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Opioid Prescribing: Long-Term Opioid Therapy Report and Recommendations

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## **Background**

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 (text in brown), the 2019 Bree Collaborative Care for Chronic Pain Report and Recommendations, and the Washington State Administrative Code (WAC) pain rules (text in blue). 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 (Dental Quality Assurance Commission), 246-840-463 (Practical and Registered Nursing), 246-853-661 (Osteopathic Physicians and Surgeons), 246-919-852 (Medical Quality Assurance Commission) or 246-922-661 (Podiatric Physicians and Surgeons) 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
  - o 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 <u>National Pain Strategy</u> and be:

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

# **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.<sup>1</sup> 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.<sup>2,3</sup>

- **Respect.** Treat patients with respect and address and validate concerns in a non-judgmental manner
- **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).<sup>5</sup> 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**. <sup>6,7,8</sup> 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. Educate patient to better understand the influence of psychological factors and the pain experience (pain related anxiety, depression, fear avoidance). 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 Examples can be found here.
  - Use the teach-back method to ensure that a patient understands complicated or new information.<sup>12</sup> Information from the Agency for Healthcare Research and Quality on the teach-back method is <a href="here">here</a>.
- 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.
- Consistency. Use consistent messaging from all team members and in all visits.
- Cultural competency. Assure that interactions with patients are culturally humble. See information <a href="https://example.com/here.">here</a>.<sup>13</sup>

#### **Assessment**

Assessment of patients on long-term opioid therapy will likely require a structured and a staged multimodal approach over several visits. Elements of this assessment could be accomplished in collaboration with a pain specialist, structured multidisciplinary pain program, or multidisciplinary team, when available. Brief screening instruments can also inform the assessment but should not replace clinical observation and judgment. Additional diagnostic assessment may be necessary in some patients to rule out other causes of chronic pain. 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.
  - Review the nature and intensity of opioid withdrawal symptoms, if experienced.
  - o "The effect of pain on physical and psychosocial function."
  - 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).
- **Assessment of sleep hygiene.** Assessment of current sleep quality and history of any sleep related disorders.
- 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. See Appendix E: Validated Tools for Screening and Assessment.
- **Prescription Monitoring Program (PMP "**Review the PMP to identify any controlled substances received by the patient in accordance with" state rules. Document all findings relevant to

- controlled substance use, including concomitant opioid and sedative, multiple opioid prescribers, and early refills.
- 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)
  - 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>.
  - 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.
  - 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 morphine equivalent dose (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

## 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. <sup>14</sup> 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)." <sup>15</sup> 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 state law. 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.
- 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.<sup>2</sup> 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:

- Cognitive-behavioral therapy
- Mindfulness
- Exercise and body awareness strategies (e.g., yoga, tai chi, qigong)
- Manual therapies (e.g., massage, spinal manipulation)
- 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.

# **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 <a href="HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics">HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics</a>, or transition to medications for opioid use disorder is present. Prescribe naloxone consistent with opioid prescribing rules for all treatment pathways.

#### 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) "without documentation in the patient record of clinical judgment and discussion of risks with the patient" following state law.
  - 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 state law.
  - "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."

## **Table 1: Problematic Opioid Use**

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

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

# 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. The Guide is available through the link above and in Appendix H. Select excerpts are included below in brown text.
- "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
- Before initiating a taper, review "important considerations prior to taper" in the 2019 HHS Guide.
  - "Avoid insisting on opioid tapering or discontinuation when opioid use may be warranted (e.g., treatment of cancer pain, pain at the end of life, or other circumstances in which benefits outweigh risks of opioid therapy).
  - Avoid misinterpreting cautionary dosage thresholds as mandates 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 noncollaborative tapering in physically dependent patients, including acute withdrawal, pain exacerbation, anxiety, depression, suicidal ideation, self-harm, ruptured trust, and 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
- 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.
- 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 for potential 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.<sup>17</sup> "If patients on high opioid dosages are unable to taper despite worsening pain and/or function with opioids, whether or not opioid use disorder criteria are met, consider transitioning to buprenorphine. Consultation with a clinician experienced in use of buprenorphine is warranted if unfamiliar with its initiation. SAMHSA's Providers Clinical Support System offers training and technical assistance as well as mentors to assist those who need to taper opioids and may have additional questions."

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

Use evidence-based medications for opioid use disorder, if opioid use disorder is present following the 2017 Bree Collaborative Opioid Use Disorder Treatment Report and Recommendations and the 2015 Agency Medical Directors Guideline on Prescribing Opioids for Pain Part VI Recognition and Treatment of opioid use disorder, or more recent guidance if available.

## **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. SIMPs are outpatient programs that deliver
  regularly scheduled, daily, interdisciplinary care for the treatment of chronic pain. The program
  is typically six to eight hours per day, five days per week for two to four weeks in duration.
  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.
- Expand access to specialty providers through the use of E-consult or TelePain services.
- Consider creating a multidisciplinary pain treatment program, such as 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.

• Establish processes to enable warm handoffs between patients and specialty providers when they are not located within the same system (e.g., pain medicine, addiction medicine, behavioral medicine).

# **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. <sup>18,19,20,21</sup> The positive effect of goals of care discussions are well-documented and should be considered early. <sup>22,23,24</sup>

#### **Assessment**

The PEG assessment has been shown to be valid in assessing pain intensity.<sup>25</sup> 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.<sup>1</sup> At a systems level, state Prescription Drug Programs have shown an impact on prescribing patterns.<sup>2</sup>

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.<sup>3,4</sup> In a system wide study in Group Health Cooperative, overdose risk was not abated by a large risk reduction initiative.<sup>5</sup>

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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>7</sup>

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.<sup>8</sup>

# **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.<sup>26</sup> 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 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.<sup>27</sup> 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).<sup>20</sup> 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.<sup>28</sup> 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 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.<sup>30</sup>

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.<sup>31</sup> Veterans Administration recommendations are for 5-20% every four weeks. Detailed example tapers are also offered.<sup>32</sup> 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.<sup>33</sup> In April 2019 the Federal Drug Administration published a Drug Safety Communication strongly advising against abrupt discontinuation among patients on long-term opioid therapy.<sup>34</sup>

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.<sup>35</sup> 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.<sup>36,37,38</sup>

# **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 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.<sup>39,40</sup> 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.<sup>41</sup>
- 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 specialist 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.<sup>45</sup> 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.

# 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,	Senior Vice President, Safety &	Washington State Hospital
FACHE	Quality	Association
Sonja Kellen	Global Benefits Director	Microsoft
Dan Kent, MD	Chief Medical Officer,	UnitedHealthcare
	Community Plan	
Wm. Richard Ludwig, MD	Chief Medical	Providence Health and Services
	Officer, Accountable Care	
	Organization	
Greg Marchand	Director, Benefits & Policy and	The Boeing Company
	Strategy	\( \text{\tin}\text{\texi}\text{\text{\text{\text{\text{\text{\texi}\text{\text{\text{\text{\texi}\text{\text{\text{\text{\text{\texi}\text{\text{\texi}\text{\text{\text{\text{\text{\tet
Robert Mecklenburg, MD	Medical Director, Center for	Virginia Mason Medical Center
Kimbark Maara MD	Health Care Solutions Associate Chief Medical	Franciscan Haalth System
Kimberly Moore, MD	Officer	Franciscan Health System
Carl Olden, MD	Family Physician	Pacific Crest Family Medicine,
Carr Olderi, MD	Failing Filysician	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	Kaiser Permanente Washington
, mgara aparna, mz	Knowledge Development &	naise i emianente i aemigeen
	Support	
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	SEIU 775 Benefits Group
	Performance and Strategy	
Judy Zerzan, MD, MPH	Chief Medical Officer	Washington State Health Care
		Authority

# **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.

# 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
Jason Fodeman, MD	Associate Medical Director	Washington State Department of Labor and Industries
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 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

Thank you to Anne Blake-Nickels, Jennifer Davies-Sandler, Katerina LaMarche, Washington State Medical Association, and Negar Golchin, PharmD, MPH, Comagine Health for contributions.

# **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)
  - Reduced functionality
  - 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 do not tell others you have them.
  - 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?

# 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



	•	
Medical risk	How common?	Description and information
Respiratory 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
Injuries		
Falls & fractures	Not known	
Motor vehicle crashes	Not known	
Gastrointestinal problems		
Constipation	30 - 40%	<ul> <li>It helps to use stool-softeners or drugs that stimulate bowel movements</li> </ul>
Serious intestinal blockage	<1% per year	Caused by severe constipation     Severe cases are treated in the hospital
Hormonal effects		
Hypogonadism, impotence, infertility,	25% - 75%	- <i>Hypogonadism</i> = lowered sex hormones, which can worsen sexual function
osteoporosis		<ul> <li>Osteoporosis can make you more likely to fracture or break a bone</li> </ul>
Cognitive and neurophysiologic effects		
Sedation	15%	- Can cause difficulty driving or thinking clearly
Disruption of sleep	Not known	
Hyperalgesia	Not known	- Hyperalgesia = being more sensitive to pain
Psychosocial		
Depression, anxiety, de- activation, apathy	Not known	<ul> <li>Depression can worsen pain, while pain can worsen depression. Opioids can cause loss of interest in usual activities, which can increase depression.</li> </ul>
Addiction, misuse, and diversion	5 - 30%	<ul> <li>Common signs of prescription opioid addiction are preoccupation with opioid use or craving, unsuccessful attempts to discontinue use or cut down, cutting down or giving up activities due to opioid use, and using more medication than prescribed.</li> </ul>
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

# 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) <a href="http://mytopcare.org/wp-content/uploads/2013/06/PEG-Pain-Screening-Tool1.pdf">http://mytopcare.org/wp-content/uploads/2013/06/PEG-Pain-Screening-Tool1.pdf</a>	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 <a href="https://www.drugabuse.gov/nidamed-medical-health-professionals/screening-tools-resources/chart-screening-tools">https://www.drugabuse.gov/nidamed-medical-health-professionals/screening-tools-resources/chart-screening-tools</a>					
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 <a href="http://integratedcare-nw.org/DIRE">http://integratedcare-nw.org/DIRE</a> 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					
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)	

# 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.

# Appendix H: Algorithm for Managing Long-term Opioid Therapy

#### Engagement Establish a relationship with patient: Discuss goals of care, including short-term goals that are specific, measurable, achievable, relevant and time-bound (SMART) Discuss realistic expectations around pain treatment Assess patient's knowledge about pain and current medication and educate on knowledge gaps Engage and educate family member or caregiver, where appropriate Respect, validate and address patient's concerns in non-judgmental manner Be consistent with message Ensure patient interactions are culturally appropriate Assessment Assess and document: Obtain a patient history, including conditions and associated treatment Observe patient's affect and behavior, including an interview with family member or caregiver, where appropriate Use validated tool to assess pain and function status Check PMP and administer UDT to identify potential pattern of problematic opioid use Review comorbidities, paying particular attention to mental health conditions, including substance use Evaluate patient's risk for opioid overdose, problematic use and substance use disorder Any of the following: All of the following: Pain-generating condition resolved Pain, function and quality of life have meaningfully Taper requested improved Pain and function have not improved from COT or dose In compliance with guidelines and rules No non-fatal overdose or other serious adverse outcome Evidence of non-fatal overdose or other serious adverse No diversion or pattern of problematic opioid use, outcome requests for early refills or lost or stolen medication Meet DSM-5 criteria for opioid use disorder Use is not consistent with guidelines and rules No recent history (≤ 5 years) of alcohol misuse or illicit Evidence of opioid misuse, unexpected results from UDT/ substance use No unexpected results from UDT or review of PMP Unclear benefit/risk profile with prolonged COT Not on a combination of opioids and chronic sedatives Comorbid conditions or concurrent medications that increase risk for adverse outcome Maintain & ransition to Taper MOUD Engage, collaborate and commit to working with patient to Monitor for opioid-related adverse outcomes improve function Prescribe appropriate medication for opioid use Repeat random UDT, PMP check and assessment of Prescribe non-opioid alternatives for pain management disorder and provide/refer for behavioral therapies function and pain Go slow to minimize opioid withdrawal symptoms: Consider buprenorphine or methadone for dual Request specialist consultation as needed Slow taper - 10% or less per month diagnosis of OUD and chronic pain Fast taper - 10% per week Continue to assess benefit/risk ratio Prescribe naloxone and counsel family member on For high risk patients, prescribe naloxone and counsel Rate may be slowed or paused to allow for management of signs of opioid-related overdose family members on signs of opioid-related overdose withdrawal symptoms Provide non-opioid alternatives for pain management Watch for signs of unmasked mental health disorders

# HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics

This HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics provides advice to clinicians who are contemplating or initiating a reduction in opioid dosage or discontinuation of long-term opioid therapy for chronic pain. In each case the clinician should review the risks and benefits of the current therapy with the patient, and decide if tapering is appropriate based on individual circumstances.

After increasing every year for more than a decade, annual opioid prescriptions in the United States <u>peaked at 255 million in 2012 and then decreased to 191 million in 2017.</u> More judicious opioid analgesic prescribing can benefit individual patients as well as public health when opioid analgesic use is limited to situations where benefits of opioids are likely to outweigh risks. At the same time opioid analgesic prescribing changes, such as dose escalation, dose reduction or discontinuation of long-term opioid analgesics, have potential to harm or put patients at risk if not made in a thoughtful, deliberative, collaborative, and measured manner.

Risks of rapid opioid taper

- Opioids should not be tapered rapidly or discontinued suddenly due to the risks of significant opioid withdrawal.
- Risks of rapid tapering or sudden discontinuation of opioids in physically dependent<sup>ii</sup> patients include acute withdrawal symptoms, exacerbation of pain, serious psychological distress, and thoughts of suicide.<sup>1</sup> Patients may seek other sources of opioids, potentially including illicit opioids, as a way to treat their pain or withdrawal symptoms.<sup>1</sup>
- Unless there are indications of a life-threatening issue, such as warning signs of impending overdose, HHS does not recommend abrupt opioid dose reduction or discontinuation.

Whether or not opioids are tapered, safe and effective nonopioid treatments should be integrated into patients' pain management plans based on an individualized assessment of benefits and risks considering the patient's diagnosis, circumstances, and unique

needs.<sup>2,3,4</sup> Coordination across the health care team is critical. Clinicians have a responsibility to provide or arrange for coordinated management of patients' pain and opioid-related problems, and they should never abandon patients.<sup>2</sup> More specific guidance follows, compiled from published guidelines (the CDC Guideline for Prescribing Opioids for Chronic Pain<sup>2</sup> and the VA/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain<sup>3</sup>) and from practices endorsed in the peer-reviewed literature.

# Consider<sup>iii</sup> tapering to a reduced opioid dosage, or tapering and discontinuing opioid therapy, when

- Pain improves<sup>3</sup>
- The patient requests dosage reduction or discontinuation<sup>2,3,5</sup>
- Pain and function are not meaningfully improved<sup>2,3,5</sup>
- The patient is receiving higher opioid doses without evidence of benefit from the higher dose<sup>2,3</sup>
- The patient has current evidence of opioid misuse<sup>3,5</sup>
- The patient experiences side effects<sup>iv</sup> that diminish quality of life or impair function<sup>3</sup>
- The patient experiences an overdose or other serious event (e.g., hospitalization, injury),<sup>2,5</sup> or has warning signs for an impending event such as confusion, sedation, or slurred speech<sup>2,6</sup>
- 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<sup>3,5</sup>
- The patient has been treated with opioids for a prolonged period (e.g., years), and current benefit-harm balance is unclear

i https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html

Physical dependence occurs with daily, around-the-clock use of opioids for more than a few days and means that the body has adapted to the drug, requiring more of it to achieve a certain effect (tolerance). Patients with physical dependence will experience physical and/or psychological symptoms if drug use is abruptly ceased (withdrawal).

Additional tools to help weigh decisions about continuing opioid therapy are available: <u>Assessing Benefits and Harms of Opioid Therapy</u>, <u>Pain Management Opioid Taper Decision Tool</u>, and <u>Tapering Opioids for Chronic Pain</u>.

iv e.g., drowsiness, constipation, depressed cognition

# Important considerations prior to deciding to taper

Overall, following voluntary reduction of long-term opioid dosages, many patients report improvements in function, sleep, anxiety, and mood without worsening pain or even with decreased pain levels. 4,7,8,9,10,11 Other patients report increased pain, insomnia, anxiety, and depression. 4,7,9,12 The duration of increased pain related to hyperalgesia or opioid withdrawal is unpredictable and may be prolonged in some patients. 12 Decisions to continue or reduce opioids for pain should be based on individual patient needs. 2,13 Consider whether opioids continue to meet treatment goals, whether opioids are exposing the patient to an increased risk for serious adverse events or opioid use disorder, and whether benefits continue to outweigh risks of opioids. 2,13

- Avoid insisting on opioid tapering or discontinuation when opioid use may be warranted (e.g., treatment of cancer pain, pain at the end of life, or other circumstances in which benefits outweigh risks of opioid therapy). The CDC Guideline for Prescribing Opioids for Chronic Pain does not recommend opioid discontinuation when benefits of opioids outweigh risks.<sup>2,4,13</sup>
- Avoid misinterpreting cautionary dosage thresholds as mandates for dose reduction.<sup>4</sup> While, for example, the CDC Guideline recommends avoiding or carefully justifying increasing dosages above 90 MME/day, it does not recommend abruptly reducing opioids from higher dosages.<sup>2,4</sup> Consider individual patient situations.
- 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.<sup>2</sup> If benzodiazepines are tapered, they should be tapered gradually<sup>v</sup> due to risks of benzodiazepine withdrawal (anxiety, hallucinations, seizures, delirium tremens, and, in rare cases, death).<sup>2</sup>
- Avoid dismissing patients from care. This practice puts
  patients at high risk and misses opportunities to provide
  life-saving interventions, such as medication-assisted
  treatment for opioid use disorder.<sup>2,4,13</sup> Ensure that patients
  continue to receive coordinated care.
- There are serious risks to noncollaborative tapering in physically dependent patients, including acute withdrawal, pain exacerbation, anxiety, depression, suicidal ideation, self-harm, ruptured trust, and patients seeking opioids from high-risk sources.<sup>1,14</sup>

# Important steps prior to initiating a taper

- Commit to working with your patient to improve function and decrease pain.<sup>2,7</sup> Use accessible, affordable nonpharmacologic and nonopioid pharmacologic treatments.<sup>2,3,7</sup> Integrating behavioral and nonopioid pain therapies before and during a taper can help manage pain<sup>10</sup> and strengthen the therapeutic relationship.
- Depression, anxiety, and post-traumatic stress disorder (PTSD) can be common in patients with painful conditions, especially in patients receiving long-term opioid therapy.<sup>15</sup> Depressive symptoms predict taper dropout.<sup>7,8</sup> Treating comorbid mental disorders can improve the likelihood of opioid tapering success.
- If your patient has serious mental illness, is at high suicide risk, or has suicidal ideation, offer or arrange for consultation with a behavioral health provider before initiating a taper.<sup>3,5</sup>
- If a patient exhibits opioid misuse behavior or other signs of opioid use disorder, assess for opioid use disorder using DSM-5 criteria.<sup>2,5</sup> If criteria for opioid use disorder are met (especially if moderate or severe), offer or arrange for medication-assisted<sup>vi</sup> treatment.<sup>2,3</sup>
- Access appropriate expertise if considering opioid tapering or managing opioid use disorder during pregnancy. Opioid withdrawal risks include spontaneous abortion and premature labor. For pregnant women with opioid use disorder, medication-assisted treatment is preferred over detoxification.<sup>2</sup>
- Advise patients that there is an increased risk for overdose on abrupt return to a previously prescribed higher dose.<sup>2</sup> Strongly caution that it takes as little as a week to lose tolerance and that there is a risk of overdose if they return to their original dose.<sup>2,3,5,6</sup> Provide opioid overdose education and consider offering naloxone.<sup>2</sup>

# Share decision-making with patients

- 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 based on opioid dosages, review benefits and risks of continued high-dose opioid therapy.<sup>2,5</sup>
- If the current opioid regimen does not put the patient at imminent risk, tapering does not need to occur immediately.<sup>4</sup> Take time to obtain patient buy-in.<sup>14</sup>
- For patients who agree to reduce opioid dosages, collaborate with the patient on a tapering plan.<sup>2</sup> Tapering is more likely to be successful when patients collaborate in the taper.<sup>vii</sup> Include patients in decisions, such as which medication will be decreased first and how quickly tapering will occur.

Example benzodiazepine tapers and clinician guidance are available at <a href="https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Benzodiazepine Provider\_AD\_%20Risk\_Discussion\_Guide.pdf">https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Benzodiazepine Provider\_AD\_%20Risk\_Discussion\_Guide.pdf</a>

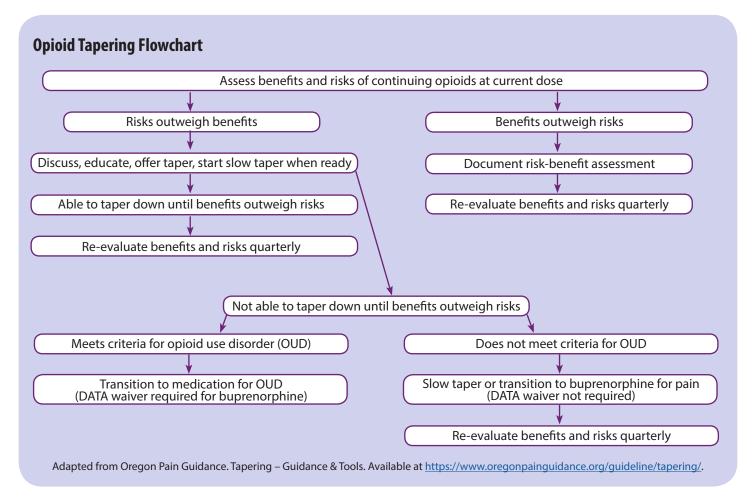
vi See SAMHSA's TIP 63: Medications for Opioid Use Disorder, SAMHSA's Buprenorphine Practitioner Locator, and SAMHSA's Opioid Treatment Program Directory

vii A recent systematic review found that when opioids were tapered with buy-in from patients who agreed to decrease dosage or discontinue therapy, pain, function, and quality of life improved after opioid dose reduction.<sup>10</sup>

# Individualize the taper rate

- When opioid dosage is reduced, a taper slow enough to minimize opioid withdrawal symptoms and signs<sup>viii</sup> should be used.<sup>2</sup> Tapering plans should be individualized based on patient goals and concerns.<sup>2,3,5,6</sup>
- The longer the duration of previous opioid therapy, the longer the taper may take. Common tapers involve dose reduction of 5% to 20% every 4 weeks.<sup>3,5</sup>
  - 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.<sup>2</sup> Longer intervals between dose reductions allow patients to adjust to a new dose before the next reduction.<sup>5</sup> Tapers can be completed over several months to years depending on the opioid dose. See "slower taper" example here.
  - 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<sup>7</sup> and can be successful for some patients, particularly after opioid use for weeks to months rather than years. See "faster taper" example here.

- At times, tapers might have to be paused and restarted again when the patient is ready.<sup>2</sup> 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.<sup>3,5</sup>
- Tapers may be considered successful as long as the patient is making progress, however slowly, towards a goal of reaching a safer dose,<sup>2</sup> or if the dose is reduced to the minimal dose needed.
- Once the smallest available dose is reached, the interval between doses can be extended <sup>2,5,7</sup> Opioids may be stopped, if appropriate, when taken less often than once a day.<sup>2,7</sup> See "example tapers for opioids" here.
- More rapid tapers (e.g., over 2-3 weeks<sup>16</sup>) 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).
- Ultrarapid detoxification under anesthesia is associated with substantial risks and *should not be used*.<sup>2</sup>



# **DSM-5 Opioid Use Disorder**

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the following, occurring within a 12-month period:

- 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, use, or recover from the effects of opioids.
- 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 is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- 10. Tolerance, as defined by either of the following:
  - a. A need for markedly increased amounts of opioids to achieve intoxication or desired effect, or
  - b. Markedly diminished effect with continued use of the same amount of an opioid.

Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

- 11. Withdrawal, as manifested by either of the following:
  - a. The characteristic opioid withdrawal syndrome, or
  - b. Opioids (or a closely related) substance is taken to relieve or avoid withdrawal symptoms.

Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.

Mild: Presence of 2-3 symptoms Moderate: Presence of 4-5 symptoms Severe: Presence of 6 or more symptoms

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# Treat symptoms of opioid withdrawal

- If tapering is done gradually, withdrawal symptoms should be minimized and manageable.
- Expectation management is an important aspect of counseling patients through withdrawal.
- Significant opioid withdrawal symptoms may indicate a need to pause or slow the taper rate.
- Onset of withdrawal symptoms depends on the duration of action of the opioid medication used by the patient. Symptoms can begin as early as a few hours after the last medication dose or as long as a few days, depending on the duration of action.<sup>7</sup> Early withdrawal symptoms (e.g., anxiety, restlessness, sweating, yawning, muscle aches, diarrhea and cramping<sup>viii</sup>) usually resolve after 5-10 days but can take longer.<sup>5</sup>
- Some symptoms (e.g., dysphoria, insomnia, irritability) can take weeks to months to resolve.<sup>5</sup>
- Short-term oral medications can help manage withdrawal symptoms, especially when prescribing faster tapers.<sup>5</sup> These include alpha-2 agonists<sup>ix</sup> for the management of autonomic signs and symptoms (sweating, tachycardia), and symptomatic medications<sup>x</sup> for muscle aches, insomnia, nausea, abdominal cramping, or diarrhea.<sup>5</sup>

# Provide behavioral health support

- Make sure patients receive appropriate psychosocial support.<sup>2,3,6,11</sup> Ask how you can support the patient.<sup>5</sup>
- Acknowledge patient fears about tapering.<sup>5</sup> While motives for tapering vary widely, fear is a common theme. Many patients fear stigma, withdrawal symptoms, pain, and/or abandonment.<sup>13,18</sup>
- Tell patients "I know you can do this" or "I'll stick by you through this." Make yourself or a team member available to the patient to provide support, if needed.<sup>3,6</sup> Let patients know that while pain might get worse at first, many people have improved function without worse pain after tapering opioids.<sup>7,8,9,10,11</sup>
- Follow up frequently. Successful tapering studies have used at least weekly follow up.<sup>10</sup>
- Watch closely for signs of anxiety, depression, suicidal ideation, and opioid use disorder and offer support or referral as needed.<sup>2,3,6</sup> Collaborate with mental health providers and with other specialists as needed to optimize psychosocial support for anxiety related to the taper.<sup>2</sup>

viii Acute opioid withdrawal symptoms and signs include drug craving, anxiety, restlessness, insomnia, abdominal pain or cramps, nausea, vomiting, diarrhea, anorexia, sweating, dilated pupils, tremor, tachycardia, piloerection, hypertension, dizziness, hot flashes, shivering, muscle or joint aches, runny nose, sneezing, tearing, yawning, and dysphoria. Worsening of pain is a frequent symptom of withdrawal that may be prolonged but tends to diminish over time for many patients.

Alpha-2 agonists clonidine and lofexidine are more effective than placebo in ameliorating opioid withdrawal.<sup>17</sup> There is not similar research in patients tapering from long-term opioid treatment for pain.<sup>7</sup> Lofexidine has an FDA-approved indication for use up to 14 days for "mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults."

NSAIDs, acetaminophen, or topical menthol/methylsalicilate for muscle aches; trazodone for sleep disturbance; prochlorperazine, promethazine, or ondansetron for nausea; dicyclomine for abdominal cramping; and loperamide or bismuth subsalicylate for diarrhea.<sup>5</sup>

# **Special populations**

- If patients experience unanticipated challenges to tapering, such as inability to make progress despite intention to taper or opioid-related harm, assess for opioid use disorder using DSM-5 criteria.<sup>2</sup> If patients meet criteria for opioid use disorder (especially if moderate or severe), offer or arrange medicationassisted treatment.<sup>2,3</sup>
- If patients on high opioid dosages are unable to taper despite worsening pain and/or function with opioids, whether or not opioid use disorder criteria are met, consider transitioning to buprenorphine. 4,12 Buprenorphine is a partial opioid agonist that can treat pain as well as opioid use disorder,19 and has other properties that may be helpful,3 including less opioid-induced hyperalgesia12 and easier withdrawal than full mu-agonist opioids,3 and less respiratory depression than other long-acting opioids.20 Buprenorphine can then be continued or tapered gradually.12 Transitioning from full-agonist opioids requires attention to timing of the initial buprenorphine dose to avoid precipitating withdrawal.xi

Consultation with a clinician experienced in use of buprenorphine is warranted if unfamiliar with its initiation. SAMHSA's <u>Providers Clinical Support System</u> offers training and technical assistance as well as mentors to assist those who need to taper opioids and may have additional questions.

 Closely monitor patients who are unable or unwilling to taper and who continue on high-dose or otherwise high-risk opioid regimens. Mitigate overdose risk (e.g., provide overdose education and naloxone).
 Use periodic and strategic motivational questions and statements to encourage movement toward appropriate therapeutic changes.<sup>14</sup>

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xi To avoid precipitating protracted withdrawal from full agonist opioids when starting buprenorphine, patients need to be in mild to moderate withdrawal (including Clinical Opioid Withdrawal Score (COWS) objective signs) before the first buprenorphine dose. 12 To do this, wait at least 8 to 12 hours after the last dose of shortacting full agonist opioids before the first dose of buprenorphine.<sup>12</sup> Buprenorphine buccal film (Belbuca) and buprenorphine transdermal system (Butrans) have FDA-approved indications for "the management of pain severe enough to require daily, aroundthe-clock, long-term opioid treatment and for which alternative treatment options are inadequate." The full Belbuca prescribing information and the full Butrans prescribing information include instructions for conversion from full agonist opioids. More time should be allowed before starting buprenorphine following the last dose of long-acting full agonist opioids (e.g., at least 36 hours after last methadone dose); in addition, transition from methadone to buprenorphine is likely to be better tolerated after methadone is gradually tapered to 40mg per day or less.<sup>12</sup> Because the duration of action for analgesia is much shorter than the duration of action for suppression of opioid withdrawal,21 "split dosing" (e.g., 8mg sublingual tablet twice a day) rather than once a day dosing is used when buprenorphine is provided for pain management.3,12

The U.S. Department of Health and Human Services Working Group on Patient-Centered Reduction or Discontinuation of Long-term Opioid Analgesics, chartered under the Assistant Secretary for Health ADM Brett Giroir, developed this guide:

#### Co-chairs

Deborah Dowell, MD, MPH CAPT, US Public Health Service Centers for Disease Control and Prevention

Christopher Jones, PharmD, DrPH CAPT, US Public Health Service Centers for Disease Control and Prevention

Wilson Compton, MD, MPE National Institutes of Health

# Workgroup members Elisabeth Kato, MD, MRP

Agency for Healthcare Research and Quality

**Joel Dubenitz, PhD**Office of The Assistant Secretary for Planning and Evaluation

Shari Ling, MD
Centers for Medicare and Medicaid Services

**Daniel Foster, DO, MS, MPH** *Food and Drug Administration* 

**Sharon Hertz, MD** *Food and Drug Administration* 

Marta Sokolowska, PhD Food and Drug Administration

**Judith Steinberg, MD, MPH** *Health Resources and Services Administration* 

Meena Vythilingam, MD CAPT, US Public Health Service Office of the Assistant Secretary for Health

**Thomas Clarke, PhD**Substance Abuse and Mental Health Services Administration

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**U.S. Department of Health and Human Services** 

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