Opioid Prescribing Guidelines for Oklahoma Health Care Providers in the Office-Based Setting

Note: These guidelines do not replace clinical judgment in the appropriate care of patients. They are not intended as standards of care or as templates for legislation, nor are they meant for patients in palliative care programs or with cancer pain. The recommendations are an educational tool based on the expert opinion of numerous physicians and other health care providers, medical/nursing boards, mental and public health officials, and law enforcement personnel in Oklahoma and throughout the United States. The guidelines are available at http://poison.health.ok.gov.

Opioid Treatment for Acute Pain

1. Opioids should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.

2. Providers should query the Oklahoma Prescription Monitoring Program (PMP) for patients presenting with acute pain, prior to prescribing an opioid medication. In circumstances where a patient’s pain is resulting from an objectively diagnosed disease process or injury, a provider may prudently opt not to review the Oklahoma PMP.

3. When opioids are prescribed for treatment of acute pain, the number of doses dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

4. When opioids are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.

5. Long duration-of-action opioids (e.g., methadone, buprenorphine, fentanyl, extended release oxycodone, and morphine) are rarely indicated for treatment of acute pain.

6. The use of opioids should be re-evaluated carefully, including assessing the potential for abuse, if persistent pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition. Health care providers should query the Oklahoma PMP as part of this re-evaluation process.

7. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

Opioid Treatment for Chronic Pain

1. Alternatives to opioid treatment should be tried, or previous attempts documented, before initiating opioid treatment.

2. A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. For chronic pain patients transferring their care to new health care providers, new opioid prescriptions should generally not be written until the previous provider’s records have been reviewed or the previous health care provider has been notified of the transfer of care.

3. The health care provider should screen for risk of abuse or addiction before initiating opioid treatment.

4. Prior to the initial prescribing of opioid medications, health care providers should query the Oklahoma Prescription Monitoring Program (PMP).

5. When opioids are used for the treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function. One health care provider should coordinate a patient’s comprehensive pain care plan and provide all opioid prescriptions required for the plan.

9/29/2014
6. The patient should be informed of the risks, benefits, and terms for continuation of opioid treatment, ideally using a written and signed treatment agreement.

7. Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. In most instances, the trial should begin with a short-acting opioid medication.

8. Regular visits for evaluation of progress toward goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma PMP more frequently.

9. Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. The Oklahoma PMP should be queried at least once per year for patients receiving opioid treatment for chronic pain.

10. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of chronic opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, weaning whenever possible, as part of the comprehensive pain care plan. A second opinion or consultation may be useful in making that decision.

11. Opioid treatment should be discontinued if adverse effects outweigh benefits or if aberrant, dangerous, or illegal behaviors are demonstrated.

12. Health care providers treating chronic pain patients with opioids should maintain records, in accordance with state and federal law, documenting patient evaluation, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.

13. Health care providers should consider consultation for patients with complex pain conditions, serious co-morbidities and mental illness, a history or evidence of current drug addiction or abuse, or when the provider is not confident of his/her ability to manage the treatment.

14. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

15. The administration of intravenous and intramuscular opioids for the relief of exacerbations of chronic pain is discouraged, except in special circumstances.

16. Long-acting opioids are associated with an increased risk of overdose death, and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.

17. When opioids are prescribed for treatment of chronic pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.
Background

Prescription drug abuse is Oklahoma’s fastest growing drug problem. Of the nearly 3,200 unintentional poisoning deaths in Oklahoma from 2007-2011, 81% involved at least one prescription drug. In 2010, Oklahoma had the fourth highest unintentional poisoning death rate in the nation (17.9 deaths per 100,000 population). Prescription painkillers (opioids) are now the most common class of drug involved in overdose deaths in Oklahoma (involved in 87% of prescription drug-related deaths, with 417 opioid-involved overdose deaths in 2011). In a 2010 National Survey on Drug Use and Health report, Oklahoma led the nation in non-medical use of painkillers, with more than 8% of the population age 12 and older abusing/misusing painkillers. Oklahoma is also one of the leading states in prescription painkiller sales per capita.

These guidelines were primarily adapted from the Utah Clinical Guidelines on Prescribing Opioids. The Opioid Prescribing Guidelines for Oklahoma Workgroup also studied other state and national recommendations in an effort to prepare guidelines most relevant to the practice of medicine in Oklahoma. The Workgroup created these guidelines in an effort to help reduce the misuse of prescription opioid analgesics while preserving patient access to needed medical treatment.

Guidelines for Acute Pain

1. Opioids should only be used for treatment of acute pain when the severity of the pain warrants that choice and after determining that other non-opioid pain medications or therapies will not provide adequate pain relief.

Most acute pain is better treated with non-opioid medications [e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs)] or physical modalities such as therapeutic exercises or stretching. Opioid medications have less desirable adverse effect profiles in acute pain patients. Care should be taken to assure that opioid treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. Non-medical use of opioids is more common among younger people, and these risks should be considered when prescribing to an adolescent.

2. Providers should query the Oklahoma Prescription Monitoring Program (PMP) for patients presenting with acute pain, prior to prescribing an opioid medication. In circumstances where a patient’s pain is resulting from an objectively diagnosed disease process or injury, a provider may prudently opt not to review the Oklahoma PMP.

The Oklahoma PMP is a real-time database of scheduled prescriptions written to persons who filled a prescription in Oklahoma. The Oklahoma PMP can be accessed at: http://www.ok.gov/obndd/Prescription_Monitoring_Program/.

Patients with a history of or current substance abuse are at increased risk of misusing opioids when prescribed. Medical providers should ask the patient about a history of substance abuse prior to prescribing an opioid regimen for the treatment of acute pain. A non-opioid regimen is preferred for patients presenting with a history of substance abuse who have acute pain. Although this should not exclude a patient from being prescribed opioids for acute pain, it should prompt a discussion with the patient about the potential for addiction. When a patient with a history of opioid addiction presents with acute pain due to an objectively diagnosed clinical or traumatic condition requiring the use of opioids for pain control, very close follow-up is indicated.

3. When opioids are prescribed for treatment of acute pain, the number of doses dispensed should be no more than the number of doses needed based on the usual duration of pain severe enough to require opioids for that condition.

Prescribing more medications than necessary can lead to non-medical use, abuse, and diversion of unused medications. Opioid pain medications should be discontinued when the pain severity no longer requires opioid medications.
4. When opioids are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.

It is important that patients understand the need to store medications securely. Health care providers should encourage patients to keep medications in a locked environment rather than in easily accessible locations, such as the bathroom or kitchen cabinet, where medications are accessible to children and can be a target for theft. After recovery from pain, leftover medications should be properly disposed of immediately to help protect the medications from being diverted.

Tools to accompany Recommendation 4:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs 

- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations  

5. Long duration-of-action opioids (e.g., methadone, buprenorphine, fentanyl, extended release oxycodone, and morphine) are rarely indicated for treatment of acute pain.

Given the epidemiological data showing a significant increase in mortality associated with long-acting opioids, the inherent difficulty in titrating these medications, and the availability of alternative medications and/or treatment modalities, health care providers are advised to refrain from the routine use of long-acting opioids in the acute pain setting.5,9

6. The use of opioids should be re-evaluated carefully, including assessing the potential for abuse, if persistent pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition. Health care providers should query the Oklahoma PMP as part of this re-evaluation process.

Patients with acute pain who fail to recover in a usual timeframe or otherwise deviate from the expected clinical course for their diagnosis should be carefully re-evaluated. The continuation of opioid treatment for acute pain in this setting may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such. At this time, the diagnosis and appropriateness of the treatment plan should be re-evaluated and the patient’s medical history should be reviewed for factors that could interfere with treatment and pose a risk for complications during opioid treatment, including substance abuse or history of substance abuse.

Tools to accompany Recommendation 6:

- Oklahoma Prescription Monitoring Program 
  http://www.ok.gov/obndd/Prescription_Monitoring_Program/

7. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

Patients misusing controlled substances frequently report their opioid medications as having been lost or stolen. Pain specialists routinely stipulate in pain agreements with patients that lost or stolen controlled substances will not be replaced. Most written agreements between chronic pain patients and pain management physicians, including the Health Resources and Services Administration (HRSA) toolkit sample pain agreement, state that prescriptions for opioids will not be replaced.10

The diversion of prescribed opioids is common. One study looked at completed patient surveys, and found that 45% of respondents reported some form of drug diversion at least once. Stolen medication was the most prevalent method of drug diversion, with 30% of respondents reporting at least one incident of stolen medication.11 In another survey study, among persons 12 years and older who abused opioid pain medications
(2009-2010), 71.2% came from friends or relatives; 55% were given to the abuser, 11.4% were purchased, and 4.8% were stolen.\textsuperscript{12,13}

**Guidelines for Chronic Pain**

1. Alternatives to opioid treatment should be tried, or previous attempts documented, before initiating opioid treatment.\textsuperscript{6,9,13,14,15}

Opioid medications are usually not the most appropriate first line of treatment for patients with chronic pain. Other measures, such as non-opioid pain medications, non-steroidal anti-inflammatory drugs (NSAIDs), antidepressants, antiepileptic drugs, and non-pharmacologic therapies (e.g., therapeutic exercise, physical therapy), should be tried first and the outcomes of those therapies documented. Opioid therapy should be considered only when other potentially safer and more effective therapies prove inadequate. This approach is consistent with the World Health Organization’s (WHO) Pain Relief Ladder.\textsuperscript{16}

1.1 Clinicians should refer to disease-specific guidelines for recommendations for treatment of chronic pain related to specific diseases or conditions.

Tools to accompany Recommendation 1:

- Non-opioid Pain Management Tool
  
  \url{http://health.utah.gov/prescription/tools.html} (see Informational Tools on website)

2. A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. For chronic pain patients transferring their care to new health care providers, new opioid prescriptions should generally not be written until the previous provider’s records have been reviewed or the previous health care provider has been notified of the transfer of care.\textsuperscript{13,14,15,17}

There are many reasons to prescribe cautiously when initiating opioid therapy; therefore a comprehensive initial evaluation is necessary to identify patients at high risk for adverse outcomes. The major goal should be to provide the greatest functional benefit while minimizing the potential for harm to patients. The potential for serious harm, including death, exists due either to overdose or to dangerous behaviors that may occur while taking opioids. The patient may be directly harmed, but others may also be harmed through diversion or by acts performed by a person taking opioids.

Initiating opioid treatment often results in short-term relief, which may not be sustainable. Safe long-term use of opioid medications requires the commitment of adequate resources. Patients need to be monitored regularly to evaluate outcomes and identify aberrant behavior or adverse side effects.

The goal of the comprehensive evaluation is to determine the nature of the patient’s pain, and to evaluate how the pain is affecting the patient’s function and quality of life. The provider should attempt to identify other conditions or circumstances that could adversely affect the treatment plan or the approach to managing the patient’s treatment plan. The provider should also re-assess and re-evaluate prior approaches to the patient’s pain management to provide a basis for establishing an effective ongoing plan of care.

The evaluation should specifically assess:

A. The character and potential cause(s) of pain, as well as prior treatments.

- The duration of the pain should be considered.
- The character of the pain should be considered. Since certain types of pain, such as neuropathic pain, might not be best treated with opioids. It is important for the clinician to consider the type and character of pain when prescribing a medication.

B. Social factors and medical or mental health conditions might influence treatment, especially those that might interfere with appropriate and safe use of opioid therapy.\textsuperscript{14}

- Obtain a history of substance use, addiction, or dependence. (If present, refer to Recommendations 13.2
Consider potential psychiatric conditions, including personality disorders that may affect pain or the treatment of pain. (If present, refer to Recommendation 13.4.)

Identify use of alcohol and other medications that might interact with opioid medications used to treat pain. Particular attention and caution should be given to alcohol, benzodiazepines, and other sedative medications.

Assess the presence of medical conditions that might complicate the treatment of pain, including medication allergy, cardiac or respiratory disease, and sleep apnea or risk factors for sleep apnea.

Central sleep apnea is common among persons treated with methadone and other opioid medications, especially at higher dosages. Some experts recommend that all patients who are considered for long-term opioid treatment receive a sleep study prior to therapy or when higher dosages are considered.

C. Effects of pain on the patient’s life and function.

Assess the patient’s baseline severity of pain, functional status, and quality of life using a valid, reliable method/instrument that can be used later to evaluate treatment effectiveness.

Tools to accompany Recommendation 2:

- Sheehan Disability Tool

- Pain Management Evaluation Tool

3. The health care provider should screen for risk of abuse or addiction before initiating opioid treatment.

3.1 Use a screening tool to assess the patient’s risk of misuse prior to prescribing an opioid medication for chronic pain.

A number of screening tools have been developed for assessing a patient’s risk of misuse of medications. The screening tools are intended to assist the health care provider in determining whether opioid treatment is appropriate and in determining the level of monitoring appropriate for the patient’s level of risk.

3.2 Consider performing drug screening before initiating long term opioid treatment for chronic pain.

Drug testing can identify problems, such as use of undisclosed medications, non-use of reported medications (i.e., potential diversion), undisclosed use of alcohol, or the use of illicit substances, not identified without testing.

Health care providers should use a urine drug screen or another laboratory test that can detect the presence of illegal drugs, unreported prescription medications, and/or unreported alcohol use. It is recommended that drug testing be strongly considered and conducted, especially when other factors suggest caution. When screening is limited to situations where there is suspicion of substance misuse, some opportunities may be missed. In one study, testing results upon first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most discrepancies involved substances not reported by the patient; a small minority reported taking medications that were not found on testing.

A positive drug screen indicates the need for caution, but does not preclude opioid use for the treatment of pain. However, consideration should be given to referral for substance abuse counseling and/or a pain management specialist. If an opioid medication is subsequently prescribed, the patient should be more carefully monitored and the conditions under which opioids are being prescribed should be well documented in the treatment plan.

Inexpensive immunoassays can be performed in the office. These tests can rapidly determine if opioids are
present but they do not identify specific substances. When necessary, specific substances can be identified by ordering confirmatory laboratory testing. However, in many cases, candidly going over the results of the initial in-office test with the patient can eliminate the need for confirmatory testing. It is extremely important to keep in mind that immunoassays have both false-positive and false-negative results. Certain over-the-counter medications may cause a positive result. The prescriber should consider confirmatory gas chromatography or mass spectrometry testing or consultation with a certified Medical Review Officer if drug test results are unclear or confirmation is clinically necessary.9

Tools to accompany Recommendation 3:

- Urine Drug Testing Devices
- Current Opioid Misuse Measure
  http://health.utah.gov/prescription/tools.html (see Tools to Screen for Risk of Complications on website)
- SOAPP-R
  http://health.utah.gov/prescription/tools.html (see Tools to Screen for Risk of Complications on website)
- Opioid Risk Tool
- Signs of Substance Misuse
- Checklist for Adverse Effects, Function, and Opioid Dependence

4. Prior to the initial prescribing of opioid medications, health care providers should query the Oklahoma Prescription Monitoring Program (PMP).

Most patients who request treatment for pain are legitimately seeking relief of pain. However, subsets of patients seeking treatment for pain are seeking drugs for recreational use, to support an established addiction, or for profit. Information about past patterns of controlled substance prescriptions filled by the patient, such as obtaining medications from multiple providers or obtaining concurrent prescriptions, can alert the provider to potential problems.

The Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDCC) maintains the Oklahoma Prescription Monitoring Program, a real time, searchable database of all controlled substance prescriptions filled in the state. The PMP is used to track and collect data on the dispensing of Schedule II-V drugs by all retail, institutional, and outpatient hospital pharmacies, and in-state/out-of-state mail order pharmacies. Access to the data is provided to authorized individuals and used to identify potential cases of drug over-utilization, misuse, and potential abuse of controlled substances throughout the state. This database is accessible online to all controlled substance prescribers.

Tools to accompany Recommendation 4:

- Oklahoma Prescription Monitoring Program
  http://www.ok.gov/obndd/Prescription_Monitoring_Program/

5. When opioids are used for the treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function. One health care provider should coordinate a patient’s comprehensive pain care plan and provide all opioid prescriptions required for the plan.

5.1 The treatment plan should be tailored to the patient’s circumstances and the characteristics and pathophysiology of the pain. The pathophysiology helps to predict whether opioid medication is likely to help reduce pain or to improve function, and should be considered when establishing treatment goals. Non-opioid treatment modalities should be included in the treatment plan, whenever possible, to maximize the likelihood of
achieving treatment goals.

5.2 Goals for the treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain.6,9,14

For most chronic pain conditions, complete elimination of pain is an unreasonable goal. Goals for treatment of chronic pain should include improvement in the tolerability of pain and function.15 The clinician should counsel the patient on reasonable expectations for treatment outcomes so that agreement is achieved on the goals of addressing pain, function, and quality of life.

The pathophysiologic basis of the pain can help establish a prognosis for future improvement (or worsening) in function and pain and should influence the goals of treatment. Goals for functional improvement and measures to track progress against those goals should be established and documented to serve as a basis of evaluating treatment outcomes.6,14 These include:

- Objective physical findings obtained by the examining health care provider (e.g., improved strength, range of motion, aerobic capacity);
- Functional status at work (e.g., increase in physical output, endurance, or ability to perform job functions); and
- Functional status at home (e.g., increased ability to perform instrumental activities of daily living, and frequency and intensity of conditioning).

Targets for improved quality of life should also be identified and documented to serve as a basis for evaluating treatment outcomes. These may include:

- Patient rating of quality of life on a measurement scale;
- Psychosocial status (e.g., increased social engagement or decreased emotional distress);
- Familial status (e.g., improved relationships with, or decreased burden, on family members); and
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Health care providers should consider cultural differences in assessing function, quality of life, and pain intensity (see http://prc.coh.org/culture.asp for examples). These measures of improvement could be reported by the patient, family members, and/or the employer. Permission to discuss the patient’s condition with these persons should have been previously obtained and documented.

5.3 Treatment goals should be developed jointly by the patient and health care provider.15

Engage patients in their own health care. Health care providers have observed that when patients assume a significant portion of the responsibility for their rehabilitation they are more likely to improve and that when they participate in goal setting they are more likely to achieve the goals. As with any other chronic illness (such as diabetes or heart disease), the health care provider should focus not just on pain control, but also on treating the patient’s underlying diseases and encouraging them to engage in ownership of their own health.

Tools to accompany Recommendation 5:

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking Chart
- Sheehan Disability Scale
- Brief Pain Inventory Form
  http://health.utah.gov/prescription/pdf/guidelines/BriefPainInvNPEC.pdf
6. The patient should be informed of the risks, benefits, and terms for continuation of opioid treatment, ideally using a written and signed treatment agreement.13

6.1 Patients should be informed not to expect complete relief from pain. The excitement and euphoria of initial pain relief that may occur with a potent opioid can lead the patient to expect long-term complete pain relief. Without careful guidance, this may lead the patient to disappointment and to seek excessive doses of opioids.

The patient should be counseled about the appropriate use of opioid medications, possible adverse effects, and the risks of developing tolerance, physical and/or psychological dependence, and withdrawal symptoms.9,19 Adverse effects can include opioid-induced hyperalgesia, allodynia, abnormal pain sensitivity, and depression.6,9,20

Sedation and cognitive impairment may occur when patients are taking opioid medications. Therefore, discuss with patients the need for caution in operating motor vehicles or equipment or performing other tasks where impairment would put them or others at risk.11

Ensure the patient does not have any absolute contraindications, and review risks and benefits related to any relative contraindications with the patient.

Absolute contraindications for opioid prescribing:

- Allergy to an opioid agent (may be addressed by using an alternative agent);
- Co-administration of a drug capable of inducing life-threatening drug-drug interaction; and
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed).

More detail about absolute contraindications is contained in the Guidelines Tools section.

Consider co-prescribing naloxone for high risk patients, and providing training to family/caregivers to reverse potential life-threatening depression of the respiratory and central nervous system. Educate patients and family/caregivers about the danger signs of respiratory depression. Everyone in the household should know to summon medical help immediately if a person demonstrates any of the following signs while on opioids:

- Snoring heavily and cannot be awakened;
- Periods of ataxic (irregular) or other sleep disordered breathing;
- Trouble breathing;
- Exhibiting extreme drowsiness and slow breathing;
- Slow, shallow breathing with little chest movement;
- Increased or decreased heartbeat; and
- Feeling faint, very dizzy, confused or has heart palpitations.

6.2 The patient and, when applicable, the family or caregiver should be involved in the education process.14

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver.14 Educating the family or caregiver about the signs of opioid overdose may help detect problems before they lead to a serious complication.

It is important to act within the constraints of the Health Insurance Portability and Accountability Act (HIPAA). HIPAA regulates the conditions under which information about the patient can be disclosed to others, such as
family members, and under what conditions discussions about the patient with others are allowed.

6.3 The treatment plan, which defines the responsibilities of both the patient and health care provider, should be documented.6,9,13,14,15

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. Patient responsibilities also include instructions to keep a pain diary, a diary or log of daily activities and accomplishments, and/or instructions on how and when to give feedback to the prescriber.14

The prescribing health care provider may consider requiring that the treatment plan be documented in the form of a treatment agreement signed by the patient. Patients should be encouraged to store opioid medications in a secure location to keep the medication away from others who should not have access to them.

6.4 The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum screening upon request, and reasons for possible discontinuation of drug therapy.9,13,14,15,17

The treatment plan (sometimes referred to as a treatment agreement) should contain the items developed jointly by the patient and health care provider, such as follow-up appointments, the pharmacy and health care provider to be used, as well as any non-negotiable demands or limitations the health care provider wishes to make, such as the prohibition of sharing or trading the medication or getting refills early. Specific grounds for immediate termination of the agreement and cessation of prescribing may also be specified, such as forgery or selling of prescriptions or medications or obtaining them from multiple providers as documented by Oklahoma’s Prescription Monitoring Program.14,20

Optional inclusions in the agreement:

- Pill counts may be required as a means to gauge proper medication use;14,19
- Prohibition of use with alcohol or certain other medications;14
- Documentation of counseling regarding driving or operating heavy machinery; and 6,14
- Specific frequencies of urine testing.

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only.14,17,19

It is not necessary to include specific consequences for specific non-compliant behaviors, but it should be documented in the treatment agreement that continuing failure by the patient to adhere to the treatment plan will result in escalating consequences, up to and including termination of the clinician-patient relationship and of opioid prescribing by that clinician.

6.5 Discuss involvement of family members in the patient’s care and request that the patient give written permission to talk with family members about the patient’s care.

This is best done before starting to treat the patient because it can be more difficult to obtain consent after an issue occurs. Prior to initiating treatment with opioids, the health care provider may want to consider a family conference to help assess the patient’s integrity.19 Consultation with others, however, must be done within the constraints of HIPAA, as noted above. (See Recommendation 6.2.)

Tools to accompany Recommendation 6:

- Absolute Contraindications to Opioid Prescribing
- Sample Treatment Plan for Prescribing Opioids
- Signs of Substance Misuse
- Guidance on HIPAA
Initiating, Monitoring, and Discontinuing Opioid Treatment

7. Opioids should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life. In most instances, the trial should begin with a short-acting opioid medication.

7.1 The health care provider should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with predetermined evaluation points. The decision to continue opioid medication treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. Criteria for cessation should be considered before treatment begins. Refer to Recommendation 11 for more information on discontinuation of treatment.

7.2 Short-acting opioid medications are, in general, safer and easier to titrate to an effective dose. If the treatment trial proves successful in achieving the goals established in the treatment plan, the health care provider may consider switching the patient to a long-acting or sustained-release formulation. The patient’s individual situation should influence whether the patient is switched from a short-acting medication. Treatment with a long-acting opioid medication before a trial using a short-acting medication has been performed is an option that should be prescribed only by those with considerable expertise in chronic pain management.

Tools to accompany Recommendation 7:
- Dosing Guidelines
- Current Opioid Misuse Measure (COMM)
  http://health.utah.gov/prescription/tools.html (see Tools to Screen for Risk of Complications on website)

Titration Phase of Opioid Treatment

8. Regular visits for evaluation of progress toward goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma PMP more frequently.14

8.1 Face-to-face follow-up visits should occur at least every 2-4 weeks during the titration period. More frequent follow-up visits may be advisable and caution should be used when prescribing an opioid medication if the patient has a known addiction problem, suspected drug-behavior problems, or co-existing psychiatric or medical problems. Frequency of visits should also be based on risk stratification (e.g., as determined by a screening tool) and the clinician’s judgment (taking into account the volume of the drug being prescribed and how likely it is to be abused).15

8.2 When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered.14,15

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than necessary by increasing too slowly with the risk of causing harm, including fatal overdose, by increasing too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient.14 Age, health, and severity of pain should be taken into consideration when deciding on increments and rates of titration. Particular caution should be used in titrating dosing of methadone.

Evidence and other guidelines are not in agreement regarding the risks and benefits of high daily doses of
opioid measured in morphine milligram equivalents (MMEs). It is likely that the risk-benefit ratio is less favorable at higher doses. Clinical vigilance is needed at all dosage levels of opioids, but is even more important at higher doses. Health care providers who are not experienced in prescribing high doses of opioids should consider either referring the patient or obtaining a consultation from a qualified provider for patients receiving high dosages. No clear threshold for a high dose has been established based on evidence. The Washington State guidelines suggest a threshold of 120 MME per day. It is important to increase clinical vigilance at doses exceeding 120 MME per day. Patients receiving 100 MME or more per day had a 9-fold increase in overdose risk. Most overdoses were medically serious, 12% were fatal.9

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to use medication only as directed, that is, not to change doses or frequency of administration without specific instructions from the health care provider.

8.3 During the titration period, and until the patient is clinically stable and judged to be compliant with therapy, it is recommended that the health care provider check the Oklahoma Prescription Monitoring Program more frequently, such as monthly or quarterly.

Tools to accompany Recommendation 8:

- Dosing Guidelines
- Electronic MME Dosing Calculator
  http://agencymeddirectors.wa.gov/mobile.html
- Prescription Monitoring Program
  http://www.ok.gov/obnbd/Prescription_Monitoring_Program/

Maintenance of Opioid Treatment

9. Once a stable dose has been established (maintenance period), regular monitoring should be conducted at face-to-face visits during which treatment goals, analgesia, activity, adverse effects, and aberrant behaviors are monitored. The Oklahoma PMP should be queried at least once per year for patients receiving opioid treatment for chronic pain.13,15

9.1 The health care provider is advised to consider baseline drug testing at the initiation of opioid treatment, compliance monitoring one to three months later, and random monitoring every 6-12 months. In the event of unexpected drug screens or suspicious patient behavior, additional monitoring can be performed. Health care providers may consider each of the following four areas of concern at each visit: Analgesia, Activity, Adverse effects, and Aberrant behavior. These assessments can be remembered as the “four A’s”: 21

- Analgesia: inquire about level of pain (current, recent, trends, etc.)
- Activity: assess the patient’s function and overall quality of life
- Adverse events: determine whether the patient is having medication side effects
- Aberrant behavior: evaluate for possible drug abuse-related behavior

9.2 During the maintenance period, the Oklahoma Prescription Monitoring Program should be checked at least annually.

After the titration period is complete and the maintenance period is underway, the frequency of checks of the Oklahoma PMP can be based on clinical judgment, but should be done no less than annually. The Oklahoma PMP should be checked more often for high risk patients and patients exhibiting aberrant behavior.

9.3 Continuation or modification of treatment should depend on the health care provider’s evaluation of progress towards stated treatment goals.13

Treatment goals include reduction in a patient’s pain scores and improved physical, psychological, and social
function. If patient compliance with agreed-upon activity levels, are not being achieved despite medication adjustments, the health care provider should re-evaluate the appropriateness of continued treatment with the current medications.9,17

A frequent need for dose adjustments after a reasonable time interval of titration is an indication to re-evaluate the underlying condition and consider the possibility the patient has developed opioid hyperalgesia, substantial tolerance, or psychological/physical dependence.

9.4 Adjustments to previously stable maintenance treatment may be considered if the patient develops tolerance, a new pain-producing medical condition arises or an existing one worsens, or if a new adverse effect emerges or becomes more clinically significant.14

Options for adjustment include reducing the medication or rotating opioid medications. If it is documented that the patient is compliant with agreed-upon recommendations such as exercise, working, etc., the addition of supplemental short-acting medications for control of break-through pain (e.g., as related to an increase in activity, end-of-dose pain, weather-related pain exacerbation, or specific medical conditions) can be considered as well. If patients do not achieve effective pain relief with one opioid, rotation to another frequently produces greater success.22 If rotating among different opioid medications, refer to a standard dosing equivalence table, taking into account the current drug’s half-life and potency.

If the patient’s situation has changed permanently and consideration is given to the increased risk of adverse events, it is reasonable to consider an ongoing increase in maintenance dosing. In general, if the patient’s underlying medical condition is chronic and unchanging, and if opioid-associated problems (hyperalgesia, substantial tolerance, important adverse effects) have not developed, it is recommended that the effective dose achieved through titration not be lowered once the patient has reached a plateau of adequate pain relief and functional level.14

9.5 Dosing changes should generally be made during a clinic visit.14

If the patient’s underlying, pain-producing, chronic medical condition improves, it is expected that the health care provider will begin tapering the patient off the opioid medication. (See Recommendation 11 for guidelines on discontinuation.)

Tapering an opioid medication with or without the goal of discontinuation may be performed as described below (Recommendation 11) or as described in the Strategies for Tapering and Weaning Tool.

Tools to accompany Recommendation 9:

- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse
- Pain Management Evaluation Tool
- Dosing Guidelines
- Strategies for Tapering and Weaning

Evaluating the Opioid Treatment Trial

10. Continuing opioid treatment should be a deliberate decision that takes into consideration the risks and benefits of chronic opioid treatment for that patient. Patients and health care providers should periodically reassess the need for continued opioid treatment, weaning
whenever possible, as part of the comprehensive pain care plan. A second opinion or consultation may be useful in making that decision.

The health care provider should clearly explain to the patient that initiation of opioid treatment is not a commitment to long-term opioid treatment and that treatment will be stopped if the trial is determined to be unsuccessful. The trial should be for a specific time period with pre-determined evaluation points. The decision to continue opioid treatment beyond the trial period should be based on the balance between benefits, including function and quality of life, and adverse effects experienced. A second opinion or consult may be useful in making the decision to continue or discontinue opioids after the treatment trial.

**Discontinuing Opioid Treatment**

11. Opioid treatment should be discontinued if adverse effects outweigh benefits, or if aberrant, dangerous, or illegal behaviors are demonstrated.9

11.1 Discontinuation of opioid treatment is recommended if any of the following occurs:

- Dangerous or illegal behaviors are identified;
- Patient claims or exhibits a lack of effectiveness;
- Pain problem resolves;
- Patient expresses a desire to discontinue therapy; and
- Opioid treatment appears to be causing harm to the patient, particularly if harm exceeds benefit.14

The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver.17 This decision should include careful consideration of the outcomes of ongoing monitoring.

11.2 When possible, offer to assist patients in safely discontinuing medications, even if they have withdrawn from treatment or been discharged for agreement violations.14

The goal is to taper all patients off opioid medications safely. If the patient is discharged, the health care provider is obliged to offer continued monitoring for 30 days post-discharge. Possible complications of opioid withdrawal should be taken into consideration when discontinuing or tapering opioid medications.

Tools to accompany **Recommendation 11**:

- Strategies for Tapering and Weaning

**Documentation and Medical Records**

12. Health care providers treating chronic pain patients with opioids should maintain records, in accordance with state and federal law, documenting patient evaluation, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.9,13,14,15,17

12.1 A written treatment plan should document objectives that will be used to evaluate treatment success.9,13,14,15,17

12.2 Opioid prescriptions should be written on tamper-resistant prescription paper to help reduce the likelihood of prescription fraud or misuse.15

To reduce the chance of tampering with the prescription, write legibly, and keep a copy.15

12.3 Assessment of treatment effectiveness should be documented in the medical record.9,13,15

Both the underlying medical condition responsible for the pain, if known, and other medical conditions that may
affect the efficacy of treatment or risks of adverse events should be assessed and documented at every visit.

Health care providers should consider utilizing a standardized approach such as “The Four A’s” or “The SAFE Tool” for medical documentation. The Four A’s considers four areas of concern: Analgesia, Activity, Adverse effects, and Aberrant behavior. The SAFE Tool is a numerical five point scoring system that helps to guide the health care provider toward broader views of treatment options. It considers four areas of concern: social functioning (S), analgesia (A), physical function (F), and emotional functioning (E).

The Four A’s can be remembered as:
- Analgesia: inquire about level of pain (current, recent, trends, etc.);
- Activity: assess both the patient’s function and overall quality of life;
- Adverse events: determine whether the patient is having medication side effects; and
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior.

The SAFE Tool can be remembered as:
- Social functioning: inquire about family and employment relationships;
- Analgesia: inquire about level of pain (current, recent, trends, etc.);
- Physical functioning: inquire about how well the patient is meeting goals; and
- Emotional functioning: ask about changes in the patient’s mental health status.

Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record.

Specific components of the treatment plan for which adherence should be assessed include:
- Use of opioid analgesics; and
- Follow-up referrals, tests, and other therapies.

Health care providers are encouraged to make use of resources designed to assist them in managing the care of patients with aberrant behavior. Serious non-adherence issues (e.g., illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid treatment.

Tools to accompany Recommendation 12:
- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse
- Federal Laws on Prescribing Controlled Substances (21 CFR 1306 et. seq.)
  http://www.deadiversion.usdoj.gov/21cfr/cfr/
- Osteopathic Rules on Prescribing for Intractable Pain (OAC 510:5-9-1 et. seq.)
  http://www.ok.gov/osboe/documents/RULES.pdf
- Medical Board Rules on Prescribing for Intractable Pain (OAC 435:10-7-11 et. seq.)
  http://www.okmedicalboard.org/download/457/MDRULES.pdf

Consultation and Management of Complex Patients

Health care providers should consider consultation for patients with complex pain conditions, serious co-morbidities and mental illness, a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her ability to manage the treatment.

Prescribers may wish to consider referring patients if any of the following conditions or situations are
present, or if other concerns arise during treatment:

- The patient has a complex pain condition and the clinician wishes verification of diagnosis;
- The patient has significant co-morbidities, including psychiatric illness;
- The patient is at high risk of aberrant behavior or addiction; or
- The clinician suspects the development of significant tolerance, particularly at higher doses.

The main goal of a consultation is for the prescribing clinician to receive recommendations for ongoing treatment.

13.2 Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be closely monitored (e.g., more frequent random drug screens, random pill counts) or considered for referral to an addiction specialist for evaluation of recurrent risk and for assistance with treatment.9,13,14

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Oklahoma where there is a shortage of readily available addiction specialists.

13.3 Pain patients addicted to medications/drugs should be referred to a pain management and/or mental health/substance use disorder specialist, if available, for recommendations on the treatment plan and assistance in management.

The health care provider may consider prescribing opioid medications for pain even if the patient has a self-reported or documented previous opioid abuse problem, as long as monitoring is performed during the titration and maintenance phase.

13.4 Patients with a coexisting psychiatric disorder should receive ongoing mental health support and treatment while receiving an opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation.17,19 Consultation can be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric condition(s).

Tools to accompany Recommendation 13:

- Strategies for Tapering and Weaning

14. Health care providers should generally not provide replacement prescriptions for opioids that have been lost, stolen, or destroyed.

Patients misusing controlled substances frequently report their opioid medications as having been lost or stolen. Pain specialists routinely stipulate in pain agreements with patients that lost or stolen controlled substances will not be replaced. Most written agreements between chronic pain patients and pain management physicians, including the Health Resources and Services Administration (HRSA) toolkit sample pain agreement, state that prescriptions for opioids will not be replaced.10

The diversion of prescribed opioids is common. One study looked at completed patient surveys and determined that 45% of respondents reported some form of drug diversion at least once. Stolen medication was the most prevalent method of drug diversion, and 30% of respondents reported at least one incident of stolen medication.11 Another survey study found that among persons 12 years and older who abused opioid pain medications (2009-2010), 71.2% came from friends or relatives; 55% were given to the abuser, while 11.4% were purchased, and 4.8% were stolen.12,13

15. The administration of intravenous and intramuscular opioids for the relief of exacerbations of chronic pain is discouraged, except in special circumstances.
Parenteral opioids should be generally avoided for the treatment of chronic pain because of their short duration and potential for addictive euphoria. For chronic pain, oral opioids are superior to parenteral opioids in duration of action and provide a gradual decrease in the level of pain control. When there is evidence or reasonable suspicion of an acute pathological process causing the acute exacerbation of chronic pain, parenteral opioids may be appropriate.

Tools to accompany Recommendation 15:

- Dosing Guidelines
- Current Opioid Misuse Measure (COMM)
  http://health.utah.gov/prescription/tools.html (see Tools to Screen for Risk of Complications)

Methadone and Extended Release/Long-Acting Opioids

16. Long-acting opioids are associated with an increased risk of overdose death, and should only be prescribed by health care providers familiar with their indications, risks, and need for careful monitoring.

16.1 The prescription use of methadone remains controversial due to concerns about its efficacy and safety. During the past two decades methadone-related death rates increased in Oklahoma and the U.S. From 2007-2011, methadone was listed in the cause of death in 21% of prescription drug-related unintentional poisoning deaths in Oklahoma.1

The half-life of methadone is long and unpredictable, increasing the risk of inadvertent overdose. The peak respiratory depressant effect of methadone occurs later and lasts longer after treatment initiation or dosage change than does the peak analgesic effect. Conversion tables that have been established to assist with converting a patient from another opioid medication to methadone are considered by many experts to be unreliable.

Methadone metabolism is complicated and varies among individuals. Methadone interacts with several other medications that can alter its metabolism, changing the effects of a given dose on pain and on respiratory depression. Potential for interactions should be considered before starting methadone in a patient taking other medications, and before starting any medication in a patient taking methadone.

Methadone can prolong the rate-corrected QT interval (QTc), increase the risk of Torsades de Pointe, and sudden cardiac death. Caution should be used in prescribing methadone to any patient at risk for prolonged QTc interval, including those with structural cardiac disease, cardiac arrhythmias or cardiac conduction abnormalities and in patients taking another medication associated with QTc interval prolongation.24 An online reference of such medications is available at: http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm.

Health care providers should consider obtaining an electrocardiogram (ECG) to measure the QTc interval in patients treated with methadone, especially at higher doses. A recently published consensus guideline recommended that an ECG be performed before prescribing methadone, within the first 30 days, and annually. Additional ECG examinations were recommended if the methadone dose exceeds 100 mg per day or if a patient on methadone has unexplained syncope or seizure. Guidance was provided for actions to be taken at two levels of QTc prolongation (450-500 ms and greater than 500 ms).25

Methadone and other opioids have been associated with worsening obstructive sleep apnea and new onset of central sleep apnea. Clinicians should question patients about symptoms and signs of sleep apnea and consider obtaining a sleep study in patients treated with opioids if they develop any signs of sleep-disordered breathing or respiratory depression. This is particularly important for patients receiving higher doses of opioid medications. In a recent study, 92% of patients on opioid doses at or above 200 MMEs had developed ataxic or irregular breathing.25
16.2 If extended release/long-acting opioids are prescribed, consideration should be given to the increased risk of overdose with these medications. Prescribers should consider the current risk evaluation and implement mitigation strategies and close monitoring to reduce the possibility of adverse events.

Tools to accompany Recommendation 16:

- Dosing Guidelines
- The Role of Methadone in the Management of Chronic Non-Malignant Pain
- Electronic MME Dosing Calculator
  http://agencymeddirectories.wa.gov/mobile.html

Education of Chronic Pain Patients on Using Opioids

17. When opioids are prescribed for treatment of chronic pain, the patient should be counseled to store the medications securely and never to share with others. In order to prevent non-medical use of the medications, it is also recommended that patients dispose of medications when the pain has resolved.

It is important that patients understand the need to store medications securely. Health care providers should encourage patients to keep medications in a locked environment rather than in easily accessible locations, such as the bathroom or kitchen cabinet, where they are accessible to unsuspecting children, curious teenagers, and can be a target for theft. Tell the patient that if they have leftover medications after they have recovered, they should dispose of their medications immediately to help protect them from being a target for theft as well as protect others from getting into the medications.

Tools to accompany Recommendation 17:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs
- Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations
Guidelines Tools

Tools to use in evaluation and monitoring:

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking
- Sheehan Disability Scale
- Brief Pain Inventory Form
  http://health.utah.gov/prescription/pdf/guidelines/BriefPainInvNPEC.pdf
- Treatment Plan for Prescribing
- SF-12

Tools to screen for risk of complications:

- Oklahoma Prescription Monitoring Program
  http://www.ok.gov/obndd/Prescription_Monitoring_Program/
- Current Opioid Misuse Measure (COMM)
  http://health.utah.gov/prescription/tools.html
- SOAP-R
  http://health.utah.gov/prescription/tools.html
- Opioid Risk Tool
- Urine Drug Testing Devices
- Signs of Substance Misuse
- Checklist for Adverse Effects, Function, and Opioid Dependence

Informational tools:

- United States Food and Drug Administration (FDA) Guidelines on Proper Disposal of Prescription Drugs
- Non-opioid Pain Management Tool
  http://health.utah.gov/prescription/tools.html
- Absolute Contraindications to Opioid Prescribing
- Strategies for Tapering and Weaning
- Information for Patients-Opioid Analgesics for Non-cancer Pain
- The Role of Methadone in the Management of Chronic Non-Malignant Pain
- Dosing Guidelines
• Prescription Drug Overdose in Oklahoma Brochure
• Oklahoma Bureau of Narcotics and Dangerous Drugs Take Back Container Locations
• Electronic MME Dosing Calculator
   http://agencyemeddirectors.wa.gov/mobile.html
• Federal Laws on Prescribing Controlled Substances (21 CFR 1306 et. seq.)
   http://www.deadiversion.usdoj.gov/21cfr/cfr/
• Osteopathic Rules on Prescribing for Intractable Pain (OAC 510:5-9-1 et. seq.)
   http://www.ok.gov/osboe/documents/RULES.pdf
• Medical Board Rules on Prescribing for Intractable Pain (OAC 435:10-7-11 et. seq.)
   http://www.okmedicalboard.org/download/457/MDRULES.pdf
Opioid Prescribing Guidelines for Oklahoma Workgroup Members

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References

1 Oklahoma State Department of Health, Injury Prevention Service. Unintentional Poisoning Fatality Surveillance System. [Data file].


