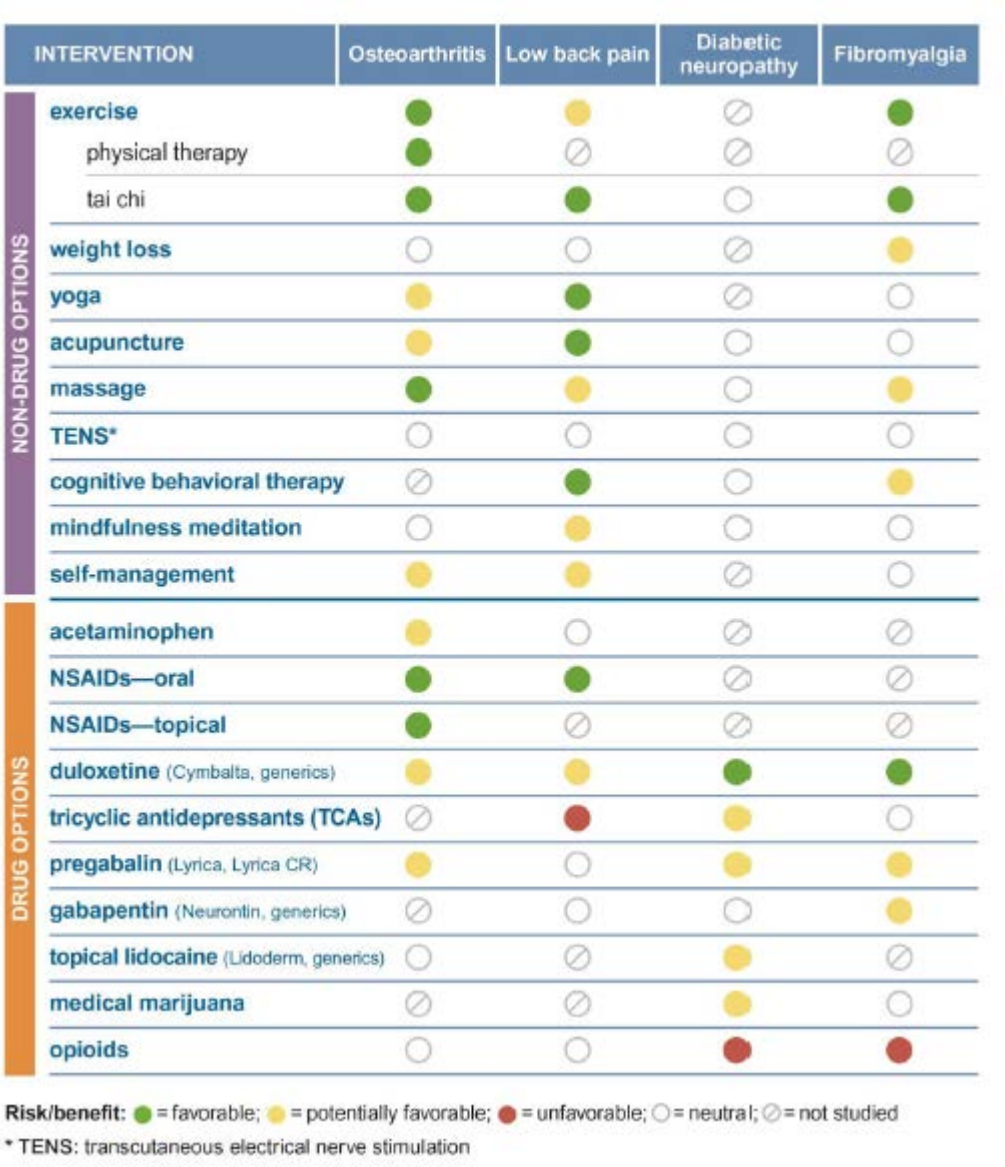
- Alford DP. Clinical Crossroads: Chronic Back Pain With Possible Prescription Opioid Misuse. *JAMA.*2013;309(9):919-925.
- Fishman, Scott M. Responsible Opioid Prescribing: A Physician's Guide, 2007.
- Krebs, EE, et al. "Development and Initial Validation of the PEG, a 3-Item Scale Assessing Pain Intensity and Interference" J Gen Intern Med. 2009 June; 24(6): 733–738.
- Safe and Effective Opioid Prescribing for Chronic Pain (BUSM and MA Board)

X. Opioid Misuse Risk Screening Tools:

- Opioid risk tool (ORT)
- SOAPP-R
- DAST 10
- ABCD-PQRS

XI. Non-opioid Pharmacologic Options for Pain Treatment:

- Please see Alosa Health guideline: Managing chronic non-cancer pain



	INTERVENTION	Osteoarthritis	Low back pain	Diabetic neuropathy	Fibromyalgia
NON-DRUG OPTIONS	exercise	●	◐	⊘	●
	physical therapy	●	⊘	⊘	⊘
	tai chi	●	●	○	●
	weight loss	○	○	⊘	◐
	yoga	◐	●	⊘	○
	acupuncture	◐	●	○	○
	massage	●	◐	○	◐
	TENS*	○	○	○	○
	cognitive behavioral therapy	⊘	●	○	◐
	mindfulness meditation	○	◐	○	○
	self-management	◐	◐	⊘	○
DRUG OPTIONS	acetaminophen	◐	○	⊘	⊘
	NSAIDs—oral	●	●	⊘	⊘
	NSAIDs—topical	●	⊘	⊘	⊘
	duloxetine (Cymbalta, generics)	◐	◐	●	●
	tricyclic antidepressants (TCAs)	⊘	●	◐	○
	pregabalin (Lyrica, Lyrica CR)	◐	○	◐	◐
	gabapentin (Neurontin, generics)	⊘	○	○	◐
	topical lidocaine (Lidoderm, generics)	○	⊘	◐	⊘
	medical marijuana	⊘	⊘	◐	○
	opioids	○	○	●	●

Risk/benefit: ● = favorable; ◐ = potentially favorable; ● = unfavorable; ○ = neutral; ⊘ = not studied

* TENS: transcutaneous electrical nerve stimulation

Source: *Managing chronic non-cancer pain* (Alosa Guideline)

XII. Efficacy of Opioids in Managing Common Chronic Pain Conditions:

- Washington State Guideline (pg. 24):
  - Severe acute injury (e.g. severe trauma, fracture, crush injury, postoperative)
    - Short-term use of opioids is unquestioned and is standard of care
  - Non-specific low back pain
    - Systematic reviews demonstrate modest improvement in pain but little improvement in function and no clear evidence that pain relief will be sustained.
    - Evidence from a population-based, prospective study of a low back pain cohort in WA workers' compensation reported that even minimal use of opioids in the first six weeks following an acute low back injury was associated with a doubling of the risk of disability one year later, after adjusting for baseline pain, function, and injury severity.

- Headaches
  - Scarce evidence: European Federation of Neurological Societies and the American Academy of Neurology recommend against the use of opioids for headache.
- Fibromyalgia:
  - No evidence from randomized trials to support the use of opioids for fibromyalgia, despite some observational studies showing that strong opioids are used in fibromyalgia patients with significant risk factors that would normally mitigate against such use.

XIII. Addiction Treatment Resources:

- Brigham Health Bride Clinic
- Faulkner Hospital Addiction Recovery Program
- MCSTAP – Free helpline for providers who need advice on managing a patient's pain/addiction
- Massachusetts State helpline
- PAATHS: offers same day navigation to detox or other types of treatment
- Find a buprenorphine prescriber
- Clean slate offers pharmacotherapy for opioid use disorder
- Adcare Boston offers same or next day intake for counseling

Appendix B: Partners Opioid Medications Management Agreement

Opioid Medicine
Management Agreement

Your care team has prescribed an opioid medicine to help with your medical condition. Thisform will provide you with information about your care plan and ways to safely use opioids. Please read it with care. If you understand and agree to the information on this form, sign your name on page 4.

Your Care Plan

I understand that I need to follow my care plan to take my opioid medicine safely. My care plan ensures that I will receive the best possible care for my medical treatment.

I understand that:

- My opioid medicines are being prescribed for the following condition: _____
- The goal of my treatment is: _____
- These opioid medicines are only one part of my treatment plan.
- I will **only** receive opioid medicines from my care team and no one else.
- If I receive opioid medicines from anyone else (such as after surgery, or from an emergency visit for a broken bone, etc.), I will let my care team know about this in person, in writing, or by phone **within the agreed upon timeframe** from my care team.
- I will only use my opioid medicines as directed by my care team.

  I will not:
  - Change the prescription in any way or increase the dose without talking to my care team. Doing this could lead to running out of medicine before my next prescription, overdose and death.
  - Suddenly stop taking my opioid medicines
  - Use them for **anything** other than treating my condition
  - Share, sell or trade them with other people, including family members

- Opioid medicines may have side effects. These include but are not limited to drowsiness or difficulty with concentration, nausea, vomiting, constipation, urinary problems, impaired sexual function, or itching. I will tell my care team if I develop these or other side effects.

- Opioid medicines can cause drowsiness or impair my ability to safely drive a car or other vehicles. Therefore, I **will not** drive any type of vehicle or operate any type of machinery unless I am completely alert. Doing so is a danger to me and to others. If I realize that I am not completely alert while I am driving a vehicle or operating machinery, I will stop immediately.

- Possible serious side effects of my opioid medicines include but are not limited to my not being alert, overdose and death. The risk is higher at higher doses or when they are taken with alcohol, other medicines such as sleeping medications, or various illegal drugs. I will not take these other medicines or drugs with my opioid medicine.

- Serious side effects can be higher when restarting the opioid medicine after being off it for more than a few days because my body gets used to a lower (or no) dose. Because of this risk of overdosing when restarting after a period of not taking, I will restart cautiously, at a lower dose.

- There is a prescription medicine called Narcan (also known as Naloxone) which can, in an emergency, reverse the effects of the opioid medicine at the beginning signs of an overdose. I can ask my care team for more information on this medicine. You can get Narcan from any pharmacy in Massachusetts without a prescription.

- Opioid medicines can sometimes cause addiction. Addiction can make me crave my opioid medicines for reasons other than what they were prescribed for. Some people have a higher risk for becoming addicted, even when opioid medicines are used properly. I will not use my opioid medicines for something other than prescribed, this includes but is not limited to, using them for anxiety, sleep, fear of pain, and to feel good. I will talk to my care team if I feel like I need to take them for any reasons not prescribed.

- People who take opioid medicines on a regular basis will develop physical dependence. I know that if I suddenly stop taking them, it is likely that I will feel physically sick. This is called withdrawal. Symptoms of withdrawal include feeling restless, irritable or sweaty. They also include diarrhea, bone and muscle aches, and difficulty sleeping.

- When it is time for me to stop taking opioids, or if you want to decrease the amount of opioid medication I am taking, I will work with my care team to create a plan on how to stop taking them safely so that I can minimize withdrawal symptoms.

- At any time while receiving opioids, I may be asked and will provide a urine sample or other sample for testing. This test is to make sure I am only taking opioid medicines prescribed to me and to monitor for use of other substances that may cause harm. My opioid care team will review my results with me. If there are unexpected findings or illegal drugs in my

sample, my care team may change my medicine plan, which may include discontinuing opioid medicines.

- When requested, I agree to come in for drug testing or pill/patch counts within the time designated by my care team.

- My opioid treatment will be kept confidential. However, my care team has permission to discuss all tests and treatment details with pharmacists and other health care professionals who are part of my care team.

- To the extent possible, I will have my opioid prescriptions filled at **only one** pharmacy.

- When I take my opioid medicine prescription to the pharmacy, I am allowed by law to ask the pharmacist for a **partial fill.** This means I may request to be given a smaller amount of medicine than prescribed by my designated opioid care team. I understand that if I am given a partial fill, I can return to the same pharmacy **within 30 days** of the prescription issue date to obtain the remaining amount of that prescription. After 30 days I cannot obtain the rest of the prescription.

- I am responsible for protecting my opioid medicines from loss, theft or damage. I will keep them in a safe, secure place, away from children or pets. I will not expect to receive replacement prescriptions for any medicines that have been lost, stolen or damaged.

- If I am no longer taking an opioid medicine, I will follow instructions on the Massachusetts state website to **safely dispose** of it, or I will bring them to a prescription drop box. The website for drop box locations is: www.mass.gov/service-details/prescription-dropbox- locations.

- To receive the best treatment and to comply with the law, my designated opioid care team will review the **Massachusetts Prescription Awareness Tool (MassPAT)** with me. This database is maintained by the Massachusetts Department of Public Health and lists when and where I am filling my opioid medicines and who is prescribing opioid medicines for me. The database includes information both from Massachusetts and other states.

- I am responsible for keeping track of the amount of medicine that I have left. I will plan ahead for renewing my prescriptions to make sure I do not run out of my medicine. I will ask the office for refills on a set schedule decided by my care team. I will call to request refills only during regular business hours, when the office is open.

- I will accept generic brands of my opioid medicine or the brand that is accepted by my health insurance.

- Disrespectful or abusive behavior to staff members of this office may result in discharge from the practice.

- I will schedule and attend follow-up appointments with my care team as discussed in my care plan. These appointments are important for monitoring and my treatment.

- My care team will look for improvements in my condition. If there is no improvement in my condition, my care team may decide the opioid medicine is not working and stop or slowly lower my opioid medicine.

- This agreement is a part of my medical record. I understand that any violation of this agreement may result in me no longer being able to receive opioid medicines from this office or affiliated offices.

- I understand that it is important to review and renew this agreement with my care team at least once a year. If I am unable to come in to review it in person, I understand, and consent to it being mailed to me to allow me to re-sign it.

Signature

My signature below means that:

- I have read and understand the information on this form
- The information on this form has been explained to me by my care team
- All my questions have been answered
- I agree to all the information explained above
- I have been given a signed copy of this form

Patient Signature:_____ Date: _____

Care Team Member Signature:_____Date: _____

Appendix C: Partners Opioid Tapering Guidance

Partners Opioid Tapering Guidelines for Chronic Pain

Background

Although not supported by level 1 and 2 data, long-term (i.e., greater than 2 months) use of opioids has been associated with harm or no clear evidence of improved function or health related quality of life; thus, it is prudent to continuously reassess the need for opioid therapy. Reasons for discontinuation may include no significant functional improvements, intolerable side effects, medication diversion, or development of an opioid use disorder. Tapering opioids should ideally be a shared decision between patient and provider(s). Whereas voluntary opioid tapers have been associated with improved function, there is no evidence to support involuntary tapers of chronic opioid therapy. In the absence of an opioid use disorder or opioid misuse, social, emotional (e.g., patient fears of abandonment), and health factors must be considered. When the decision is made to taper down or off of opioids, an individualized tapering plan should be used. In general, tapering should occur gradually, though there may be cases in which a rapid taper or no taper is warranted.

Purpose/Scope

To assist prescribers in tapering chronic opioid therapy

Eligibility

Discontinuation of long-term opioid therapy should be considered in any of the following situations (concurrent referral to pain specialist is recommended):

- Inability to achieve or maintain significant pain relief or functional improvement despite reasonable dose escalation. This depends upon the clinical situation but would generally reflect dose escalations no greater than the range of 50 to 90 MME/day per CDC guidelines.
- Intolerable adverse effects at the minimum dose that produces effective analgesia despite adequate attempts to treat where possible
- Meaningful non-adherence with a Partners opioid patient agreement (Link to Partners Opioid Medication Management Agreements)
- Deterioration in physical, emotional or social functioning attributed to opioid therapy
- Resolution of the painful condition
- Patient desire to discontinue opioid therapy
- Development of an opioid use disorder (Note: discontinuation of opioids without proper treatment of opioid use disorder can exacerbate symptoms)
- Evidence of non-medical use of prescription opioids

Tapering plan

- **General tenants**
  - Speed of taper should be inversely correlated to duration of opioid treatment. Also consider dose, type of pain being treated and the physical and psychological attributes of the patient.
  - Taper plans should be individualized, and doses decreased as indicated (e.g., weekly, bi- weekly, monthly, etc.).
  - The time between dose changes may vary and slowing down the taper based on patient discomfort or symptoms of withdrawal may be warranted.

- Frequent follow-up during tapering period is recommended. Assessments should include those related to pain, withdrawal, suicidal thoughts, use of other substances, and mood changes.

- **Example**
  - Decrease original dose by 10% every 1 to 4 weeks
    - The longer the duration of opioid treatment, the longer the interval between dose changes

Pharmacologic adjuvants

- Withdrawal management strategies
  - Clinical Opioid Withdrawal Scale (COWS) may assist in assessment of withdrawal symptoms: (https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf)
  - Supportive agents for opioid withdrawal:
    - loperamide for diarrhea
    - ondansetron for nausea
    - dicyclomine for abdominal cramping
    - diphenhydramine for nasal congestion
    - methocarbamol for muscle cramps
    - melatonin, trazodone or mirtazapine for insomnia
    - clonidine for anxiety or hypertension
  - Use supportive agents in conjunction with psychological support where appropriate
- Non-opioid pharmacologic pain management therapies may be prescribed to facilitate a taper (e.g., ibuprofen or acetaminophen for pain), though may be associated with other risks (e.g., inadequate pain control) and adverse effects.
- If a patient has developed an opioid use disorder, patients may be initiated on buprenorphine/naloxone (Suboxone) by a buprenorphine waivered physician or referred directly to an addiction specialist and/or a methadone maintenance program (further information available on PCOI website: https://oi.mgh.harvard.edu/pcoi/frontpage_frames.asp). For transition to buprenorphine/naloxone (Suboxone), no tapering is necessary as long as the total daily opioid requirement is not greater than 200 mg oxycodone equivalents (in this case, a taper to 200 mg first may be warranted).
- If clear evidence of diversion is present, opioid prescribing should be ceased entirely without a taper.

Non-pharmacological interventions

- Cognitive behavioral therapy, other behavioral approaches, and group support, in isolation or part of interdisciplinary program, are highly recommended.
- Maximizing physical therapy and alternative pain management approaches may facilitate tapering.

References

1. Berna C, Kulich RJ, and Rathmell JP. Tapering long-term opioid therapy in chronic noncancer pain: evidence and recommendations for everyday practice. Mayo Clin Proc 2015;90(6):828-842.
2. CDC guideline for prescribing opioids for chronic pain — United States, 2016: Recommendations and Reports / March 18, 2016 / 65(1);1–49 Available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
3. Chou R, Turner JA, Devine DB, et al. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a National Institutes of Health Pathways to Prevention Workshop. Ann of Intern Med 2015; 162 (4): 276-86.
4. FDA Drug Safety Communications: Safety Announcement. FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering. April 9, 2019.
5. Matthias MS, Johnson NL, Shields CG, et al. I'm not going to pull the rug out from under you": patient-provider communication about opioid tapering. J Pain 2017; 18(11): 1365-1373.
6. Noble M, Treadwell JP, Tregear SJ, et al. Opioids for long-term treatment of non-cancer pain. Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD006605. DOI: 10.1002/14651858.CD006605.pub2
7. Pocket guide: tapering opioids for chronic pain. Guideline for prescribing opioids for chronic pain. Center for Drug Control and Prevention. Available at: www.cdc.gov/drugoverdose (accessed 8/6/18).
8. Stephen G, Paterniti DA, Feng B, et al. Patients' experience with opioid tapering: A conceptual model with recommendations for clinicians. J Pain 2018 Sep 20. pii: S1526-5900(18)30589-3. doi: 10.1016/j.jpain.2018.09.001
9. Sullivan MD, Turner JA, DiLodovico C, et al. Prescription opioid taper support for outpatients with chronic pain: a randomized controlled trial. J Pain 2017; 18(3):308-318.
10. Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). J Psychoactive Drugs, 35(2), 253–9.

Acknowledgements and Disclosures

This document was developed by the Partners Center for Drug Policy in collaboration with the clinical experts representing all relevant PHS hospitals. These Guidelines were developed by Partners for informational and educational purposes only. Any clinical decision for an individual patient must be made by a qualified, licensed, health care provider based on his or her own professional assessment and judgment of all the facts involving a particular patient. These Guidelines are not intended to be, and should not be used, to replace or as a substitute for, the professional judgment of the health care provider.

Reviewed by the Partners opioid expert panel: February 2019
Approved by Partners Opioid Steering Committee: April 2019
To be revised: April 2023

Appendix D: Safe Use, Storage, and Disposal of Prescription Opioid Medicines

Opioids (narcotics) are stronger pain medicines that work well to reduce severe pain for a short time, but can be dangerous if used improperly. Opioids can become addictive and may also have serious side effects. Prescription drug abuse is a serious public health issue. The information below will help keep you safe.

Safe Use

- Take medications only as prescribed.
  - Never take more than instructed.
  - Never take somebody else's medicine.
  - Never give or sell your medicine to someone else.
- Improper use of pain medicine is a leading cause of accidental death.
  - Combining opioids with alcohol or other drugs increases the risk of death.
  - Combining opioids with medicines used to calm anxiety can result in overdose.
- Using opioids for something other than pain (anxiety, sleep, fear of pain, to feel good) can create a harmful dependence/addiction.

Safe Storage

- Your medications are prescribed only for you.
- Hide or lock up opioid medications so that family members, friends and houseguests do not take them.
  - Pain medications are a leading cause of serious poisoning of children and pets when they are not stored properly.
- Keep prescription medications in their original packaging so it is clear for whom the medications were prescribed and to save the directions for appropriate use.

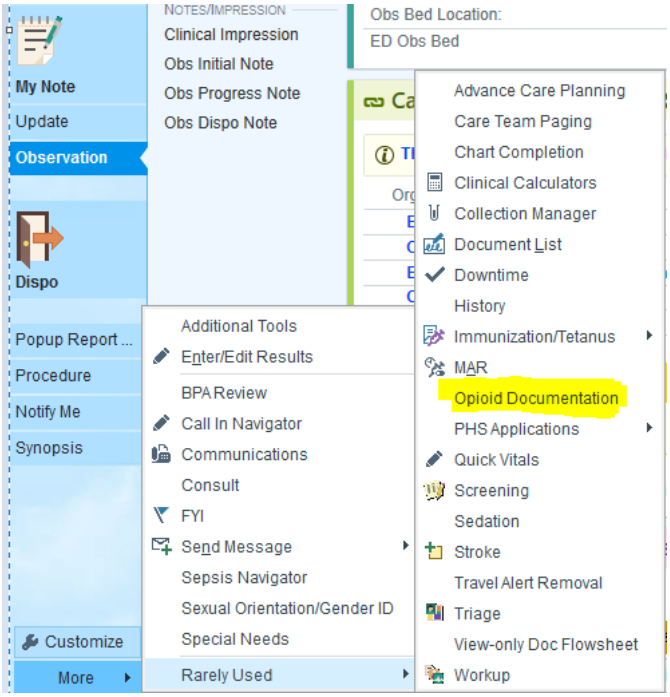
Safe Disposal

- Return unused opioids to a special medication disposal unit (a disposal unit is located in BWH Outpatient Pharmacy and most police stations and commercial pharmacies now have disposal or "take back" units).
  - Find a disposal site near you
- Do not flush medication down the toilet.
- If no medicine take-back program is available in your area, follow these simple steps to get rid of most medicines in the household trash:
  - Mix medicines (do NOT crush tablets or capsules) with kitty litter or used coffee grounds (children, pets or other people will be less likely to eat or take them);
  - Place the mixture in a sealed plastic bag or empty can; and
  - Throw the container in your household trash.
- Before throwing out your empty pill bottle or other empty medicine packaging, remember to scratch out all information on the label to make it unreadable.

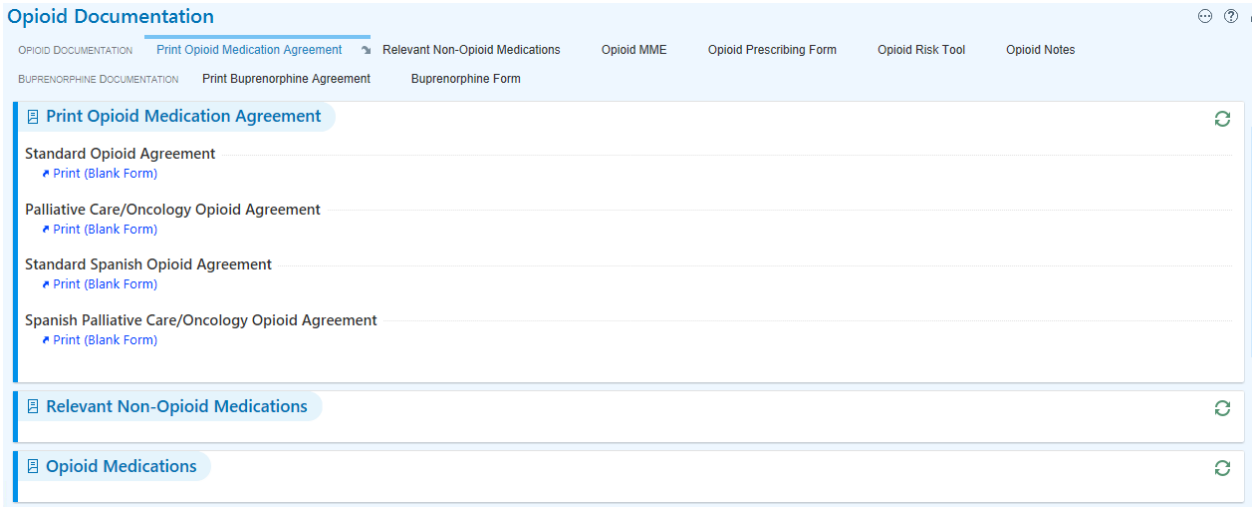
* See FDA website for medicines recommended for disposal by flushing.

Appendix E: Epic Opioid Documentation Workflow

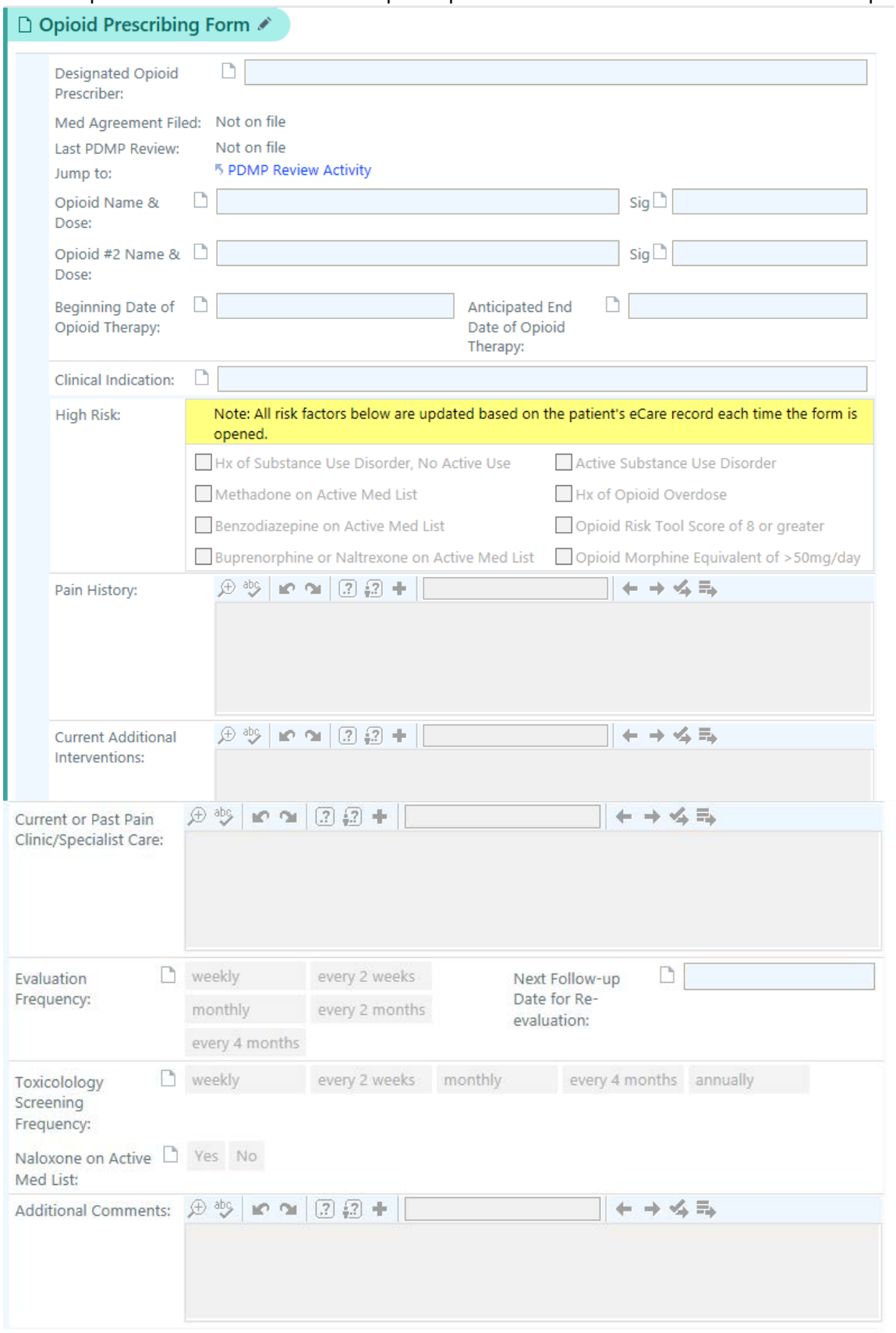
Located under "Rarely used, Opioid Documentation"



The first section contains the Opioid Medication Management Agreements

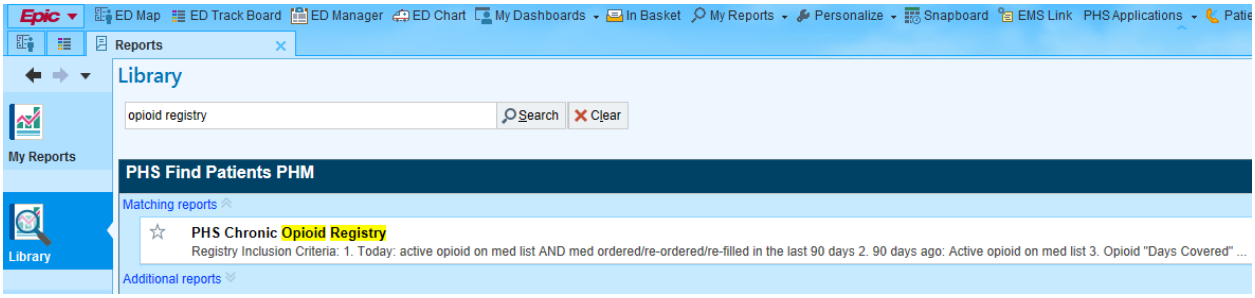


The next part of the form will create an opioid-specific note that also feeds into the chronic opioid registry (Appendix F)



Appendix F: Chronic Opioid Registry

Located under “My Reports” – search for “PHS Chronic Opioid Registry”



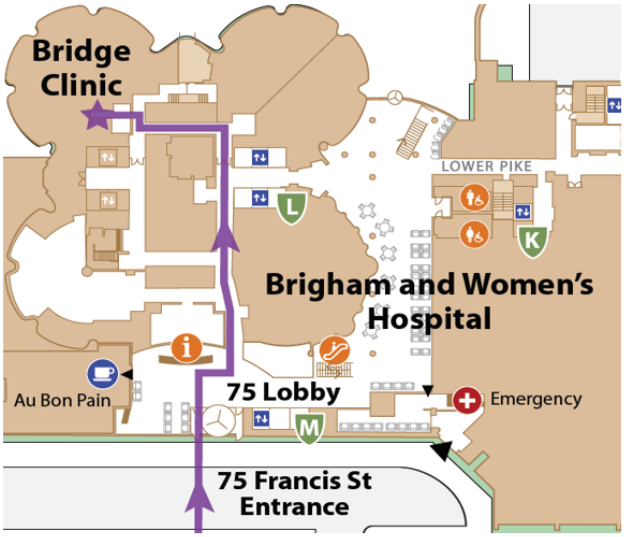
The output will list all your patients on chronic opioids as well as their safety indicators:

Opioid Agreem	Dt of Opioid Ag	Tox Screen Wit	ORT Score	Active Methadc	Active Bupreno	History of SUD	History of Over	Active SUD?	MME/day>50?	Dt of Last Mas	Enc in Primary	Next Enc in Pri	GFR	Dt of Last Opio
Yes	✓			No	No	No	No	No			12/09/2019		Unknown ideal weight.	02/20/2020
	!			No	No	No	No	No		4/17/2020 1:32 PM	04/17/2020		44	04/17/2020
Yes	!			No	No	No	No	No		4/14/2020 3:25 PM	02/11/2020		Unknown ideal weight.	05/14/2020
Yes	✓			No	No	No	No	No		6/17/2019 3:11 PM	11/18/2019	07/20/2020	No successful lab value found.	02/25/2020
Yes	!			No	No	No	No	No		3/3/2020 9:52 AM	04/07/2020		106	04/03/2020
	✓			Yes	No	No	No	No		8/27/2019 3:17 PM	03/23/2020		77	05/17/2020
				No	No	No	No	No		11/21/2019 3:23 PM	05/08/2020	10/14/2020	Unknown ideal weight.	05/08/2020
	✓			No	No	No	No	No		11/26/2019 3:57 PM	04/22/2020	05/20/2020	Unknown ideal weight.	04/22/2020
Yes	✓			No	No	No	No	No		4/29/2020 2:10 PM			Unknown ideal weight.	04/29/2020
Yes	✓			No	No	No	No	No		4/30/2020	02/03/2020	05/18/2020	31	04/30/2020

Appendix G: Bridge Clinic Referral Process

Follow-Up (next business day):
****Arrive between 9:00am – 11:30am****

Brigham Health Bridge Clinic
75 Francis Street, Tower 1st floor, Suite 159
Boston, MA 02115
Phone: 617-278-0172
Monday – Friday (8:30am – 5:00pm)



Referral in Epic: