

**Executive Summary: Use of Opioid Therapy for Chronic, Non-malignant Pain at Brigham and Women's Hospital**

**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 use' is the continuous use of an opioid medication as prescribed for greater than 90 days.

**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 'BWH Agreement and Informed Consent for Receiving Controlled Substances,' to be stored in the EMR.**
- **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.**
- Providers should consider prescribing intranasal naloxone (Narcan) rescue kits to patients if appropriate.

**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 ideally 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.

**Provider Monitoring:** Patients receiving opioids for chronic pain should have a **regular clinical reassessment of pain, functional goals, treatment plan, and adherence.**

- 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**  
**Date Updated: 3/25/2017**  
**Brigham Health**

## 1. Introduction: Overview and Intent

All members of the BWPO, Brigham and Women's Hospital, and Brigham and Women's Faulkner Hospital should review and adhere to the documented procedures below for the use of opioid medications in the treatment of chronic pain. It 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 the Massachusetts BORIM 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, have serious side effects, or exhibit 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. In particular, 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 BWPO 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 use' 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 BWH 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 \(ORT\)](#). 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 opiates for our moderate to highest risk patients (those with history of opioid overdose, active SUD 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 urine tox 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 B](#)].**
  - 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 MA Substance Use Legislation of March 2016, 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.
  - **In compliance with MA Substance Use Legislation of March 2016, MassPAT must be reviewed for all opioid prescriptions and for first time benzodiazepine prescriptions.**

## 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 'post date' 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 so as 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. Contact information about the sole pharmacy will be entered into the pain agreement and EMR.
- 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 when 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.** 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 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 not be mailed to patient unless pick up is unfeasible due to logistics.
- A patient or their designee must show a form of picture identification or have their identity directly confirmed by a practice member when picking up a prescription for an opioid pain medication from the office.
- Prescriptions to be picked up must be held in a secure and monitored location.
- **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 'BWH Agreement and Informed Consent for Receiving Controlled Substances'** [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 'BWH Agreement and Informed Consent for Receiving Controlled Substances' [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 C]
- 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.
- **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 'BWH Agreement and Informed Consent for Receiving Controlled Substances' [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]
- It is best practice to check the PMP yearly—or more frequently if deemed appropriate—and with any concerns for diversion or misuse. Effective October 15, 2016, review of the PMP is mandatory each time a CII or CIII narcotic prescription is issued.

#### 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 BWH Agreement and Informed Consent for Receiving Controlled

Substances. [[Appendix A, Section V](#)]

- If a clinician is discontinuing opioid medications and there is concern about opioid use disorder, s/he should provide the patient with contact information for addiction treatment programs and/or should outline or provide an appropriate tapering schedule. In the inpatient setting, the Psychiatry Consult/Liaison Service can be consulted for guidance. In the outpatient setting, use a psychiatry e-consult in Epic to connect with a primary care clinic's imbedded 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.

**g. Controlled Substance Agreements**

- **All patients prescribed opioids on a chronic basis (>90 days) to manage pain must review and sign the established 'BWH Agreement and Informed Consent for Receiving Controlled Substances'** [[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 opioid agonists/antagonists, 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. Analgnesia- 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 VPAIN panel screens for pain medications and VDAU panel for common drugs of abuse.

**New Orders**

**Toxicology screen, urine** ☆ ✕

**P** STAT, Once First occurrence Today at 0953

Qualitative screen for PCP, Barbiturates, THC, Amphetamines, Benzodiazepines, Opiates, and Cocaine. Drugs NOT tested include Oxycodone, Buprenorphine, Methadone, Meperidine, LSD, and Propoxyphene. Providers wishing to test for Oxycodone, Buprenorphine, or Methadone should order the Pain Management Profile in addition to or instead of the Drugs of Abuse (urine) test. In the Pain Management Profile testing is performed for Buprenorphine, Oxycodone, Methadone, and 6-Monoacetyl morphine. Please note that the Pain Management Profile is not a stat test; testing is performed daily, M-F. Contact the laboratory for other information at 6-3636.

- 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?
<b>Amphetamines</b>  DRI	1000 ng/mL	d-methamphetamine (calibrator)  d-amphetamine MDA MDMA	<i>l</i> -methamphetamine  <i>l</i> -amphetamine phentermine pseudoephedrine phenylpropanolamine ephedrine	9% false positive rate either pseudoephedrine or unknown	Yes  Cutoff 50 ng/mL
<b>Barbiturates</b> DRI	200 ng/mL	Amobarbital Aprobarbital Butobarbital Butalbital Pentobarbital* (500 ng/mL) Phenobarbital* (600 ng/mL)	Barbital (1500 ng/mL)	no data on % false positive rarely confirmed	No, but can be done by request. Cutoff 100 ng/mL

		Secobarbital (calibrator)			
*Pentobarbital and Phenobarbital may be missed due to lower cross-reactivity in the assay.					
<b>Buprenorphine*</b>  LinZhi	5 ng/mL	Buprenorphine Norbuprenorphine (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
<b>Cocaine</b>  DRI	150 ng/mL	Benzoylcegonine	Cocaine  Ecgonine Cocaethylene Ecgonine methyl ester	0% false positive Never seen a false positive with this assay	Yes  Cutoff 50 ng/mL
<b>Fentanyl</b>  Immunalysis	2 ng/mL	Fentanyl  Despropionylfentanyl  Acetylfentanyl Butyrylfentanyl	Norfentanyl  Opiates  Trazadone	12% false positive rate labetalol metabolite likely responsible, others unknown	Yes Fentanyl - 0.2 ng/mL Norfentanyl - 1 ng/mL
<b>Heroin Metabolite*</b>  LinZhi	10 ng/mL	6-AM  Heroin	Opiates	0% false positive, but we get very few positive screens	Yes  5 ng/mL
<b>Methadone</b>  DRI	300 ng/mL	Methadone Methadol	EDDP (methadone metab)	Tapentadol? Propafenone?	If discrepant with metabolite 10 ng/mL
<b>Methadone Metabolite</b>  CEDIA	100 ng/mL	EDDP	Methadone EMDP (secondary metabolite)	Unknown, rarely confirmed	If discrepant with methadone  10 ng/mL
<b>THC</b>  DRI	50 ng/mL	$\Delta$ 9-carboxy-THC  THC metabolites		1% False positive rate due to Cannabinol. Marinol Niflumic acid?	Yes  3 ng/mL
<b>Tramadol</b>  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<sup>®</sup>, 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:*

[Review of Overdose Facts for Families](#)

[Simulation of an Overdose](#)

[When Overdose Happens, What to do](#)

[When Overdose Happens, Call 911 Risk](#)

[Factors for Opioid Overdose Preventing](#)

[Overdose, Nasal Narcan How to Assemble](#)

[Nasal Narcan](#)

### IX. References and Resources:

- [Managing pain without overusing opioids](#)
- 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](#)
- [ABCD-PQRS](#)
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### XI. Non-opioid Pharmacologic Options for Pain Treatment:

- Please see [Alosa Guideline](#), pages 4-12 and 22-23

**Table 6: Potential therapeutic interventions for selected pain conditions**

Condition	Intervention
Neuropathies (e.g., diabetic, post-herpetic)	Antidepressants (TCAs, SNRIs) Anticonvulsants Percutaneous electrical nerve stimulation
Osteoarthritis	Exercise/strength training <sup>117,118</sup> Weight loss (combined with exercise) <sup>119</sup> Tai Chi <sup>120</sup> Electromagnetic stimulation <sup>121</sup> Braces and insoles <sup>122</sup>
Fibromyalgia	Cognitive behavioral therapy <sup>123</sup> Exercise/strength training <sup>124</sup> Tai Chi <sup>125</sup>
Low back pain	Yoga <sup>115</sup> Exercise/strength training <sup>126</sup> Spinal manipulation <sup>127</sup> Massage <sup>127</sup> Cognitive behavioral therapy <sup>128</sup>
Trigeminal neuralgia	Anticonvulsants <sup>129</sup>
Rheumatoid arthritis	Disease-modifying antirheumatic medication <sup>130</sup>
Polymyalgia rheumatica	Corticosteroid medications <sup>131</sup>
Migraine	Abortive and prophylactic therapies (e.g., triptans) <sup>3</sup>

Source: *Managing pain without overusing opioids* (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.
- [Alosa Guideline](#) (pgs. 16-17)

XIII. Addiction Treatment Resources:

- [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 BWH Agreement and Informed Consent for Receiving Controlled Substances

I realize that my prescribing clinician has decided to try to relieve my pain partly with the use of opioid analgesics (pain medicines). These medicines have risks and benefits which have been explained to me by my prescribing clinician, and I understand that these medicines are only one part of my whole pain treatment plan. I have been informed and understand the policies regarding the use of controlled substances that are followed by my provider and his/her staff.

In order to provide the best possible care for my pain treatment, there needs to be a plan that allows for these medicines to be provided safely. As such, I understand and agree to the following:

My pain medications are being prescribed for the following condition: \_\_\_\_\_

The goal(s) of my treatment is: \_\_\_\_\_

1. I accept that these pain medicines are only one part of my treatment plan. I agree to follow the plans of care as discussed with my prescribing clinician. I will use the pain medications only as directed by my provider.
2. I will receive pain medicines from only my BWH prescribing provider (or coverage), and from no one else.
3. If I do receive pain medicines from anyone else (such as after surgery, or from an emergency visit for a broken bone, etc.), I will let my prescribing clinician know about this in person, in writing or by phone, **within three days**.
4. I recognize that my chronic pain represents a complex problem, which may benefit from physical therapy, psychotherapy, consult to a Pain Management Clinic and behavioral medicine strategies. I also recognize that my active participation in the management of my pain is extremely important. I agree to actively participate in all aspects of the Pain Management Program to maximize functioning and improve coping with my condition.
5. I understand that pain medications will be used only as directed for my pain. I WILL NOT:
  - a) Increase the dose without talking to my prescribing clinician (which could lead to overdose and death)
  - b) Suddenly stop taking these medications
  - c) Use them for **anything** other than for treating my pain
  - d) Share, sell or trade them with others (including family members)
  - e) Change my prescription in any way
6. I understand that pain medications may have side effects including drowsiness or difficulty with concentration. Alcohol, illegal drugs, and many medications (prescribed and over the counter) may also interact with this medication and could result in impairment, overdose or death.
7. If I have any doubt that I am not **completely** alert, I will not drive any type of vehicle or operate any type of machinery. Doing so would create a danger to myself or to others. If while driving a vehicle or operating equipment, I realize that I am not completely alert, I will immediately stop.
8. I know that other possible side effects of my pain medications include: nausea, vomiting, constipation, urinary problems, impaired sexual function, sleep apnea or itching. I will tell my prescribing clinician if I develop these or other side effects.

9. I understand that there is a risk of psychological and/or physical dependence and addiction when taking controlled substances. If my prescribing clinician is concerned that I have become dependent or addicted, I will be referred to an addiction specialist or drug treatment program.
10. I know that possible serious side effects of my pain medications also include overdose and death. This risk is higher at higher doses or when mixed with other medications, alcohol, or street drugs. It is also higher when restarting after being off the pain medicine for more than a few days. There is a prescription medication called Narcan®/Naloxone which may reverse this effect at the beginning signs of an overdose. I can ask for additional information about this medicine from my prescribing clinician.
11. I agree to random drug testing “tox screens” if and when my prescribing clinician feels it is appropriate. There may be a cost involved depending on insurance. I agree to random pill/patch counts as requested by my prescribing clinician. I must report for the testing or counts within the time requested by my prescribing clinician. I know that evidence of non-prescribed substances in my system may result in my prescribing clinician no longer prescribing my medication.
12. If I violate any of the above conditions and the violation involves obtaining controlled substances, or any prescription, for my pain condition from another individual or, if I engage in any illegal activity such as altering a prescription, I understand that the incident may be reported by my PCP. As deemed appropriate for the violation, my PCP may report my violations to other physicians caring for me, local medical facilities, pharmacies, local police departments, and/or Drug Enforcement Agencies.
13. I give this office permission to discuss all tests and treatment details with pharmacists and other health care professionals who participate in my health care. I permit my provider to review all sources of medical information for an accurate medication history, including the Massachusetts Prescription Awareness Tool (Mass PAT).
14. I will have my opioid prescriptions filled at only one pharmacy:  
  
PHARMACY NAME: \_\_\_\_\_  
LOCATION: \_\_\_\_\_
15. I know that it is my responsibility to protect my prescriptions from loss, theft or damage. I should keep them in a safe, secure place, away from children or pets. I will not expect to receive replacement prescriptions for any medications that have been lost or stolen.
16. I am responsible for keeping track of the amount of medication that I have left. I will plan ahead for the renewal of my prescriptions in a timely manner so that I will not run out of medications. I will ask the office for renewal on a set schedule as requested by my prescribing clinician.
17. I will accept generic brands of my prescription medication except as required by my insurance carrier.
18. I am responsible for keeping track of the amount of medication that I have left and to plan ahead for arranging the refill of my prescriptions in a timely manner so I will not run out of medications. I will call to request renewals only during regular business hours when the office is open.
19. I understand that unnecessary repeated phone calls or disrespectful behavior to staff members of this office may result in discharge from the practice.

20. I agree to schedule and keep follow-up appointments with my prescribing clinician at regular intervals and as frequently as he or she sees fit. The purpose of these appointments is in part to monitor my pain and its treatment. I will need to be seen at least every four months for these follow-up appointments. I understand that failure to keep appointments may lead to discontinuation of treatment.

**21. If it appears to my prescribing clinician that there is no improvement in my daily function or quality of life from the controlled substance, I may be referred for additional pain consultation and/or my medication may be stopped or gradually decreased as prescribed by my prescribing clinician.**

I know that 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 controlled substances from this office or affiliated offices.

Patient's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Prescribing Clinician Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**If you choose not to use the treatment agreement above, we recommend that the treatment agreement includes the items below and that it is reviewed by risk management.**

**Items to be included in all treatment agreements:**

1. Informed consent
2. Patient must agree to ongoing risk assessment efforts, including a PMP search, random urine tox and pill counts at any time, psychological screening questions and any requested documentation covering compliance with all treatment recommendations.
3. Compliance with prescribed dosing, and if symptoms become worse, communication is required with the prescriber
4. One prescriber only, unless approved by the prescriber and or covering physician, for emergencies, prescriber must be notified as soon as possible
5. Office visit required for all significant changes in therapy.
6. One pharmacy only which should be listed as preferred in eCare.

## Appendix C

### Safe Use, Storage, and Disposal of Prescription Opioid (Narcotic) 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 now have disposal or "take back" units).
  - [Find a disposal site near you](#)
- If no medicine take-back program is available in your area, you can flush some medications down the toilet\* or 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.