U.S. Attorney's Maine Addiction Task Force

Treatment and Recovery Arm

Subcommittee on Prescribing Standards for Chronic Non-Cancer Pain

March 31, 2016

Preamble: Given the known risks and significant potential harms of opioid medications, as well as the current epidemic of opioid use in the state, it is imperative that Maine physicians and other prescribing clinicians implement explicit and consistent standards of care related to the use of opioids for chronic non-cancer pain. Responsible opioid prescribing should incorporate best available evidence, safety considerations for both the patient and of the community being served, recognition of the critical intersection of chronic opioid use with addiction, and to the extent possible, a team-based approach to care.

At the same time, prescribers must recognize the need for sustained compassionate engagement so that difficult conversations, communication of necessary adjustments in treatment plans, and the identification and treatment of addiction are undertaken with compassion and in the same therapeutic context as other chronic diseases. Maintaining a therapeutic relationship throughout the spectrum of caring for these individuals is imperative, and discharging patients when they manifest behaviors related to a diagnosis of Substance Use Disorder* is not consistent with our roles as caregivers.

The components of responsible chronic opioid prescribing for chronic pain should include standards for practice policy, standards for managing chronic pain patients and standards for addressing non-reassuring behaviors.

Standard Practice Policy for Prescribing of Opioid Medications for Chronic Non-Cancer Pain:

1. Clear definition of when chronic opioid prescribing is occurring (e.g. a continuous prescription lasting more than 6 weeks)

2. Clinical standard for maintaining lowest effective daily opioid dose, and establishing ceiling dose in order to mitigate the risk of overdose and mortality related to opioid medication. We recommend a benchmark of 80% of a patient panel maintained below 50 morphine equivalent daily dose (MED) and 100% maintained below 100 MED, with clear documentation for rationale for exceptions and review of exceptions by peer group or supervisors.

    a. Mortality odds ratio 1.92 for doses 50 to 99 MED 2.04 for doses 100-199, and 2.88 for doses 200 MED or higher http://www.ncbi.nlm.nih.gov/pubmed/21482846

    b. Overdose risk increased 3.7 fold for 50 to 99 MED and 8.9 fold for 100 MED or higher. http://rsds.org/wp-content/uploads/2015/02/DunnKM_AnnInternMed_2010.pdf

3. Requirement for patient visits for re-evaluation every 3 months for any patient receiving chronic opioids

4. Standard that prescriptions not exceed 28 day supplies; for shorter duration prescriptions, prescriptions should be written in multiples of 7 days, or in amounts that result in refills being due on weekdays when taken as prescribed

5. Explicit definitions for what the practice will consider to be a failure of pill counts and of urine drug screens

6. Adoption and expectations for practice-wide and consistent use of Patient Provider Agreement and Patient Informed Consent (which includes particular risks of high dose opioids) for all patients receiving opioid prescriptions

7. Definition of consequences for patient violations of the Patient Provider Agreement, including arrests for possession charges, intent to distribute and arrests for other relevant charges (theft, DUI, assault, etc.)

8. Specific outline of practice policies and processes to meet compliance with Maine Board of Licensure Chapter 21 rules for the Use Of Controlled Substances For Treatment Of Pain, including random pill counts and random urine drug screens

9. Identification of staff roles that promote a team-based approach to care that includes expanded roles of staff (e.g. nurses, medical assistants, social workers, substance abuse counselors) to enhance clinical work flows needed to support requirements of chronic opioid prescribing (e.g. checking PMP, conducting random urine drug screens and pill counts, etc.)

10. Identification of practice-based prescriber peer group to review requests for exceptions to any of these policies, with clear documentation of requests and responses

11. Regular review of PMP profiles for prescribers in the practice by practice peer group or supervisors

12. Explicit policy on concomitant use of marijuana (allowed or not, medical and/or illicit)

Standards for Managing Chronic Non-Cancer Pain Patients:

1. **Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.**
    a. Assess whether safer and more effective, evidence-based treatments have been used (e.g. CBT, PT, OMT, chiropractic care, non-opioid medications, lifestyle changes, Tai Chi, Physiatry, Integrative Medicine), and consider repeating alternative treatments if significant time has elapsed since last use
2. **Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.**
    a. Identify and document the specific pain related diagnosis which will be treated
    b. Carry out a functional assessment using a validated tool (e.g. Pain Assessment and Documentation Tool, Centrality of Pain Scale Instrument)
    c. Rule out conditions for which opioids are known not to be helpful
        i. Fibromyalgia
        ii. Chronic low back pain
        iii. Chronic Regional Pain Syndrome
        iv. Headaches
        v. Screen all patients for risk of Substance Use Disorder (SUD) using a validated tool (e.g. DAST, AUDIT, CRAFFT, STAR)

vi. Complete Opioid Risk Tool (ORT) and/or Screener and Opioid Assessment for Patients With Pain(SOAPP)

3. **Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.**
    a. Use a Patient Provider Agreement and review and renew annually
    b. Use an informed consent as described in the section on practice policy and review and renew annually
4. **When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.**
    a. Once on a stable dose, the extended release preparations are more abuse resistant and are preferred
5. **When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME) per day, and should avoid increasing dosage to ≥90 MME per day or carefully justify a decision to titrate dosage to ≥90 MME per day.**
    a. See benchmarks in in the section on practice policy
    b. See process for exceptions in the section on practice policy
6. **Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.**
7. **Clinicians should evaluate benefits and harms with patients within 1–4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.**
    a. In these instances efficient and compassionate tapering should be the goal and can be achieved through the use of a tapering calculator
    b. Document functional assessment and justification for ongoing opioid treatment at every visit
8. **Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use are present.**
    a. Complete Opioid Risk Tool (ORT) and/or Screener and Opioid Assessment for Patients With Pain(SOAPP)
9. **Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain**

and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.
    a. Review Diversion Alert Database monthly
10. **When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.**
    a. Conduct random pill counts at least annually
    b. Adhere to practice policy on consequences of failed pill count or uds
11. **Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.**
    a. Avoid using opioids in people with Alcohol Use Disorder or at risk use of alcohol
12. **Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid-use disorder.**
    a. Screen regularly (at least annually) for Opioid Use Disorder

Standards for Addressing Non-Reassuring Behaviors*:

1. Reevaluate for addiction and, if identified, maintain therapeutic relationship and make efforts to keep patient engaged; initiate or refer for appropriate treatment
2. If addiction is not diagnosed:
    a. Increase frequency of pill counts, urine drug screens (assuming no violations of Patient-Provider Agreement have occurred)
    b. Consider changing treatment plan and tapering off opioids

*Non-reassuring behaviors include:

- Requests for early refills
- Refusal to submit to a pill count
- Refusal to submit to a Urine Drug Screen (UDS)
- Inability (more than twice in a year) to reach a patient to schedule a pill count or UDS
- Reports of lost or stolen drugs
- Reports of diversion or abuse
- Failure to keep scheduled appointments with prescriber or those to whom the patient is referred

Attachments:

- Chronic Pain and Controlled Medication Playbook

- Opioid Prescribing Best Practices
  (Established by the Opioid Prescribing Best Practice Task Force, a collaborative effort of Mid Coast Hospital, Martin's Point Health Care, Parkview Hospital, Bath Iron Works, Addiction Resource Center, Maine Rehabilitation Associates and Mid Coast Hospital Emergency Department)

- Bangor Area Controlled Substance Workgroup (BACSW) – Controlled Substance Clinical Documents Resources:
    1. BACSW Controlled Substance Practice Standards
    2. BACSW Patient Provider Agreement for Controlled Drug Prescription
    3. BACSW Informed Consent for Opioids for Chronic Pain
    4. BACSW Informed Consent for Stimulants for Adult Attention Deficit Disorders
    5. BACSW Adult ADD Guidelines
    6. BACSW Informed Consent for Benzodiazepines for Anxiety Disorders
    7. BACSW Community Guidelines of Chronic Care for Anxiety Disorders in Primary Care

- DSM V criteria for the diagnosis of Substance Use Disorder

- CDC Guideline for Prescribing Opioids for Chronic Pain