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Opioid Prescribing: Long-Term Opioid Therapy Report and Recommendations

Opioid Prescribing: Long-Term Opioid Therapy Updated: February 14, 2020

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This supplement was developed by the Dr. Robert Bree Collaborative (Bree Collaborative) and the Washington Agency Medical Directors' Group (AMDG) in collaboration with an advisory group of the state's academic pain leaders, pain experts, providers in primary care and specialty areas, addiction medicine experts, and patients. The supplement updates the evidence and aligns best practice recommendations with those from the 2015 AMDG Interagency Guideline on Prescribing Opioids for Pain, guidelines from the HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, the 2019 Bree Collaborative Care for Chronic Pain Report and Recommendations, and the Washington State Administrative Code (WAC) pain rules. Recommendations are based on current best available clinical and scientific evidence from the literature and a consensus of expert opinion and are intended for use in addition to, rather than a replacement of, the guidelines for treating patients on chronic opioid therapy in the 2015 AMDG guidelines.

Recommendations are intended for providers managing adult patients (>18 years old) with chronic pain who are receiving long-term opioid therapy. Following the Washington Administrative Code (WAC), these guidelines do not apply to (1) treatment of patients with cancer-related pain; (2) provision of palliative, hospice, or other end-of-life care; (3) treatment of inpatient hospital patients who have been admitted for more than twenty-four hours; or (4) provision of procedural medications. See **WAC 246-817-905, 246-840-463, 246-853-661, 246-919-852 or 246-922-661** for further definitions.

Providers managing patients on long-term opioid therapy should start with patient engagement followed by thorough assessment and careful deliberation regarding an appropriate treatment pathway. Management should be individualized and should focus, in addition to reducing the intensity of pain, on goals of improving function and quality of life, and optimizing patient independence, while avoiding serious adverse outcomes. Recommendations are organized into:

- Establishing a relationship: patient engagement
- Assessment
- Treatment including selecting a treatment pathway
 - Maintain and monitor
 - Tapering or discontinuation
 - Transition to medications for opioid use disorder (MOUD)
- Recommendations for Health Plans and Health Delivery Systems

Guiding principles for systematically addressing, to the extent possible, every patient on long-term opioid therapy should follow those laid out by the National Pain Strategy and be:

- Patient-centered, accounting for individual preferences, risks, and social contexts
- Comprehensive, meeting biopsychosocial needs
- Multimodal and integrated, using evidence-based treatments

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Establishing a Relationship: Patient Engagement

The development of a trusting relationship and honest communication between a provider and patient is foundational to the successful management of chronic pain, particularly when a change in the treatment plan might be indicated.¹ Taking the time to understand the role chronic pain plays in a person's life and impact on work, relationships, and social activities is an important part of successful patient engagement and the development of a trusting relationship. As each person's circumstance and pain experience is unique, chronic pain management should always be individualized.^{2,3}

- **Discuss goals of care**. (e.g., "what are your expectations?", "what do you hope to accomplish?", "what meaningful parts of your life are you currently missing out on?"). Work to understand the social and emotional dynamics that may impact chronic pain management. Goals are about things patients want to do (e.g., walk around the block). Having a goal discussion helps you get to know the patient as a person, demonstrates you care about their individual experience, and provides a basis for future conversations.
 - Clarify "bigger picture" or life goals and short-term goals driven by longer-term goals. Short-term goals should be specific, measurable, achievable, relevant and time-bound (SMART).⁵ This framework can be helpful for reframing conversations and promoting behavior change. Information on setting SMART goals can be found here.
- **Set expectations**. Assure the patient that your **goal is to keep them safe while maximizing function**. 6,7,8 The first visit should be used to develop rapport and begin a thorough assessment.
 - Talk about realistic expectations around pain (e.g., that becoming pain free is unlikely).
 - Make sure the patient knows who to contact with questions or concerns.
 - Assure the patient that you will act as a partner with them and support continuity of their care, unless patient- or provider-specific factors prohibit effective partnership.
- Gain an understanding of the patient's knowledge about pain and their current medication(s), educate on knowledge gaps. Discuss current medication purpose, how medications work, and potential side effects. 910 Talk about chronic pain treatment approaches outside of chronic opioid therapy. Discuss any fear or concern around pain, abandonment, stigma, and safety. Understand that fear of pain may be more meaningful to a patient than risk of overdose. 11
 - Use the teach-back method to ensure that a patient understands complicated or new information.¹² Information from the Agency for Healthcare Research and Quality on the teach-back method is here.
- Engage and educate significant others, where appropriate. Ask if the patient's spouse, parents, children or others could be included in the discussion of any treatment plan. Social support has been shown to be a facilitator to effective chronic pain management. Understand concerns from family and others. See Appendix C: Questions for Family Members.
- **Respect.** Treat patients with respect and address and validate concerns in a non-judgmental manner.
- Consistency. Use consistent messaging from all team members and in all visits.
- Cultural competency. Assure that interactions with patients are culturally humble.¹³

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Assessment

Assessment of patients on long-term opioid therapy will likely require a structured and a staged approach over several visits. Brief screening instruments can inform the assessment but should not replace clinical observation and judgment. The following elements should be part of the assessment:

- Patient history. Complete a detailed, appropriate medical history including conditions and associated treatment from personal interview as well as by reviewing medical records. Note the pain-related diagnosis, including documentation of indications for the use of pain medication. History should include:
 - o The nature and intensity of the pain.
 - Location of pain(s). This can be documented using a pictorial representation of the body.
 Fill in all the parts of the body affected by chronic pain.
 - o Review the nature and intensity of opioid withdrawal symptoms, if experienced.
 - o The effect of pain on physical and psychosocial function.
 - o Current and relevant past treatments for pain, including opioids and other medications and their efficacy; and
 - Document history of long-term opioid use from the first prescription, as accurately as possible. Include dosage and changes in dosage over time.
 - Document pain-related interventions, including spine and extremity surgery, injections, any integrative health interventions and impact on pain and function.
 - Review and document the current treatment agreement if one is in place.
 - Document all medications including those prescribed and over the counter.
 - Assess opioid-related adverse outcomes and significant side effects. See Appendix D:
 Medical Risks of Long-Term Opioid Use.
 - o Review any pertinent diagnostic, therapeutic, and laboratory results
 - Review any pertinent consultations
- Observation and reporting of the patient's affect and behavior. Interviewing a family member
 or caregiver may reveal problems or benefits otherwise missed. Documenting this type of
 information may be important in accurately assessing the patient's physical and psychosocial
 functioning on opioids and successfully implementing treatment pathways (See Treatment on
 page 7).
- Physical exam. Perform an appropriate physical exam, including a detailed examination of all
 pain-related regions; for patients with neuropathic pain of any kind, document a detailed
 neurological examination.
- Pain and functional status. Use a validated tool such as the PEG (Pain intensity, interference
 with Enjoyment of life, and interference with General activity) scale. To the extent possible,
 from medical records and from patient self-report, estimate functional improvement in
 response to opioids.
- Prescription Monitoring Program (PMP). Review the PMP to identify any controlled substances received by the patient in accordance with the provisions of WAC 246-817-980, 246-840-4990, 246-853-790, 246-919-985 or 246-922-790. Document all findings relevant to controlled substance use, including concomitant opioid and sedative, multiple opioid prescribers, and early refills.

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- Urine drug test (UDT). Administer urine drug screening. Unexpected results require discussion
 with the patient and if necessary, confirmation testing. For further guidance on UDT, see
 Appendix D in the 2015 AMDG Opioid Guideline.
- Review comorbidities with particular attention to psychiatric and substance use disorders.
 Obtain a complete history of alcohol and other substance use. Follow the 2017 Bree
 Collaborative Behavioral Health Integration Report and Recommendations, 2018 Bree
 Collaborative Suicide Care Report and Recommendations, and 2015 Bree Collaborative
 Addiction and Dependence Treatment Report and Recommendations. Use validated
 instrument(s) to screen for co-occurring conditions that can influence the experience and
 intensity of chronic pain (See Appendix E: Validated Tools for Screening and Assessment):
 - o **Depression** (e.g., Patient Health Questionnaire-2, PHQ-3 and/or PHQ-9)
 - o Anxiety (e.g., Generalized Anxiety Disorder-2)
 - Suicidality (e.g. ninth question of the PHQ-9, first and second questions of the Columbia Suicide Severity Rating Scale (C-SSRS), the Ask Suicide-Screening Questions (ASQ) as well as current plans and any past attempts).
 - o **Post-traumatic stress disorder** (e.g. PTSD Checklist)
 - Adverse childhood experiences. More information <u>here</u>.
 - o Alcohol misuse (e.g., Alcohol Use Disorders Identification Test or AUDIT-C)
 - Substance use (e.g., single-item screener, Alcohol, Smoking, and Substance Involvement Screening Test or ASSIST, Drug Abuse Screening Test or DAST-10, single item cannabis and other drug use questions).
- Use a validated tool to determine the patient's level of risk for opioid or other substance use disorders as high-, moderate-, or low-risk category or use a two-tier tool. See Appendix E: Validated Tools for Screening and Assessment
- **Evaluate for opioid use disorder.** If there are indications of opioid misuse, or concomitant illicit opioid use, evaluate the patient for the presence of an opioid use disorder.
 - o See **Appendix F: DSM-5 criteria** for diagnosis of Opioid Use Disorder.
 - Tolerance and withdrawal are expected physiologic phenomena associated with chronic opioid use. The physical symptoms of withdrawal occur with the cessation of opioids prescribed for chronic use in individuals in pain and in persons who have an opioid use disorder. Their presence alone does not define the presence of an opioid use disorder or addiction.
- Health record. This information may be used to supplement the assessment but not replace the
 provider's decision making regarding the treatment pathway. Risk of opioid overdose and
 problematic opioid use increases with the number of factors present as follows:
 - Long-term opioid therapy daily dose >50 MED
 - Use of extended release/long acting opioids
 - Any use of sedatives/benzodiazepines
 - Opioid use disorder diagnosis
 - Alcohol, tobacco, or non-opioid drug use disorder diagnosis
 - Other behavioral health disorder diagnosis such as major depression, anxiety disorder,
 PTSD or bipolar disorder

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Treatment

Develop a Treatment Plan

Treatment plans should be developed in collaboration with the patient, and family or others if appropriate. See **Appendix G** for a flow chart showing treatment options after assessment. Determine together whether to continue opioids, reduce opioid dose at a rate consistent with patient's clinical and social situation, or transition to medications for opioid use disorder. Patients may want to stop chronic opioid therapy due to a variety of reasons, including lack of efficacy, side effects, impact on quality of life, and concerns about addiction. ¹⁴ In determining a treatment pathway, clinicians and patients may have divergent priorities. While providers may be most concerned about overdose or addiction, many patients may consider that they personally have low risk of serious adverse outcomes. Patients are more likely to fear pain, suffering, and loss of control than a serious adverse event. However, patients also are likely to have priorities for effective pain treatment beyond simple pain relief, including wanting better emotional wellbeing, improved physical activity, better sleep, and greater social participation.

One method for achieving consensus is the use of motivational interviewing. This approach involves "expressing empathy and avoiding arguing, developing discrepancy, rolling with resistance, and supporting self-efficacy (client's belief s/he can successfully make a change)." The goal of motivational interviewing is understanding the patient's motivations and barriers to change in order to change a behavior such as with smoking cessation.

Exercise professional judgment in selecting appropriate treatment modalities for acute nonoperative, acute perioperative, subacute, or chronic pain including the use of multimodal pharmacologic and nonpharmacologic therapy as an alternative to opioids whenever reasonable, clinically appropriate, evidence-based alternatives exist as outlined in WAC 246-817-908, 246-840-4653, 246-853-680, 246-919-910 or 246-922-680. Ideally, chronic pain should be managed through a collaborative care model as described in the 2019 Bree Collaborative Care for Chronic Pain Report and Recommendations. Rather than a primary focus on pain relief, these guidelines focus on the use of a care team to achieve goals of improved function, increased quality of life, and greater patient autonomy. However, this system-supported approach is not available in all areas and should not preclude high-quality chronic pain management and the following of these recommendations.

Develop a treatment plan in collaboration with the patient:

- Counsel patients, including discussion of opioid-related risks and safe storage and disposal. See
 WAC 246-817-907, 246-840-4651, 246-853-675, 246-919-865 or 246-922-675.
- Document any medication prescribed, biologic specimen testing ordered, any labs, diagnostic evaluations, referrals, or imaging ordered, and other planned treatments.
- Involve behavioral health providers, where possible.² Pain alone does not cause depression, anxiety, or substance use disorder, although it can exacerbate these conditions. These diagnoses should be treated as needed. In addition, patients may experience anxiety or fear associated with changes in treatment approach.
- **Use non-opioid pharmacological pain management**. This can include acetaminophen, non-steroidal anti-inflammatory drugs, topicals (e.g., capsaicin, lidocaine, diclofenac), anticonvulsants, serotonin/norepinephrine reuptake inhibitors, and others as indicated.
- Use non-pharmacological pain management, as available. Identify, support and enhance what patients are already doing to manage chronic pain with life activity impacts. Discuss:

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- o Cognitive-behavioral therapy
- Mindfulness
- o Exercise and body awareness strategies (e.g., yoga, tai chi, qigong)
- Manual therapies (e.g., massage, spinal manipulation)
- o Acupuncture
- o Reactivation methods (e.g., physical therapy, activity coaching)
- Multidisciplinary rehabilitation
- Sleep hygiene
- Use a treatment agreement that includes all the necessary and agreed-upon requirements. See
 WAC 246-817-930, 246-840-475, 246-853-725, 246-919-915 or 244-922-725.

Treatment Pathways

In light of the above assessment, and in collaboration with the patient, where possible, decide whether to maintain and monitor the current opioid regimen, taper, or wean off long-term opioids following the 2019 HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics, or transition to medications for opioid use disorder if opioid use disorder is present.

Maintain and Monitor

- o Consider this pathway for patients meeting the following criteria:
 - Pain, function, and life role status have been meaningfully improved as described by the patient (e.g., playing with grandchild)
 - No history of non-fatal overdose or other serious adverse events
 - Not on combinations of opioids and chronic sedatives (e.g., benzodiazepines, barbiturates, carisoprodol, sedative-hypnotics).
 - No significant side effects that impair function and impact quality of life.
 - No recent history (i.e., in the last five years) of alcohol misuse or illicit substance use.
 - No history of diversion
 - No pattern of problematic opioid use. See Table 1, on the next page, for examples.
 - No pattern of unexpected controlled substances on PMP or unexpected results from urine drug screen.
 - No pattern of requesting early refills or history of lost or stolen medication.
 - Opioid prescribing is consistent with WAC.
- Periodically review the course of treatment for chronic pain. The frequency of visits, biological testing, and PMP queries as well as the content of the review should follow WAC 246-817-935, 246-840-477, 246-853-730, 246-919-985 or 246-922-730.
 - For a high-risk patient, at least quarterly;
 - For a moderate-risk patient, at least semiannually;
 - For a low-risk patient, at least annually;
 - Immediately upon indication of concerning aberrant behavior; and
 - More frequently at the physician's discretion.

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Table 1: Problematic Opioid Use

Source: AMDG Interagency Guideline on Prescribing Opioids for Pain, 2015

Less suggestive for addiction but are increased in depressed patients	More suggestive of addiction and are more prevalent in patients with substance use disorder
 Frequent requests for early refills; claiming lost or stolen prescriptions Opioid(s) used more frequently, or at higher doses 	 Buying opioids on the street; stealing or selling drugs Multiple prescribers ("doctor shopping")
than prescribedUsing opioids to treat non-pain symptoms	Trading sex for opioidsUsing illicit drugs, +UDT for illicit drugs
 Borrowing or hoarding opioids Using alcohol or tobacco to relieve pain 	Forging prescriptions
Requesting more or specific opioids	Aggressive demand for opioidsInjecting oral/topical opioids
 Recurring emergency room visits for pain Concerns expressed by family member(s) 	 Signs of intoxication (ETOH odor, sedation, slurred speech, motor instability, etc.)
Unexpected drug test resultsInconsistencies in the patient's history	

o Tapering or discontinuation

- Consider tapering to a reduced opioid dosage or tapering and discontinuing opioid therapy by following the 2019 HHS Guide for Clinicians on the
 Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics (more detailed information available on the link above)
- Tapers may be considered successful as long as the patient is making progress, however slowly, towards a goal of reaching a safer dose, or if the dose is reduced to the minimal dose needed.¹⁶
- Review important considerations prior to taper in the 2019 HHS Guide.
 - Avoid insisting on opioid tapering or discontinuation when opioid use may be warranted
 - Avoid misinterpreting cautionary dosage thresholds as a mandate for dose reduction
 - Some patients using both benzodiazepines and opioids may require tapering one or both medications to reduce risk for respiratory depression. Tapering decisions and plans need to be coordinated with prescribers of both medications
 - Avoid dismissing patients from care.
 - There are serious risks to non-collaborative tapering in physically dependent patients, including acute withdrawal, pain exacerbation, anxiety, depression, suicidal ideation, self-harm, ruptured trust, ad patients seeking opioids from high-risk sources
- A taper should be considered when:
 - Pain-generating condition resolved
 - The patient requests dosage reduction or discontinuation
 - Pain and function are not meaningfully improved
 - The patient is receiving higher opioid doses without evidence of benefit from the higher dose
 - The patient has current evidence of opioid misuse

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- The patient experiences side effects that diminish quality of life or impair function
- The patient experiences an overdose or other serious event (e.g., hospitalization, injury) or has warning signs for an impending event such as confusion, sedation, or slurred speech
- The patient is receiving medications (e.g., benzodiazepines) or has medical conditions (e.g., lung disease, sleep apnea, liver disease, kidney disease, fall risk, advanced age) that increase risk for adverse outcomes
- The patient has been treated with opioids for a prolonged period (e.g., years), and current benefit-harm balance is unclear
- Share decision-making with the patient except in cases of clear opioid use disorder, illicit drug use, diversion of prescribed opioids or imminent risk.
 - Discuss with patients their perceptions of risks, benefits, and adverse
 effects of continued opioid therapy, and include patient concerns in
 taper planning. For patients at higher risk of overdose, review benefits
 and risks of continued high-dose opioid therapy.
 - If the current opioid regimen does not put the patient at imminent risk, tapering does not need to occur immediately. Take time to obtain patient buy-in.
 - For patients who agree to reduce opioid dosages, collaborate with the
 patient on a tapering plan. Tapering is more likely to be successful when
 patients collaborate in the taper. Include patients in decisions, such as
 which medication will be decreased first and how quickly tapering will
 occur.
- Follow tapering flowchart outlined in the 2019 HHS guidelines. The rate of taper should be individualized. When opioid dosage is reduced, a taper slow enough to minimize opioid withdrawal symptoms and signs should be used. Tapering plans should be individualized based on patient goals and concerns. The longer the duration of previous opioid therapy, the longer the taper may take.
 - Slower tapers (e.g., 10% per month or slower) are often better
 tolerated than more rapid tapers, especially following opioid use for
 more than a year. Longer intervals between dose reductions allow
 patients to adjust to a new dose before the next reduction. Tapers can
 be completed over several months to years depending on the opioid
 dose
 - Faster tapers can be appropriate for some patients. A decrease of 10% of the original dose per week or slower (until 30% of the original dose is reached, followed by a weekly decrease of 10% of the remaining dose) is less likely to trigger withdrawal and can be successful for some patients, particularly after opioid use for weeks to months rather than years.
 - More rapid tapers (e.g., over 2-3 weeks) might be needed for patient safety when the risks of continuing the opioid outweigh the risks of a rapid taper (e.g., in the case of a severe adverse event such as overdose).
 - Ultra-rapid detoxification under anesthesia is associated with substantial risks and should not be used.

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- At times, tapers might have to be paused and restarted again when the
 patient is ready. Pauses may allow the patient time to acquire new skills
 for management of pain and emotional distress, introduction of new
 medications, or initiation of other treatments, while allowing for
 physical adjustment to a new dosage.
- Once the smallest available dose formulation is reached, the interval between doses can be extended. Opioids may be stopped, if appropriate, when taken less often than once a day.
- See AMDG Opioid Taper Calculator to help develop a taper plan.
- Treat symptoms of opioid withdrawal. See Table 2, on the next page, for treatment options. Emergence of opioid withdrawal symptoms may require adjustment in the rate, intensity, and duration of taper.
- Provide behavioral health support (aid in coping with taper; provide nonpharmacologic treatment for pain) as described earlier in the document
- In many cases, a clear diagnosis of opioid use disorder using DSM-5 criteria may not be apparent. Failed attempts at tapering, or persistent and severe withdrawal symptoms in spite of best medical treatment to address these symptoms, or failed multidisciplinary treatment for chronic pain, may indicate the need for a trial of medications for opioid dependence which may not meet criteria for opioid use disorder.¹⁷

Table 2: Treatment of Opioid Abstinence Syndrome (withdrawal)

Source: AMDG Interagency Guideline on Prescribing Opioids for Pain, 2015

Restlessness, sweating or tremors	Clonidine 0.1-0.2 mg orally every 6 hours or transdermal patch 0.1-0.2 mg weekly (if using the patch, oral medication may be needed for the first 72 hours) during taper. Monitor for significant hypotension and anticholinergic side effects.	
Nausea	Anti-emetics such as ondansetron or prochlorperazine	
Diarrhea	Loperamide or anti-spasmodics such as dicyclomine	
Muscle pain, neuropathic pain or myoclonus	NSAIDs, gabapentin or muscle relaxants such as cyclobenzaprine, tizanidine or methocarbamol	
Insomnia	Sedating antidepressants (e.g. nortriptyline 25 mg at bedtime or mirtazapine 15 mg at bedtime or trazodone 50 mg at bedtime). Do not use benzodiazepines or sedative-hypnotics.	

Medications for opioid use disorder

Refer to the 2015 AMDG Interagency Guideline on Prescribing Opioids for Pain, Part VI (Recognition and Treatment of opioid use disorder):

- Use evidence-based therapy including medications for opioid use disorder, if opioid use disorder is present. Follow the 2017 Bree Collaborative <u>Opioid Use Disorder Treatment Report and Recommendations</u> and the <u>2015 Agency Medical Directors Guideline on Prescribing Opioids for Pain Part VI Recognition and Treatment of opioid use disorder.</u>
 - **Note:** Co-prescribing of sedatives and medications for opioid use disorder increases risk of overdose.
- Buprenorphine. Once a patient is having mild-to-moderate withdrawal, administer 2 to 4 mg of sublingual buprenorphine or buprenorphine plus

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naloxone. If patient has no unacceptable side effects, administer an additional 4–8 mg sublingually at 1–2 hours, followed by adjustment according to response up to 32 mg daily in divided doses

- For those on buprenorphine, patients must abstain from short acting opioid agonists for at least 8 to 12 hours (best accomplished overnight; a longer interval is usually required for long acting opioids or fentanyl) and the patient must be in mild-to-moderate withdrawal (a score of ≥8 on the Clinical Opiate Withdrawal Scale)
- **Methadone**. Referral if indicated.
- Naltrexone. Requires full withdrawal off opioids for 7 to 10 days.



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Health System Recommendations

The Centers for Disease Control and Prevention chronic opioid guidelines, in addition to advocating for more cautious opioid prescribing by primary care providers, also call for payment and delivery system reform to align with and support these efforts. Specifically, the guidelines call for "strengthened coverage for non-pharmacologic treatments, appropriate urine drug testing, and medications for opioid use disorder; reimbursable time for patient counseling; and payment models that improve access to interdisciplinary, coordinated care."

Primary care providers on the frontlines of the opioid epidemic need support from health plans and health systems. Infrastructure to support best-practice care is critical to the success and sustainability of primary care providers' ability to assess, address, and help patients on long-term opioid therapy. This section makes recommendations for health care systems and health plans to support and elevate the unique education, training, and experience of primary care providers so they can better meet the complex needs of patients on long-term therapy.

Health Plans

Health plans should follow guidelines in the Collaborative Care for Chronic Pain recommendations including for reimbursement for collaborative care programs. Additionally, health plans should:

- Expand reimbursement for Structured Intensive Multidisciplinary Programs (SIMP) to increase
 access and availability when medically necessary. Quality measures and expectations for SIMP
 should also be developed to support and coincide with these efforts.
- Develop payment models that fairly reimburse for the time and effort required to assess
 patients on chronic opioid therapy. The full evaluation may take several hours, which is not
 accounted for by any current E/M codes.

Health Care Systems

Health care systems should follow the Collaborative Care for Chronic Pain recommendations including access to collaborative care programs, identifying chronic pain patients, and developing a multidisciplinary team that may include pharmacists and nurse care managers, and others. Additionally, health care systems should:

- Develop metrics sufficient to monitor the process and outcomes of these recommendations.
- Train staff on motivational interviewing.
- Consider creating a SIMP at the health care system or collaborating with one to ensure access to
 intensive, multimodal treatment options when indicated. This can be a helpful venue for
 patients being tapered off opioids.
- Academic Detailing. Academic detailing can offer support to primary care providers to help gain
 confidence in managing patients on chronic opioid therapy. These one-on-one conversations
 with a senior clinician can offer general knowledge on related principles as well as guidance and
 validation on challenging cases.
- **Hub and spoke**. Hub and spoke models for opioid use disorder treatment can expand access to medications for opioid use disorder and also offer support and guidance to primary care providers managing patients with addiction.

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Evidence

Engagement

Additional components of successful patient engagement in chronic pain care include discussing goals of care and preferences, setting expectations, understanding individual patient needs and talking about concerns and fears around pain and treatment. ^{18,19,20,21} The positive effect of goals of care discussions are well-documented and should be considered early. ^{22,23,24}

Assessment

The PEG assessment should be done at each visit.²⁵ General reviews of factors to consider in the assessment of patients with chronic pain include the importance of a thorough history and an interview where the patient's behavior can be observed.¹ At a systems level, state Prescription Drug Programs have shown an impact on prescribing patterns.²

Use of screening instruments, urine drug test, or patient treatment agreements to determine risk of overdose, misuse, or development of opioid use disorder among patients on long-term opioid therapy has been recommended but not proven in studies to be strongly predictive of improved outcomes. Earlier reviews have not demonstrated, for example, that use of urine drug test or implementation of a patient treatment agreement can meaningfully improve patient outcomes.^{3,4} In a system wide study in Group Health Cooperative, overdose risk was not abated by a large risk reduction initiative.⁵

A large Veterans Administration Health system cohort study identified risk factors obtained from administrative data most likely to be associated with either prescription opioid overdose or serious opioid-induced respiratory depression.⁶ The highest risk subgroups most commonly included factors such as diagnosis of opioid dependence, ≥100 mg/day MED, emergency department visits or hospitalizations, use of any extended release or long-acting opioid formulations, and opioid doses between 50-<100 mg/day MED. Information obtained from electronic health records (EHR) using natural language processing may supplement a search for ICD diagnostic terms in the medical record that can help identify problematic opioid use among patients on chronic opioid therapy.⁷ Among over 22,000 patients on long-term opioid therapy in a large health system, 10% were found to have traditional ICD codes indicating problematic opioid use, and another third (about 3%) were identified using electronic health record-derived data.⁷

More recently, the concept of refractory dependence or complex, persistent opioid dependence has been suggested as a diagnosis for patients who exhibit both physical and emotional symptoms from withdrawal of prolonged opioid use, but who do not fully meet the criteria for opioid use disorder.⁸

Treatment Pathways

Substantially more evidence on tapering has been published since the literature review on the 2015 AMDG guideline was completed in December 2014. Frank et al (2017), using GRADE methodology, conducted a systematic review of 67 studies, including 11 randomized trials. ²⁶ The review concluded that, based on very low quality of evidence, several interventions may be effective at promoting tapering, and found that pain, function, and quality of life may improve with tapering. The strongest evidence with fair-good studies included interdisciplinary programs with mean opioid discontinuation

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rates of 87% and behavioral interventions, with mean opioid discontinuation rates of 21%. Very weak studies included buprenorphine dose reduction and ketamine-assisted dose reduction. The authors concluded that:

- 1. Education for patients on long-term opioid therapy should include the message that pain severity, function, and quality of life may improve after opioid tapering
- 2. There should be consideration of referral to a multidisciplinary, multimodal pain program to support opioid dose reduction
- 3. Providers should employ team-based strategies with close follow-up to support opioid tapering when multidisciplinary programs are not available.

Berna et al (2015) conducted a comprehensive review of 117 articles and offered recommendations for everyday practice targeted at primary care physicians.²⁷ An overarching conclusion was that discontinuing long-term opioid therapy is most often hindered by patients' psychiatric co-morbidities and under-developed coping skills, as well as a lack of formal guidelines for prescribers to successfully taper. Several issues pointed out by Berna et al (2015) provide additional potential guidance:

- 1. Immediately following a successful taper of long-term opioid therapy, or after discontinuing post-op opioids, sensory hyperalgesia may occur;
- 2. The potential utility of use of objective and subjective opiate withdrawal scales (Clinical Opiate Withdrawal Scale [COWS]; Subjective Opiate Withdrawal Scale [SOWS]);
- 3. Overall, aggregating patients across numerous studies, patients report improvements in function without associated worsening in pain (N=1007) or even decreased pain levels (N=513);
- 4. Patients who take opioids only intermittently (<once daily) do not need a formal taper;
- 5. Empirical protocols since the 1990s favor tapers using the patient's long-term opioid treatment medication, vs switching to another medication for the taper;
- 6. Psychological support may be needed to address possible anxiety related to the taper, underlying depression, and deficient pain- and stress-coping strategies;
- 7. A taper agreement, including a collaboratively formulated plan, may help foster an effective therapeutic relationship and minimize the risk of breaking trust; and
- 8. In patients with opioid dependence, buprenorphine may reverse opioid-induced hyperalgesia and reduce opioid tolerance. Convincing evidence from eight studies (aggregated N=14,224), including three randomized clinical trials and a large open-label observational study, supports the benefits of this practice.

Several recent randomized trials of tapering have been reported since 2015; they have in common difficulty in recruitment or high drop-out rates, emphasizing the importance of patient and provider engagement in any tapering program. Sullivan et al reported a 22 week randomized controlled trial with opioid taper support vs usual care (N=35).²⁰ Although this study did not achieve significant differences in opioid dose reduction or pain severity ratings between the supported group vs the usual care group, self-reported pain interference and pain self-efficacy were improved in the intervention group. This was essentially a feasibility study to launch a larger funded study now underway.

In an observational study at a single pain clinic at Stanford University, Darnall et al (2018) reported that 75% of eligible patients on long-term opioid therapy (82/110) volunteered to enter a tapering protocol.²⁸ Patients were followed for four months (completers) on a slow taper, with education (a self-help book) and physician support, but no behavioral intervention; 38% (31/82) of enrolled patients did not complete the four month end-date survey and were considered drop outs. Among completers, baseline opioid dose (median dose =288 MED/day) was reduced to a median of 150 mg MED. Dose reduction was not associated with worse pain intensity or pain interference. Duration of opioid use did

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not predict taper success. Thus, even patients on very high doses followed closely in a pain clinic may be willing to at least initiate a taper protocol.

Frank et al conducted key informant interviews among 24 Colorado patients who were currently on long-term opioid therapy and had not tried tapering (6/24, 25%), were currently tapering (12/24, 50%), or who had discontinued long-term opioid therapy (6/24, 25%). Patients perceived a low risk of overdose and a higher and more immediate risk of increased pain with tapering. Fear of withdrawal and a perceived lack of effectiveness of non-opioid options were identified as barriers. Social support and a trusted health care provider to facilitate tapering were identified as helpful among those with tapering experience. Improved quality of life was reported following successful tapering. Another qualitative study on a small number of patients emphasized the individualized nature of communications regarding possible tapering and emphasized assuring patients they would not be abandoned.³⁰

Evidence on taper speed is almost entirely based on studies of patients with opioid use disorder related to heroin use (not chronic pain). Consensus opinions on taper speed range from 5-10% every two to four weeks to 2-10% every four to eight weeks, with pauses as needed.³¹ Veterans Administration recommendations are for 5-20% every four weeks. Detailed example tapers are also offered.³² Sudden discontinuation is strongly NOT recommended. A cohort study from Vermont Medicaid, in whom discontinuation occurred in a median of one day, indicated that most patients either had no taper or rapid taper. Forty-nine percent of these patients had an opioid related hospitalization or emergency department visit subsequent to the sudden or rapid discontinuation. A majority (60%) of these Medicaid recipients had a diagnosed substance use disorder prior to tapering, and <1% had been transitioned to a medication for opioid use disorder.³³ In April 2019 the Federal Drug Administration published a Drug Safety Communication strongly advising against abrupt discontinuation among patients on long-term opioid therapy.³⁴

Studies published to date have not been designed to evaluate effects of tapering on overdose risk, use of illicit opioids, or suicidality or death by suicide. Research is needed on effectiveness of adjunctive treatments; buprenorphine taper in the context of chronic pain with or without prescription opioid taper; speed of taper; and the effects of patient and clinical factors on taper outcomes. More research is also needed evaluating tapering in primary care and the health systems support necessary for effective tapering in primary care. Multiple randomized trials of interventions to promote opioid taper are underway.

Medications for opioid use disorder have been shown to improve outcomes for people with opioid use disorder.³⁵ Often medication is combined with behavioral therapy (e.g., counseling) for a whole-person approach, augmenting behavioral therapy alone and has been shown to be more effective than behavioral therapies, medically-supervised withdrawal, or abstinence alone.^{36,37,38}

Health Systems Interventions

Sustaining evidence-based interventions to support patients relies on support from the health care system. Providers cannot deliver the care outlined above alone. Various models have been proposed, many are profiled in the Bree Collaborative's 2018 Collaborative Care for Chronic Pain Recommendations. Some models can be adopted by individual systems, such as the six building blocks or telemedicine, while others need the involvement of the entire state, such as a hub and spoke model.

• Use of the Six Building Blocks, as originally devised for chronic disease management at Group Health Cooperative in Washington, and expanded by work at the MacColl Institute, has been

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- recently applied to assist primary care practitioners in safety net clinics, such as Federally Qualified Health Centers, to improve management of patients on long-term opioid therapy.
- Use of telecare to deliver collaborative management is an emerging area in the treatment of chronic pain.³⁹,⁴⁰ In this model, lower intensity intervention can be delivered by a pharmacist care manager.
- Delivery of multimodal pain care in the community has the most evidence in randomized controlled trials for the effective treatment for chronic musculoskeletal pain, one of the most important contributors to years lived with disability in the United States.⁴¹
- A peer support specialist has been used in the Southern Oregon Pain Guidance effort to assist
 the patient on long-term opioid therapy. The peer support specialists serves as a
 teacher/mentor, a tapering and withdrawal coach, an advocate, and as a resource purveyor
 such as with available community resources. The peer support specialist has also worked with
 providers on difficult conversation training.
- Institutional multidisciplinary panel support for primary care practitioners to assist with the care
 and assessment of patients on long-term opioid therapy has been employed at Veterans
 Administration health Centers in Portland and New Haven. The Department of Labor and
 Industries in now exploring similar types of support mechanisms through its Centers for
 Occupational Health and Education. 42,43,44 Multidisciplinary pain clinics have been used at the
 University of California-San Francisco, Cleveland Clinic, the Mayo Clinic, and by the WA
 Department of Labor and Industries, to assist with prescription opioid tapering.
- A hub and spoke model, as implemented in the state of Vermont, allows access to a center of
 expertise from a network of more widely dispersed catchment areas, or spokes.⁴⁵ In Vermont,
 this model allowed for increases in the state's opioid use disorder treatment capacity, now the
 highest capacity in the country. This model may also be applicable in treatment of long-term
 opioid therapy.

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Appendix A: Bree Collaborative Members

Member	Title	Organization
Susie Dade, MS	Deputy Director	Washington Health Alliance
Peter Dunbar, MB ChB, MBA (Vice-	CEO	Foundation for Health Care
Chair)		Quality
Gary Franklin, MD, MPH	Medical Director	Washington State Department of Labor and Industries
Stuart Freed, MD	Chief Medical Officer	Confluence Health
Richard Goss, MD	Medical Director	Harborview Medical Center – University of Washington
Darcy Jaffe, MN, ARNP, NE-BC, FACHE	Senior Vice President, Safety & Quality	Washington State Hospital Association
Sonja Kellen	Global Benefits Director	Microsoft
Dan Kent, MD	Chief Medical Officer, Community Plan	UnitedHealthcare
Wm. Richard Ludwig, MD	Chief Medical Officer, Accountable Care Organization	Providence Health and Services
Greg Marchand	Director, Benefits & Policy and Strategy	The Boeing Company
Robert Mecklenburg, MD	Medical Director, Center for Health Care Solutions	Virginia Mason Medical Center
Kimberly Moore, MD	Associate Chief Medical Officer	Franciscan Health System
Carl Olden, MD	Family Physician	Pacific Crest Family Medicine, Yakima
Drew Oliveira, MD	Executive Medical Director	Regence BlueShield
Mary Kay O'Neill, MD, MBA	Partner	Mercer
John Robinson, MD, SM	Chief Medical Officer	First Choice Health
Jeanne Rupert, DO, PhD	Provider	One Medical
Angela Sparks, MD	Medical Director Clinical Knowledge Development & Support	Kaiser Permanente Washington
Hugh Straley, MD (Chair)	Retired	Medical Director, Group Health Cooperative; President, Group Health Physicians
Shawn West, MD		
Laura Kate Zaichkin, MPH	Director of Health Plan Performance and Strategy	SEIU 775 Benefits Group
Judy Zerzan, MD, MPH	Chief Medical Officer	Washington State Health Care Authority

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Appendix B: Opioid Prescribing Guidelines Workgroup Charter and Roster

Background

The Washington State Agency Medical Directors Group (AMDG) developed a comprehensive <u>Guideline</u> on <u>Prescribing Opioids for Pain</u> in June 2015. The Guidelines were subsequently adopted by the Bree Collaborative at the July 2015 meeting with the goal of developing implementation strategies.

Aim

To facilitate implementation of the Agency Medical Directors Opioid Prescribing Guidelines.

Purpose

To design and carry out strategies to implement the Agency Medical Directors Opioid Prescribing Guidelines.

Duties & Functions

The Opioid Implementation workgroup will:

- Consult members of stakeholder organizations and subject matter experts for feedback, as appropriate.
- Recommend evidence-based implementation strategies.
- Define intended outcomes, targets, metrics, and data collection methods.
- Develop change strategies as needed.
- Enlist the assistance of other Bree members as well as non-Bree members to pursue the implementation of workgroup recommendations.
- Meet as needed.
- Provide updates at Bree Collaborative meetings.
- Create and oversee subsequent subgroups to help carry out the work, as needed.

Structure

The workgroup will consist of individuals appointed by the chair of the Bree Collaborative or the workgroup chair and confirmed by Bree Collaborative members.

The chair of the workgroup will be appointed by the chair of the Bree Collaborative.

The Bree Collaborative project director will staff and provide management and support services for the workgroup.

Less than the full workgroup may convene to: gather and discuss information; conduct research; analyze relevant issues and facts; or draft recommendations for the deliberation of the full workgroup. A quorum shall be a simple majority and shall be required to accept and approve recommendations to send to the Bree Collaborative.

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Meetings

The workgroup will hold meetings as necessary. The program director will conduct meetings along with the chair, arrange for the recording of each meeting, and distribute meeting agendas and other materials prior to each meeting.

Name	Title	Organization
Gary Franklin, MD, MPH (Co-Chair)	Medical Director	Washington State Department of Labor and Industries
Charissa Fotinos, MD (Co- Chair)	Deputy Chief Medical Officer	Washington State Health Care Authority
Andrew Saxon, MD (Co-Chair)	Director, Center of Excellence in Substance Abuse Treatment and Education (CESATE)	VA Puget Sound Health Care System
Rose Bigham and Cyndi Hoenhous (Co-Chairs)	Patient Advocates	Washington Patients in Intractable Pain
Pamela Stitzlein Davies, MS, ARNP, FAANP	Nurse Practitioner	Departments of Neurology & Nursing, University of Washington
Andrew Friedman, MD	Physical Medicine and Rehabilitation	Virginia Mason Medical Center
Kelly Golob, DC	Chiropractor	Tumwater Chiropractic Center
Dan Kent, MD	Chief Medical Officer	UnitedHealthcare
Kathy Lofy, MD	Chief Science Officer	Washington State Department of Health
Jaymie Mai, PharmD	Pharmacy Manager	Washington State Department of Labor and Industries
Mark Murphy, MD	Addiction Medicine and Pain Management	MultiCare Health System
Anne Blake-Nickels	Patient Advocate	
Gregory Rudolph, MD	Addiction Medicine	Swedish Pain Services
Jennifer Davies-Sandler	Patient Advocate	
Mark Stephens	President	Change Management Consulting
Mark Sullivan, MD, PhD	Psychiatrist	University of Washington
David Tauben, MD	Chief of Pain Medicine	University of Washington Medical Center
Gregory Terman MD, PhD	Professor	Department of Anesthesiology and Pain Medicine and the Graduate Program in Neurobiology and Behavior, University of Washington
John Vassall, MD, FACP	Physician Executive for Quality and Safety	Comagine Health
Michael Von Korff, ScD	Senior Investigator	Kaiser Permanente Washington Research Institute
Mia Wise, DO	Medical Director, Collaborative Healthcare Solutions	Premera Blue Cross

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Appendix C: Questions for Family Members

- How can I best support my family member?
- What should I do if I see their well-being deteriorate?
- How can I best advocate for my family member?
- What are some red flags I should watch for related to the chronic pain in my family member?
 - Mental health concerns (Depression, Anxiety, Suicide)
 - o Reduced functionality
 - o Isolation
- Opioids are increasing my family member's function and quality of life. Will that continue?
- If opioids stop working or my family member's health goes downhill, what do I do?
- Are there additional therapies they can try?
- What safety issues should I watch for?
 - o Misuse, Addiction, Overdose, Diversion, Withdrawal
 - o Help them keep their pill log
 - o Help them track side effects
 - Watch for over sedation
 - o Lock up the meds and don't tell others you have them.
 - o Know the signs of addiction
 - o Know the signs of withdrawal. This will happen if your spouse misses a dose.
- When is my spouse going to get better?
- How can I help him?
- Are the opioids making him better or worse?
- How can I tell if he is becoming dependent or addicted?
- I am worried about having opioids in my house. What can I do to make sure these are safely stored?

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Appendix D: Medical Risks of Long-Term Opioid Use

Long-term opioid use can cause diverse adverse effects that differ across patients. A brief, simple information sheet like that shown above can be used with patients to review common medical risks of opioids to identify problems that patients may not realize are being caused by their use of opioid analgesics, while educating patients about opioid-related risks.

Reference: Baldini A, Von Korff M, Lin EHB. A review of potential adverse effects of long-term opioid therapy: A practioner's guide. The Primary Care Companion for CNS Disorders 2012; 14(3): pii: PCC.11m01326.

Medical Risks of Long-term Opioid Use



ledical Risks of Long	j-terni Opioid Us	se Grouphealtr
Medical risk	How common?	Description and information
espiratory depression		
Opioid overdose	< 1% per year but increases with dose	Caused by severely slowed breathing, which you may not notice Severe cases are treated in the hospital Can cause death
Breathing problems during sleep	Not known	- Opioids may cause or worsen sleep apnea - You may not notice breathing problems
njuries		
Falls & fractures	Not known	
Motor vehicle crashes	Not known	
astrointestinal problems		
Constipation	30 - 40%	 It helps to use stool-softeners or drugs that stimulate bowel movements
Serious intestinal blockage	<1% per year	Caused by severe constipation Severe cases are treated in the hospital
ormonal effects		
Hypogonadism, impotence, infertility,	25% - 75%	 Hypogonadism = lowered sex hormones, which can worsen sexual function
osteoporosis		 Osteoporosis can make you more likely to fracture or break a bone
ognitive and europhysiologic effects		
Sedation	15%	- Can cause difficulty driving or thinking clearly
Disruption of sleep	Not known	
Hyperalgesia	Not known	- Hyperalgesia = being more sensitive to pain
sychosocial		
Depression, anxiety, de- activation, apathy	Not known	 Depression can worsen pain, while pain can worsen depression. Opioids can cause loss of interest in usual activities, which can increase depression.
Addiction, misuse, and diversion	5 - 30%	 Common signs of prescription opioid addiction are preoccupation with opioid use or craving, unsuccessful attempts to discontinue use or co down, cutting down or giving up activities due opioid use, and using more medication than prescribed.
Oral Health		
Dry mouth that may sometimes cause tooth decay	Dry mouth is common	Brush your teeth and rinse your mouth often Chew sugarless gum and drink water or sugar free, non-carbonated fluids
Myoclonus	Not Known	- Myoclonus = muscle twitching
-		-

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Appendix E: Validated Tools for Screening and Assessment

	Tool Characteristics				
	Administration	Time to Complete	Length	Available for Public Use (Cost)	
Assessing Function and Pain					
Pain, Enjoyment of life, General Activity (PEG) http://mytopcare.org/wp-content/uploads/2013/06/PEG-Pain-Screening-Tool1.pdf	Patient self-report	1 minute	3 items	X (Free)	
Two Item Chronic Pain Scale	Clinician or patient self-report	1 minute	2 items	X(Free)	
Risk of Transitioning to Chronic Pain					
StarTBack http://www.keele.ac.uk/sbst/startbacktool/	Patient self-report	<5 minutes	9 items	X (Free)	
Functional Restoration Questionnaire (FRQ)				X (after email registration)	
Screening for Risk of Opioid Addiction and Substance Abuse https://www.drugabuse.gov/nidamed-medical-health-professionals/screening-tools-resources/chart-screening-tools					
Opioid Risk Tool (ORT)	Clinician or patient self-report	1 minute	5 questions	X (Free)	
Tobacco, Alcohol, Prescription medication, and other Substances use (TAPS)	Clinician or patient self-report	<2 minutes	5 items	X (Free)	
CAGE Adapted to Include Drugs (CAGE-AID)	Clinician	<5 minutes	4 questions	X (Free)	
DIRE http://integratedcare-nw.org/DIRE score.pdf	Clinician	<2 minutes	7 items	X(Free)	
Alcohol Use Disorders Identification Test (AUDIT)	Clinician or patient self-report	<5 minutes	10 items	X (Free)	
Screening for Mental Health Disorders	Screening for Mental Health Disorders				
Patient Health Questionnaire-9 (PHQ-9)	Patient self-report	<5 minutes	9 items	X (Free)	
GAD-7 http://www.mpho.org/resource/d/34008/ GAD708.19.08Cartwright.pdf	Patient self-report	<5 minutes	7 items	X (Free)	
Primary Care PTSD Screen (PC-PTSD)	Clinician	<5 minutes	4 items	X(Free)	
Assessing Opiate Withdrawal					
Clinical Opiate Withdrawal Scale (COWS) https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/files/ClinicalO piateWithdrawalScale.pdf	Clinician	<5 minutes	11 items	X(Free)	

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Appendix F: DSM-5 Criteria for Opioid Use Disorder

These criteria not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

- 1. Opioids are often taken in larger amounts or over a longer period than was intended.
- 2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
- 3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
- 4. Craving, or a strong desire or urge to use opioids.
- 5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
- 6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
- 7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
- 8. Recurrent opioid use in situations in which it is physically hazardous.
- 9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- 10. Exhibits tolerance
 - a) Need for markedly increased amounts of opioids to achieve intoxication or desired effect
 - b) Markedly diminished effect with continued use of the same amount of opioid
- 11. Exhibits withdrawal (discussed in the next section).
 - a) Characteristic opioid withdrawal syndrome
 - b) Same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms

Severity: Mild: 2-3 symptoms.

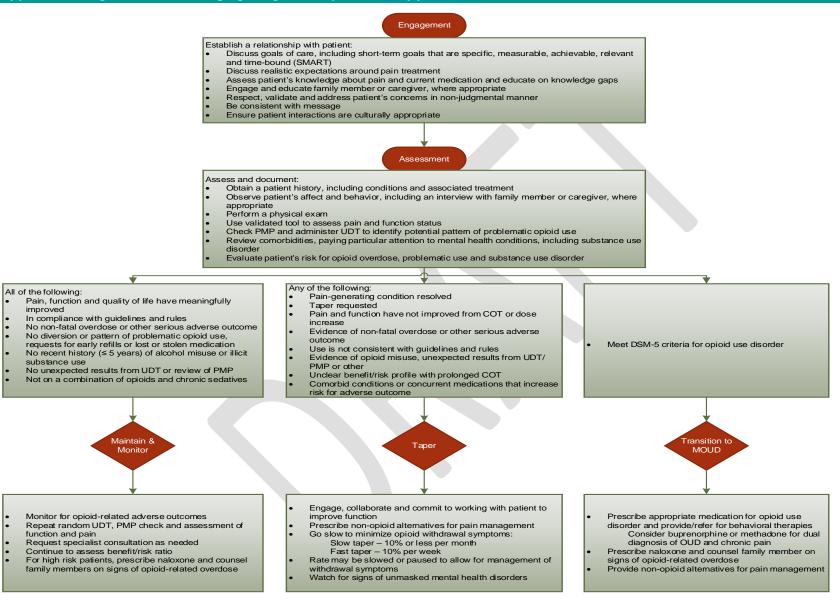
Moderate: 4-5 symptoms.

Severe: 6 or more symptoms

Criteria from American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition,. Washington, DC, American Psychiatric Association page 541.

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Appendix H: Algorithm for Managing Long-term Opioid Therapy



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