Utah Clinical Guidelines on Prescribing Opioids for Treatment of Pain

Utah Department of Health
2009

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I am pleased to provide a copy of "Utah Clinical Guidelines on Prescribing Opioids for Pain." This document represents the results of many months of work on the part of many people, all of whom contributed considerable time, effort, experience, and expertise. This effort is an attempt to address what I consider one of the most pressing and challenging public health problems—premature deaths, dependency and disability associated with misuse and/or abuse of prescription drugs, especially, narcotic medications.

Utah's Medical Examiner, Dr. Todd Grey, brought to my attention soon after I assumed my position as Executive Director of the Utah Department of Health in 2005, the alarming increase in deaths in our state related to misuse of prescription drugs. In recent years, prescription medications used alone, in combination, or mixed with illicit drugs, has resulted in the death of hundreds of our fellow citizens. For the past 17 years, prescription drug-related deaths have increased and now exceed deaths resulting from automobile crashes in our state. In fact, it is now the **number one cause of unintentional death.**

These guidelines are meant to be just that—suggestions on how to properly use and prescribe opioid medication. As with any effort to achieve consensus, there were members who participated in the preparation of this document who disagree at both ends of the spectrum, i.e., some believe that the guidelines are too lax, others believe they impose barriers to access of much needed narcotic medications for the control of pain. It is our hope that the guidance in this document will educate both the public and clinicians about appropriate use of these medications which will, if followed, significantly reduce deaths from misuse and abuse, but at the same time allow for the control of chronic pain with proper use of opioid medications.

I want to thank the many individuals and organizations that contributed to the preparation of this document. Thousands of hours were spent in meetings and in reviewing related literature. I particularly want to acknowledge the outstanding work of Dr. Robert Rolfs, Utah State Epidemiologist and Erin Johnson, Prescription Pain Medication Program Manager. I would also like to acknowledge that the Utah State Legislature directed the Department of Health by law to produce this report on, "Medical Treatment and Quality Care Guidelines that are Scientifically Based; and Peer Reviewed," and provided the necessary funds. Additional encouragement and strong support was provided along with matching funds from the Labor Commission Workplace Safety Fund.

I'm hopeful that these guidelines will prove to be a "living document" that will be updated over time to reflect new knowledge and science and thereby improve the public's health in our state.

Sincerely,

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The Department of Health is grateful for the leadership in addressing this issue by Representative Bradley Daw who introduced House Bill 137: Pain Medication Management and Education, which was passed by the 2007 Utah legislature providing funding and directing production of these guidelines.

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Disclosure of Funding

These Guidelines are based on research conducted at the Utah Department of Health with funding from the Utah State Legislature. Additional funds were contributed to the program by the Utah Labor Commission (from the Utah Workplace Safety Account) and by the Worker's Compensation Fund of Utah.

Statutory Authority

These Guidelines were authorized by the Utah Legislature which directed the Utah Department of Health to produce "medical treatment and quality care guidelines that are scientifically based; and peer reviewed" (§26-1-36 Utah Code Annotated).

Disclosure of Conflicts

Alan L. Colledge, MD, is the Medical Director of the Labor Commission of Utah which oversees the care of approximately 60,000 injured individuals a year provided by over 250 different insurance and payer sources.

Edward B. Holmes, MD, MPH, is an appointed member of the Utah Labor Commission Workers Compensation Advisory Council. He is also Chief Medical Consultant for Disability Determination Services for Social Security.

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Lynn R. Webster, MD, conducts research for the following pharmaceutical companies: Abbott Laboratories, Ameritox, Merck & Co., Inc., Arryra, AstraZeneca, Boehringer Ingelheim, Elite Pharmaceuticals, King Pharmaceuticals, Medtronic, Merck & Co., Inc., Durect Corp., Nektar, NeurogesX, Inc., PTI, Purdue Pharma, QRZ, Respironics, Takeda Pharmaceuticals, TorreyPines Therapeutics, Wyeth, and Zars Pharma. He also conducts research for Nervo and Advanced Bionics (device companies), Ameritox (urine drug testing company), and Respironics (manufacturer of sleep apnea machines). Dr. Webster is a consultant for Advanced Bionics, Alpharma Pharmaceuticals, LLC, Cephalon, Inc., King Pharmaceuticals, Medtronic, Nektar, and Nervo. He is also an advisor to Purdue Pharma.

Background and Introduction

Unintentional fatalities due to prescription medications are an increasing problem in the United States and Utah. In the year 2000, the Utah Medical Examiner noted an increase in the number of deaths occurring due to an overdose of prescription opioid medications that are typically used for pain management. Epidemiologic studies conducted in Utah using death certificate data, Office of the Medical Examiner data, emergency department encounter data, and data from the Utah Controlled Substances Database confirmed the increases and uncovered an alarming problem.

During the years 1999–2007 deaths attributed to poisoning by prescription pain medications increased by over 500%, from 39 to 261. Deaths of Utah residents from non-illicit drug poisoning (unintentional or intent not determined) have increased from about 50 deaths per year in 1999 to over 300 in 2007. The increase was mostly due to increased numbers of deaths from prescription opioid pain medications, including methadone, oxycodone, hydrocodone, and fentanyl (CDC, 2005).

Prescribing of opioid medications has substantially increased over the past 10-15 years, including greater use for treating acute and chronic pain. Distribution to Utah of opioids such as hydrocodone, oxycodone, and methadone increased 6-fold from 1997-2002. In addition, national data document an increase in non-medical use of prescription opioids during the past several years (Substance Abuse and Mental Health Services Administration [SAMHSA], 2004; SAMHSA, 2007). From 1990 to 2002, the number of people in the U.S. who reported using prescription pain medications non-medically for the first time that year increased from 600,000 to over 2 million people (SAMHSA, 2004).

In 2007, recognizing the need for intervention, the Utah State Legislature passed House Bill 137 appropriating funding to the Utah Department of Health (UDOH) to establish a program aimed at reducing deaths and other harm from prescription opiates. Additionally, the program's charge was to develop medical treatment and quality care guidelines for the state of Utah. The resulting Prescription Pain Medication Program is being led by the Utah Department of Health in collaboration with the Utah Attorney General, the Labor Commission, the Division of Occupational and Professional Licensure, Department of Commerce, and Division of Substance Abuse and Mental Health, Department of Human Services.

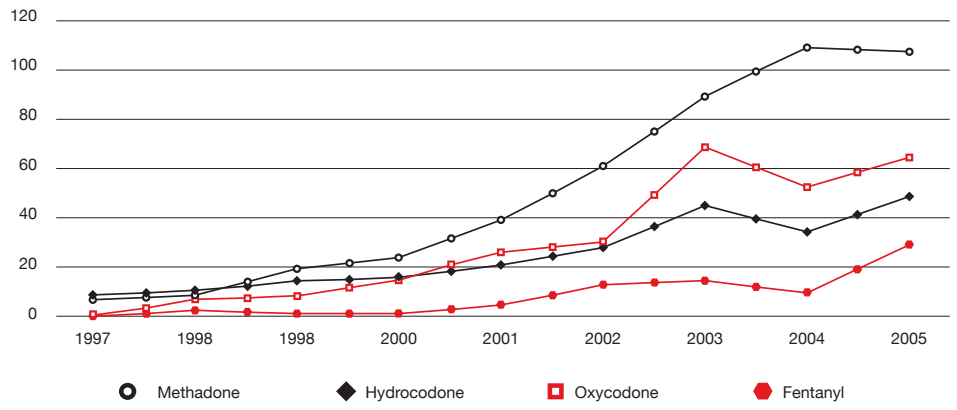
A key goal of this Guideline is to seek a balance between appropriate treatment of pain and safety in the use of opioids for that purpose. The Model Policy for the Use of Controlled Substances for the Treatment of Pain[1] (Federation of State Medical Boards, 2004) acknowledged that "undertreatment of pain is…a serious public health problem," but also sought to establish the importance of balance in treating pain as stated in the following sentence:

"…the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments."

As of the time these Utah Guidelines were produced, **adequate evidence was not available to determine the benefits of long-term treatment with opioids for persons with chronic pain due to musculoskeletal and other non-cancer causes on patient function and quality of life** (Von Korff & Deyo, 2004). Despite that lack of evidence, the use of these medications for treatment of these conditions has increased substantially in recent years. In the absence of adequate evidence to determine the true benefits and best practices in use of these medications,

[1] The Model Policy for the Use of Controlled Substances for the Treatment of Pain was developed by the Federation of State Medical Boards and endorsed by the Division of Occupational and Professional Licensing on recommendation of the Physicians Licensing Board.

Figure 1. *Number of Utah Deaths by Year and Drug: Accidental and Undetermined Cause*



these Guidelines were developed to assist physicians who choose to use opioids to treat patients with pain to manage that treatment as safely as possible.

The principal focus of these Guidelines is on the use of opioids in the long term treatment of chronic pain, especially chronic, non-cancer pain[2]. These guidelines were not developed to guide treatment of patients with malignant cancer or for patients in hospice or palliative care settings and should not limit treatment for patients for whom pain relief is the primary goal and improved function is not expected.

The diversion of opioid medications to non-medical uses also has contributed to the increased numbers of deaths. Therefore, these guidelines also include several recommendations on the use of opioids to treat acute pain to help address that public health problem. For purposes of these guidelines, acute pain is considered to be an episode of pain lasting six weeks or less and chronic pain to be pain lasting more than three months. Episodes of pain lasting from one to three months are sometimes referred to as subacute pain and were not explicitly addressed by these guidelines, however many of the recommendations are applicable to subacute pain.

The Utah Department of Health and its advisors recognized that clinicians have many demands on their time and have attempted to make these guidelines as practical and concise as possible. However, long-term use of opioid medications to treat chronic pain carries substantial risks and the benefits of this treatment approach have not been adequately established by appropriate studies. The time commitment required to safely manage patients on these medications should be considered when they are prescribed. The Utah Department of Health agrees with Von Korff and Deyo (2004) that,

"Long-term opioid therapy should only be conducted in practice settings where careful evaluation, regular follow-up and close supervision are ensured."

Medicine is practiced one patient at a time and each patient is unique with individual needs and vulnerabilities. The Guidelines have attempted to guide clinicians but not to inappropriately constrain practice. The art of medicine is recognized. However, these Guidelines were based on evidence or consensus recommendations by experts. They are intended to improve outcomes of patient care and in particular to prevent deaths due to opioid use. Departures from these recommendations will be appropriate for some patients, but should be justified and documented.

[2] This Guideline uses the term chronic non-cancer pain to refer to chronic pain that is not associated with active cancer or occurs at the end of life (Chou et al., 2009). Some of the tools and references included in this Guideline use the term, "chronic non-malignant pain" to describe a similar or identical set of conditions.

Summary of Recommendations

Opioid Treatment for Acute Pain

1) Opioid medications 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) When opioid medications are prescribed for treatment of acute pain, the number 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.

3) When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, to not share with others, and to dispose of medications properly when the pain has resolved in order to prevent non-medical use of the medications.

4) Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.

5) The use of opioids should be reevaluated carefully, including assessing the potential for abuse, if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

Opioid Treatment for Chronic Pain

1) A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain.

2) Alternatives to opioid treatment should be tried (or adequate trial of such treatment by a previous provider documented), before initiating opioid treatment.

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

4) When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.[3]

5) The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement.

6) Opioid treatment for chronic pain should be initiated as a treatment trial, usually using short-acting opioid medications.

7) Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period).

8) 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.

9) Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient. A second opinion or consult may be useful in making that decision

10) An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated.

11) Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed.

12) Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment.

13) Methadone should only be prescribed by clinicians who are familiar with its risks and appropriate use, and who are prepared to conduct the necessary careful monitoring.

[3] "Function" as used here is defined broadly to include physical, emotional, cognitive, psychological and social function.

Methods

Purpose and Target Audience

These Guidelines provide recommendations for the use of opioids for management of pain that are intended to balance the benefits of use against the risks to the individual and society, and to be useful to practitioners. The target audience for these Guidelines includes all clinicians who prescribe opioids in their practice.[4]

Guideline Evidence Review

The steering committee of the Utah Department of Health's Prescription Pain Medication Program developed the key questions, scope, and inclusion criteria used to guide the evidence review process. The process began with a literature review to identify existing guidelines on pain, chronic pain, opioids, pain management, and related topics. Guidelines were identified through electronic databases, reference lists from evaluated guidelines, and recommendations from experts. Electronic databases that were searched include: PubMed, Medline, CINAHL, and the National Guideline Clearinghouse. Investigators identified and evaluated 40 individual guidelines.

Grading of the Evidence and Recommendations

As guidelines were identified they were reviewed for key information. They were evaluated based on the following categories:

- Title
- Year Published: Guidelines were included only if they were published after the year 1999. Articles published before 2000 were merely noted in the grid by their title and date with no additional information.
- Sponsorship and funding
- Medical Perspective
- Target Audience
- The Process: This describes how the guidelines were created. Most guidelines fell into two categories: "evidence-based" and/or "consensus"
- The Rating Scale: This was based on the quality of research that went into the development of the guidelines. Explicit evidence-based guidelines received higher ratings and less explicit, consensus-based guidelines received lower ratings

The complete evaluation matrix of the 40 guidelines is available from the Utah Department of Health, Bureau of Epidemiology upon request.

In total, 40 guidelines for pain management were reviewed and evaluated. As each guideline was reviewed, it received a rating from 1-10 (for a breakdown of the rating scale, see Appendix A). Guidelines that received scores of seven (7) or lower were excluded. Four (4) sets of guidelines received scores of eight (8) or above. Three (3) public health professionals reviewed the ratings to ensure that the scores were consistent with the rating scale.

Panel Composition

The Utah Department of Health convened two multidisciplinary panels (see page 4 for complete list of panel members). The Guideline Recommendation Panel convened on four (4) occasions between May and July 2008. Their purpose was to review the evidence and formulate recommendations based on the evidence in the selected guidelines. Each member signed a Conflict of Interest disclosure. Conflicts were reported as described below (See Disclosure of Conflicts on page ii). The Guideline Implementation and Tool Panel convened twice (2) between July and August 2008 to review the recommendations to ensure that they were implementable as well as to identify tools needed in order to put the recommendations into use. The first panel consisted of twelve (12) experts and the second consisted of nine (9) experts from throughout the state of Utah.

Recommendation Development Process

The Guideline Recommendation Panel met in person on four occasions between May and July 2008. The purpose of the first meeting was to provide panel members with copies of the selected, high-scoring guidelines and to present the purpose and plan for developing the guidelines. Prior to the second meeting, panel members were asked to review the four guidelines for commonalities. The recommendations that were supported by multiple guidelines created the basis of the first draft of the recommendations used by the Guideline Recommendation Panel. Consideration was given to adopting one of the existing evidence-based guidelines outright, but the panel

[4] In Utah as of January 2009 (R156-37), clinicians who can be licensed to prescribe controlled substances as part of practice (human) includes physicians and surgeons, osteopathic physicians and surgeons, podiatrists, dentists, physician assistants, advanced practice registered nurses, certified nurse midwives, certified nurse anesthetists, and optometrists.

felt that no single guideline represented sufficiently what was desired of the Utah guidelines. The panel voted to include two (2) additional sets of guidelines that had not met the inclusion criteria for consideration while drafting the recommendations. In total, content for the Utah guidelines was drawn from six (6) guidelines. The key topics to be developed into specific recommendations were posted on a website where the Guideline Recommendation Panel members posted comments and edited the text. The panelists' postings were the basis on which content was selected from the chosen guidelines. This content was then used to create a draft of actual recommendation statements and supporting paragraphs. At the third meeting, a straw poll was taken on the recommendation draft. Through discussion and rewording, consensus on content was achieved for all of the recommendations discussed over the course of the two meetings. Outside the meetings, non-content editing of the recommendations and supporting statements was performed, based on the panel's discussions, to create the final draft of the recommendations and supporting paragraphs.

Tool Development Process

The Guideline Implementation and Tools Panel met in person on two occasions between July and August 2008. Prior to the first meeting, a book was compiled that included all tools that were identified in the forty (40) guidelines. Sample tools were solicited from panel members as well. In total, the workbook contained forty-seven (47) tools. At the first meeting, the panel reviewed the draft recommendations and discussed whether any specific recommendations were impossible or burdensome to implement. Panel members were each given a book containing all the tools. In between the first and second meeting, panel members reviewed and graded each tool according to usefulness and whether or not it should be included in the guidelines. Votes and rating were tallied prior to the second meeting. Tools that received an average rating of below two (2) were eliminated. At the second meeting, the remaining tools were discussed and it was determined which of the remaining tools should be included, modified, or eliminated.

Following the final panel meetings, Utah Department of Health staff formally drafted the complete guidelines document.

Drafts of the complete guidelines were then distributed to all panel members and several Utah Department of Health internal staff for feedback and revisions. External peer reviewers were solicited for additional comments. The final draft recommendations were posted for public comment during November–December 2008 and revisions were made based on consideration of those comments (copies of comments are available online at **health.utah.gov/prescription**). Prior to publication, the Guideline was submitted to the Utah Department of Health Executive Director for approval.

Recommendations

Previously published evidence-based or consensus-based guidelines have been used as the foundation for many of the Utah recommendations. Each guideline has been assigned a number. After each recommendation, the numbers of the guidelines with similar or supporting recommendations are listed.

Reference Guidelines:

1. Department of Veterans Affairs, Department of Defense. (2003). *VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain*
2. College of Physicians and Surgeons of Ontario. (2000). *Evidence-based recommendations for medical management of chronic non-malignant pain*
3. American College of Occupational and Environmental Medicine's Occupation Medicine Practice Guidelines. (2008).
4. *Opioids in the Management of Chronic Non-Cancer Pain: An Update of American Society of the Interventional Pain Physicians' (ASIPP) Guidelines.* (2008).
5. Washington State Agency Medical Directors' Group. (2007). *Interagency guideline on opioid dosing for chronic non-cancer pain: An educational pilot to improve care and safety with opioid treatment*
6. Federation of State Medical Boards of the United States, Inc. (2004). *Model policy for the use of controlled substances for the treatment of pain*

Opioid treatment recommendations for acute pain:

Acute Pain Recommendation 1:
Opioid medications 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. *Reference Guidelines: 3*

Most acute pain is better treated with non-opioid medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs (NSAID), or therapies such as exercise, or specific stretching) than opioid medications which have less desirable adverse effect profiles in acute pain patients. Care should be taken to assure that use of opioid pain treatment does not interfere with early implementation of functional restoration programs such as exercise and physical therapy. The developing brain may be more susceptible to addiction when exposed to opioid medications and nonmedical use is more common among younger people. Those risks should be considered when prescribing to an adolescent.

Acute Pain Recommendation 2:
When opioid medications are prescribed for treatment of acute pain, the number dispensed should be no more than the number of doses needed based on usual duration of pain severe enough to require opioids for that condition.

Prescribing more medications than the amount likely to be needed leads to unused medications being available for non-medical use or abuse. Use of opioid pain medications should be stopped when pain severity no longer requires opioid medications.

Acute Pain Recommendation 3:
When opioid medications are prescribed for treatment of acute pain, the patient should be counseled to store the medications securely, not share with others, and to dispose of properly when the pain has resolved in order to prevent non-medical use of the medications.

It is important that patients understand the need to store medications securely. Encourage patients to keep medications in a locked environment rather than in typical 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 medication after they have recovered, they should dispose of their medication immediately to help protect them from being a target for theft as well as protect others from getting into the medications. The Federal Guidelines on Proper Disposal of Prescription Drugs are included in the Tool Section.

Acute Pain Recommendation 4:
Long duration-of-action opioids should not be used for treatment of acute pain, including post-operative pain, except in situations where adequate monitoring and assessment for adverse effects can be conducted. Methadone is rarely if ever indicated for treatment of acute pain.

Acute Pain Recommendation 5:
The use of opioids should be reevaluated if persistence of pain suggests the need to continue opioids beyond the anticipated time period of acute pain treatment for that condition.

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 evaluated. The continuation of opioid treatment in this setting may represent the initiation of opioid treatment for a chronic pain condition without being recognized as such at the time. The diagnosis and appropriateness of interventions should be reevaluated and the patient's medical history should be reviewed for comorbidities that could interact with opioid treatment and for risk factors for problems during opioid treatment, including substance abuse or history of substance abuse. It is recommended that the provider check the Utah Controlled Substances Database at this time as well.

Opioid treatment recommendations for chronic pain:

Before prescribing opioid treatment for chronic pain:

1. Comprehensive initial evaluation/assessment of patient

1.1 Recommendation:
A comprehensive evaluation should be performed before initiating opioid treatment for chronic pain. *Reference Guidelines: 1, 2, 4, 6*

There are many reasons for using caution when initiating opioid therapy, therefore the recommended comprehensive initial evaluation is very important. A major goal when prescribing opioids should be to provide greater benefit than harm to patients. Potential for serious harm exists, up to and including death, due either to overdose or to dangerous behaviors that occur while under the influence of these medications. The patient may be harmed, but others may also be harmed through diversion or because of an act performed by the patient on opioids. The most frequent harms are diversion, misuse, abuse, addiction, and overdose and predicting which patients will be affected by these harms is difficult. Initiating opioid treatment often results in short term relief, but that relief might not be maintained. Long-term use of opioid medications to treat chronic pain safely requires the commitment of adequate resources to regularly monitor and evaluate outcomes and identify occurrence of adverse consequences.

The goal of the comprehensive evaluation is to determine the nature of the patient's pain, evaluate how the pain is affecting the patients function and quality of life, identify other conditions or circumstances that could affect the choice of treatment or the approach to managing that treatment, assess and evaluate prior approaches to pain management, and serve as a basis for establishing a plan for treatment and evaluation of treatment outcomes.

The evaluation should specifically address these issues:

1) Assess pain and prior treatment of pain.
   - Determine the cause of the pain and whether the pain is acute or chronic.
   - Assess previous treatment approaches and trials for appropriateness, adequacy, and outcome.

2) Assess presence of social factors, and medical or mental health conditions that might influence treatment especially those that might interfere with appropriate and safe use of opioid therapy (Department of Veterans Affairs & Department of Defense [VA/DOD], 2003):
   - Obtain history of substance use, addiction or dependence (if present, refer to Recommendations 12.2 and 12.3).
   - Identify psychiatric conditions that may affect pain or treatment of pain (if present, refer to Recommendation 12.4).
   - Identify use of other medications that might interact with medications used to treat the pain. Particular attention should be given to benzodiazepines and other sedative medications.
   - Assess social history, including employment, social network, marital history, and any history of legal problems especially illegal use or diversion of controlled substances.
   - Assess for presence of medical conditions that might complicate treatment of the 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 clinicians 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.

3) Assess the effects of pain on the person's life and function.
   - Assess the severity of pain, functional status of the patient, and the patient's quality of life using a method/instrument that can be used later to evaluate treatment effectiveness.

Tools to accompany Recommendation 1:
- Sheehan Disability Tool
- Pain Management Evaluation Tool

2. Consider alternative treatment options

2.1 Recommendation:
Alternatives to opioid treatment should be tried (or an adequate trial of such treatments by a previous provider documented) before initiating opioid treatment. *Reference Guidelines: 1, 2, 3, 4, 5*

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

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

Tools to accompany Recommendation 2:

- Non-opioid Pain Management Tool

3. Screening for risk of addiction or abuse

3.1 Recommendation:
Use a screening tool to assess the patient's risk of misuse prior to prescribing an opioid medication long-term for chronic pain. *Reference Guidelines: 3*

A number of screening tools have been developed for assessing a patient's risk of misuse of medications. Several of these are included in the Tool Section. The screening tool results are intended to assist the clinician in determining whether opioid therapy is appropriate and in determining the level of monitoring appropriate for the patient's level of risk.

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

Research and experience have shown that drug testing can identify problems, such as use of undisclosed medications, non-use of reported medications (i.e., diversion), undisclosed use of alcohol, or use of illicit substances, that are not identified without that testing. Several experts involved in the development of these guidelines recommended that drug screening be done on all patients before initiating opioid treatment for chronic pain. However, drug testing can damage a provider-patient relationship, the results of testing can be difficult to interpret, and that recommendation attracted a substantial number of negative comments during the public comment period. It is recommended that drug testing be strongly considered and conducted especially when other factors suggest caution.

The drug screening should be either a urine drug screen or another laboratory test that can screen for the presence of illegal drugs, unreported prescribed medication, or unreported alcohol use. It is recommended that this testing be considered for all patients. When screening is limited to situations when there is suspicion of substance misuse, some misuse may be missed. In one study, testing results at first admission to a pain clinic did not correlate with reported medication use for nearly one-fourth of patients. Most of these discrepancies involved finding substances not reported by the patient; a small minority reported taking medications that were not found on testing (Berndt, Maier, & Schutz, 1993).

The clinician may consider testing for illegal substances (See list of Urine Drug Testing Devices in the Tool Section) in addition to screening for opioids.

A positive drug screen indicates the need for caution, but does not preclude opioid use for treatment of pain. Consideration should be given to referral to substance abuse counseling and/or to a pain management specialist. If opioid medication is subsequently prescribed, the patient should be more carefully monitored and conditions

under which opioids are being prescribed should be well documented in the treatment plan (See Recommendations 5, 6, 8, 12).

Immunoassays can be done in the office. These can determine if opioids are present but do not identify specific ones, which can subsequently be determined by confirmatory laboratory testing. However, in many cases, going over the results of the initial in-office test carefully with the patient can eliminate the need for confirmation testing. It is extremely important to keep in mind that immunoassays have both false positive and false negative results. Over-the-counter medication, for example, can cause a positive result (Washington State Agency Medical Directors' Group [WSAMDG], 2007).The prescriber may want to consider confirmatory testing or consultation with a certified Medical Review Officer if drug test results are unclear (WSAMDG, 2007).

3.3 Recommendation:
The prescriber should check Utah's Controlled Substance Database before prescribing opioids for chronic pain.

Most patients who request treatment for pain are legitimately seeking relief of the pain. However, a subset of patients who present 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 the potential for problems.

The State of Utah's Division of Occupational and Professional Licensing (DOPL) maintains the Controlled Substance Database Program, which is a searchable record of all prescriptions that are filled in the state for controlled substances. The Utah Controlled Substance Database Program was legislatively created and put into effect in 1995. It 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 to all controlled substance prescribers online at **www.csdb.utah.gov**. A "Getting Started" presentation is available to help orient users to the site and to appropriate uses of the database.

Tools to accompany Recommendation 3:

- SOAPP-R
- Opioid Risk Tool
- Prescription Drug Use Questionnaire
- List of Recommended Urine Drug Screens

Establishing Treatment Goals and a Written Treatment Plan:

4. Establish treatment goals

4.1 Recommendation:
When opioids are to be used for treatment of chronic pain, a written treatment plan should be established that includes measurable goals for reduction of pain and improvement of function.

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 therefore 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.

4.2 Recommendation:
Goals for treatment of chronic pain should be measurable and should include improved function and quality of life as well as improved control of pain.
Reference Guidelines: 1, 3, 5

For most chronic pain conditions, complete elimination of pain is an unreasonable goal (College of Physicians and

Surgeons of Ontario, 2000). Goals for treatment of chronic pain should include improvement in the tolerability of the pain and in function (College of Physicians and Surgeons of Ontario, 2000). The clinician should counsel the patient on reasonable expectations for treatment outcomes so that together they can agree on achievable treatment goals 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 outcome (VA/DOD, 2003; Hegmann, Feinberg, Genovese, Korevaar, & Mueller, 2008). These include:

- Objective physical findings obtained by the examining clinician (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)
- Physical status (e.g., increased ability to exercise, perform chores, or participate in hobbies).

Pain intensity should be assessed at each visit using a standard instrument such as the Numerical Rating Scale. See the Pain Management Evaluation Tool, Patient Pain and Medication Tracking Chart, Sheehan Disability Scale, and Brief Pain Inventory Form in the Tool Section or page 17 of VA/DOD guidelines.

Clinicians 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 previously been obtained and documented (See Recommendation 5.5).

4.3 Recommendation:
Treatment goals should be developed jointly by patient and clinician. *Reference Guidelines: 2*

Engage patients in their own healthcare. Clinicians 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 clinician 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 4:

- Pain Management Evaluation Tool
- Patient Pain and Medication Tracking Chart
- Sheehan Disability Scale
- Brief Pain Inventory Form
- Sample Treatment Plan for Prescription Opioids
- Cultural considerations in assessing function, quality of life, and pain intensity: **http://prc.coh.org/culture.asp**

5. Informed consent and formulation of a treatment plan

5.1 Recommendation:
The patient should be informed of the risks and benefits and any conditions for continuation of opioid treatment, ideally using a written and signed treatment agreement.
Reference Guidelines: 4

The patient should be counseled about appropriate use of the medication, possible adverse effects, and the risks of developing tolerance, physical or psychological dependence, and withdrawal symptoms (Trescot et al., 2008; WSAMDG, 2007). Adverse effects can include nausea, constipation, decreased libido, sexual dysfunction, hypogonadism with secondary osteoporosis (Hegmann et al., 2008), opioid-induced hyperalgesia (Hegmann et al., 2008; WSAMDG, 2007), allodynia (WSAMDG, 2007), abnormal pain sensitivity (WSAMDG, 2007), and depression (Daniell, 2007).

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 seek excessive dosing of opioids and to disappointment.

Sedation and cognitive impairment may occur when patients are taking opioid medication. 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.[5]

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 drug capable of inducing life-limiting drug-drug interaction
- Active diversion of controlled substances (providing medication to someone for whom it was not prescribed)

More detail about absolute contraindications is contained in the Tool Section.

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:

Signs of respiratory depression:

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

5.2 Recommendation:
The patient and, when applicable, the family or caregiver should both be involved in the educational process.
Reference Guidelines: 1

Educational material should be provided in written form and discussed in person with the patient and, when applicable, the family or caregiver (VA/DOD, 2003). Educating the family about the signs of opioid overdose may help detect problems before they lead to a serious complication.

It is crucial 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.

[5] Health care professionals are responsible to "counsel their patients about how their condition affects safe driving. For example, if medication is prescribed for a patient which may cause changes in alertness or coordination, the health care professional shall advise the patient about how the medication can affect safe driving, and when it would be safe to operate a vehicle." R708-7-6(1)(b) Utah Administrative Code A health care professional or other person who becomes aware of a physical, mental, or emotional impairment that appears to present an imminent threat to driving safety and reports this information to the division in good faith has immunity from any damages claimed as a result of making the report. (§53-3-303(14)(c) Utah Code Annotated) Federal law prohibits driving a commercial motor vehicle while under the influence of a narcotic (CFR §391.15).

5.3 Recommendation:
The treatment plan, which defines the responsibilities of both patient and clinician, should be documented. *Reference Guidelines: 1, 2, 3, 4, 5*

Patient responsibilities include properly obtaining, filling, and using prescriptions, and adherence to the treatment plan. They could 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 (VA/DOD, 2003).
The prescribing clinician may consider requiring that the treatment plan, be documented in the form of a treatment "contract" or "agreement" that is signed by the patient. Patients should be encouraged to store opioid medication in a lock box to keep the medication out of the hands of others who should not have access to them.

5.4 Recommendation:
The treatment plan should contain goals of treatment, guidelines for prescription refills, agreement to submit to urine or serum medication level screening upon request, and reasons for possible discontinuation of drug therapy. *Reference Guidelines: 1, 2, 4, 5, 6*

The treatment plan (sometimes referred to as treatment "contracts" or "agreements") should contain the items that were developed jointly by patient and clinician, such as follow-up appointments, the pharmacy and clinician to be used, as well as any non-negotiable demands or limitations the clinician 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 (VA/DOD, 2003; Trescot et al., 2008) or obtaining them from multiple providers as documented by Utah's Controlled Substance Database Program.

Optional inclusions in the agreement:

- Pill counts may be required as a means to gauge proper medication use (VA/DOD, 2003; Trescot et al., 2008).
- Prohibition on use with alcohol or certain other medications (VA/DOD, 2003)
- Documentation of counseling regarding driving or operating heavy machinery (VA/DOD, 2003 Hegmann et al., 2008)
- Specific frequencies of urine testing

Ideally, the patient should be receiving prescriptions from one prescriber only and filling those prescriptions at one pharmacy only (VA/DOD, 2003; Trescot et al., 2008; Federation of State Medical Boards, 2004).

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.

A Sample Treatment Plan for Prescribing Opioids is included in the Tool Section.

5.5 Recommendation:
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 physician may want to consider a family conference to help assess the patient's integrity (Trescot et al., 2008). Consultation with others, however, must be done within the constraints of HIPAA, as noted above (See Recommendation 5.2). Guidance about communications with family and others under HIPAA can be found at: **http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/provider_ffg.pdf**

Tools to accompany Recommendation 5:

- Absolute Contraindications to Opioid Prescribing
- Sample Treatment Plan for Prescribing Opioids

Initiating, Monitoring, and Discontinuing Opioid Treatment:

6. Initiate opioid therapy as a treatment trial

6.1 Recommendation:
Opioid medication should be initiated as a short-term trial to assess the effects of opioid treatment on pain intensity, function, and quality of life.

The clinician 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 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 9 for more information on discontinuation of treatment.

6.2 Recommendation:
In most instances, the trial should begin with short-acting opioid medication.

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 prescriber may consider switching the patient to a long-acting or sustained-release formulation (See the Dosing Guidelines in the Tool Section). The patient's individual situation should influence whether the patient is switched from short-acting medication. Treatment with 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.

6.3 Recommendation:
Parenteral[6] (intravenous, intramuscular, subcutaneous) administration of opioids for chronic pain is, in general, discouraged. *Reference Guidelines: 2*

Daily IM or SC injections should be avoided except under a highly supervised environment such as during an admission to the hospital or hospice.

Tools to accompany Recommendation 6:

- Dosing Guidelines
- COMM

7. Titration phase

7.1 Recommendation:
Regular visits with evaluation of progress against goals should be scheduled during the period when the dose of opioids is being adjusted (titration period). Reference Guidelines: 1

Follow-up face-to-face visits should occur at least every 2-4 weeks during the titration phase. More frequent follow-up visits may be advisable and caution should be used when prescribing 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) (College of Physicians and Surgeons of Ontario, 2000).

7.2 Recommendation:
When pain and function have not sufficiently improved on a current opioid dose, a trial of a slightly higher dose could be considered. *Reference Guidelines: 1, 2*

The rate at which the dosing is increased should balance the risk of leaving the patient in a painful state longer than

[6] These guidelines did not consider intrathecal administration and this recommendation was not intended to discourage trained and qualified physicians from using intrathecal opioid medications.

necessary by going too slowly with the risk of causing harm, including fatal overdose, by going too fast. Ideally, only one drug at a time should be titrated in an opioid-naïve patient (VA/DOD, 2003). 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 equivalents. 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. Clinicians 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 high dose has been established based on evidence. The Washington State guideline (WSAMDG, 2007) suggested a threshold of 120 mg of morphine equivalent per day, but has been criticized for that decision. It seems reasonable to increase clinical vigilance at daily doses that exceed 120-200 mg of morphine equivalent per day.

During titration, all patients should be seen frequently until dosing requirements have stabilized. Patients should be instructed to Use Only as Directed, that is, not to change doses or frequency of administration without specific instructions from the clinician.

7.3 Recommendation:
During the titration phase, until the patient is clinically stable and is judged to be compliant with therapy, it is recommended that the clinician check the Controlled Substances Database at least quarterly.

For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Tools to accompany Recommendation 7:

- Dosing Guidelines

8. Maintenance – Periodic monitoring and dose adjustments:

8.1 Recommendation:
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. *Reference Guidelines: 2, 4*

Assess 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" (Passik & Weinreb, 2000):

- 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
- Aberrant behavior: regularly evaluate for possible drug abuse-related behavior

A sample checklist for signs of aberrant behavior is included in the Tool Section.

8.2 Recommendation:
Providers should consider performing drug screening on randomly selected visits and any time aberrant behavior is suspected.

As discussed in recommendation 3, drug testing has been shown to identify problems that might otherwise go undetected. It may not be appropriate or necessary for all patients, but should be strongly considered by providers and may provide an opportunity to discuss the risks and problems that can occur with opioid treatment. Base the frequency of random drug screening on the assessed degree of risk of aberrant behavior for the individual patient. Pill counts may also be useful in some circumstances.

8.2 Recommendation:
During maintenance phase, Controlled Substances Database should be checked at least annually.

After the titration phase is complete and the maintenance phase is underway, the frequency of checks of the Controlled Substances Database can be based on clinical judgment, but should be done no less than annually. The Controlled Substances Database should be checked more often for high risk patients and patients exhibiting aberrant behavior. For more information about the Controlled Substances Database, refer to Recommendation 3.3.

Consider evaluating for possible drug abuse-related behavior at each visit. A sample checklist is included in the Tool Section.

Provide reinforcement for previous counseling and additional education for patients at follow-up visits (Trescot et al., 2008).

Review the pathophysiologic hypothesis (to see if the diagnosis is still valid) at each visit (Trescot et al., 2008).

8.3 Recommendation:
Continuation or modification of therapy should depend on the clinician's evaluation of progress towards stated treatment goals. *Reference Guidelines: 4*

These include reduction in a patient's pain scores and improved physical, psychological and social function. If treatment goals, including patient compliance with agreed-upon activity levels, are not being achieved despite medication adjustments, the clinician should reevaluate the appropriateness of continued treatment with the current medications (WSAMDG, 2007; Federation of State Medical Boards, 2004).

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

8.4 Recommendation:
Adjustments to previously stable maintenance therapy 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. *Reference Guidelines: 1*

Options for adjustment include reducing medication or rotating opioid medication. If it is documented that the patient is compliant with agreed-upon recommendations such as exercise, working, etc., addition of supplemental short-acting medications for control of break-through pain exacerbation (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 (Quang-Cantagrel, Wallace, & Magnuson; 2000).

Only if the patient's situation has changed permanently and consideration has been given to increased risk of adverse events, is it reasonable to consider an ongoing increase in maintenance dosing (VA/DOD, 2003).

If rotating among different opioid medications, refer to a standard dosing equivalence table taking into account the current drug's half-life. (See the Dosing Guidelines in the Tool Section)

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 (VA/DOD, 2003).

8.5 Recommendation:
Dosing changes should generally be made during a clinic visit. *Reference Guidelines: 1*

If the patient's underlying pain-producing chronic medical condition improves, it is expected that the clinician will begin tapering the patient off the opioid medication (See Recommendation 10 for guidelines on discontinuation.)

Tapering opioid medication with or without the goal of discontinuation may be performed as described below (Recommendation 10) or as described in Strategies for Tapering and Weaning in the Tool Section.

Tools to accompany Recommendation 8:

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

9. Evaluate the treatment trial

9.1 Recommendation:
Continuing opioid treatment after the treatment trial should be a deliberate decision that considers the risks and benefits of chronic opioid treatment for that patient.

9.2 Recommendation:
A second opinion or consult may be useful in making the decision to continue or discontinue the opioid treatment trial.

10. Discontinuing opioid treatment

10.1 Recommendation:
An opioid treatment trial should be discontinued if the goals are not met and opioid treatment should be discontinued at any point if adverse effects outweigh benefits or if dangerous or illegal behaviors are demonstrated. *Reference Guidelines: 5*

10.2 Recommendation:
Discontinuation of opioid therapy 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
- Opioid therapy appears to be causing harm to the patient, particularly if harm exceeds benefit

Reference Guidelines: 1

The decision to discontinue opioid treatment should ideally be made jointly with the patient and, if appropriate, the family/caregiver (Federation of State Medical Boards, 2004). This decision should include careful consideration of the outcomes of ongoing monitoring.

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

Reference Guidelines: 1

The goal is to taper all patients off opioid medication safely. "Strategies for Tapering and Weaning" in the Tool Section contains advice on tapering opioid medications (WSAMDG, 2007). If the patient is discharged, the clinician is obliged to offer continued monitoring for 30 days post-discharge.

Tools to accompany Recommendation 10:

- Strategies for Tapering and Weaning

Other Issues:

11. Documentation and Medical Records

11.1 Recommendation:
Clinicians treating patients with opioids for chronic pain should maintain records documenting the evaluation of the patient, treatment plan, discussion of risks and benefits, informed consent, treatments prescribed, results of treatment, and any aberrant behavior observed. *Reference Guidelines: 1, 2, 4, 5, 6*

11.2 Recommendation:
A written treatment plan should document objectives that will be used to evaluate treatment success. *Reference Guidelines: 1, 2, 4, 5, 6*

The objectives should address pain relief, improved physical and psychosocial function, including work and exercise compliance, and should indicate if additional diagnostic tests, consultations, or treatments are planned (Trescot et al., 2008). Use of validated instruments to measure pain and function is preferred. Details on establishing treatment goals and formulation of a treatment plan are covered elsewhere in these guidelines (Recommendations 4 and 5.)

11.3 Recommendation:
The prescription for opioid therapy should be written on tamper-resistant prescription paper in a manner to help reduce the likelihood of prescription fraud or misuse. *Reference Guidelines: 2*

The written prescription for opioid therapy should contain the name of the drug, the strength, the number of dosage units, (written numerically and in text), how the drug is to be taken, the full name, address, and age of the patient, the name, address, and DEA registration number of the practitioner, and the signature of the physician or other authorized practitioner. It shall be dated and signed on the day when issued. After a stable maintenance therapy dosage has been established and therapy goals have been achieved, schedule II opioid medications may be prescribed for three months by providing the patient with prescriptions for each of the three months. Each prescription for a one month supply of medication should include the date the prescription is written and the date when that prescription is to be filled.

To reduce the chance of tampering with the prescription, write legibly, and keep a copy (College of Physicians and Surgeons of Ontario, 2000). (See the Tamper Resistant Requirements in the Tool Section.)

11.4 Recommendation:
Assessment of treatment effectiveness should be documented in the medical record. *Reference Guidelines: 2, 4, 5*

Document the patient's progress toward treatment goals, including functional status, at every visit, rather than merely reporting the patient's subjective report of decreased pain. Ideally, this progress would be evaluated using validated tools (Trescot et al., 2008).

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 evaluated and documented at every visit.

11.5 Recommendation:
Adherence to the treatment plan, including any evidence of aberrant behavior, should be documented in the medical record. *Reference Guidelines: 1*

Specific components of the treatment plan for which adherence should be assessed include:

- Use of opioid analgesics
- Follow-up referrals, tests, and other therapies

Clinicians are encouraged to make use of resources provided by the state of Utah that are designed to assist them in managing patients with aberrant behavior (See Checklist for Adverse Effects, Function, and Opioid Dependence and Signs of Substance Misuse in Tool Section). Referral to law enforcement/legal agencies may be appropriate if actions by patients are occurring that could be criminal in nature (VA/DOD, 2003). Clinicians

should consider consulting with legal counsel before contacting law enforcement (VA/DOD, 2003). Serious non-adherence issues (illegal, criminal, or dangerous behaviors, including altering of prescriptions) may also warrant immediate discontinuation of opioid therapy. See Recommendation 10.

Tools to accompany Recommendation 11:

- Tamper Resistant Requirements
- Checklist for Adverse Effects, Function, and Opioid Dependence
- Signs of Substance Misuse

12. Consultation and management of complex patients

12.1 Recommendation:
Clinicians should consider consultation for patients with complex pain conditions, patients with serious co-morbidities including mental illness, patients who have a history or evidence of current drug addiction or abuse, or when the provider is not confident of his or her abilities to manage the treatment. *Reference Guidelines: 4, 5*

Prescribers may wish to consider referring patients if any of the following conditions or situations is 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 high-risk for aberrant behavior or addiction; or
- The clinician suspects 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.

12.2 Recommendation:
Patients with a history of addiction or substance use disorder or who have positive drug screens indicative of a problem should be considered for referral to an addiction specialist for evaluation of recurrence risk and for assistance with treatment.
Reference Guidelines: 1, 4, 5

Although this is a desirable approach, it is recognized that following this recommendation may not be feasible in parts of Utah where there is a shortage of readily available addiction specialists. The Directory of Resources in the Tool Section includes information on available resources for these patients.

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

The clinician may consider prescribing opioid medication for pain even if the patient has a self-reported or documented previous problem with opioids, as long as monitoring is performed during titration and maintenance phase.

12.4 Recommendation:
Patients with coexisting psychiatric disorder should receive ongoing mental health support and treatment while receiving opioid medication for pain control.

Management of patients with a coexisting psychiatric condition may require extra care, monitoring, or documentation (Trescot et al., 2008; Federation of State Medical Boards, 2004). Unless the clinician treating the patient is qualified to provide the appropriate care and evaluation of the coexisting psychiatric disorder, consultation should be obtained to assist in formulating the treatment plan and establishing a plan for coordinated care of both the chronic pain and psychiatric conditions.

Tools to accompany Recommendation 12:

- Strategies for Tapering and Weaning
- Directory of Resources

13. Methadone

13.1 Recommendation:
Methadone should only be prescribed by clinicians familiar with its risks and use, and who are prepared to conduct the necessary careful monitoring.

Methadone-related death rates have been increasing in Utah and the U.S. In 2006, methadone was implicated in 30% of non-illicit drug-related deaths in Utah. Methadone was the most common drug identified by the Utah Medical Examiner as causing or contributing to accidental deaths, accounting for a disproportionate number of deaths compared to its frequency of use. Methadone was the single drug most often associated with overdose death and had the highest prescription adjusted mortality rate (PAMR) with an average of 150 deaths for every 100,000 prescriptions during 1998-2004. From 1997–2004, population-adjusted methadone prescriptions increased 727%. The increase in the methadone prescription rate was for treatment of pain and not addiction therapy.

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) and 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 (Arizona Center for Education and Research on Therapeutics 2008). A useful on-line reference of such medications is available at: **http://www.azcert.org/medical-pros/drug-lists/drug-lists.cfm**

Clinicians should consider obtaining an electrocardiogram (ECG) to evaluate the QTc interval in patients treated with methadone, especially at higher doses. A recently published consensus guideline (Krantz 2009) 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).

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 one recent study, 92% of patients on opioid doses at or above 200 mg morphine equivalents had developed ataxic or irregular breathing (Walker, 2007).

Some clinicians recommend that all patients for whom higher doses of opioid medications are considered should be tested with a sleep study.

Tools to accompany Recommendation 13:

- Dosing Guidelines
- The Role of Methadone in the Management of Chronic Non-Malignant Pain

GLOSSARY

Term	Definition
Aberrant drug-related behavior	A behavior associated with drug abuse, addiction, and diversion.
Abuse	Maladaptive pattern of drug use that results in harm or places the individual at risk of harm. Often with the intent of seeking a psychotropic/ euphoric effect.
Acute pain	An episode of pain lasting six weeks or less
Addiction	A primary, chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving.
Breakthrough pain	An acute worsening of pain in a person with chronic pain.
Chronic pain	An episode of pain lasting more than three months
Chronic non-cancer pain	Chronic pain that is not associated with active cancer or occurs at the end of life
Diversion	The intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution.
Hyperalgesia	Increased or heightened sensation to pain or pain stimulation.
IADL	Instrumental activities of daily living are activities related to independent living and include preparing meals, managing money, shopping for groceries or personal items, performing light or heavy housework, and using a telephone
Misuse	Use of a drug in ways other than prescribed by a health professional. Misuse usually does not include use for euphoric or psychotropic effects—that would be classified as “abuse”

Term	Definition
Physical Dependence	A state of adaptation manifested by a drug class-specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist.
Pseudo addiction	The development of abuse-like behaviors due to unrelieved pain, and that should be eliminated by measures that relieve the pain.
Trial Period	A period of time during which the effectiveness of using opioids is tested to see if goals of functionality and decreased pain are met. A trial should occur prior to treating someone with long-acting opioids and should include goals. If trial goals are not met, the trial should be discontinued and an alternative approach taken to treating the pain.
Tolerance	A state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more opioid effects over time.

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- Non-Opioid Pain Management Tool
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- The Role of Methadone in the Management of Chronic Non-Malignant Pain
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- Directory of Resources
- Utah's Tamper Resistant Requirements

For more tools and information visit:

http://prc.coh.org/culture.asp

http://www.PainEdu.org

The tools found in this publication can be downloaded from:

www.health.utah.gov/prescription

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TOOLS

TOOLS

Pain Management and Evaluation Tool

Pain Management Work up and Risk Assessment

Name	ID#	Date
Pain Dxs:		DOB
		Gender M/F

Opiod Risk Tool[1]	Mark all that apply	Score if Female	Score if Male	Additional Risk Assessments		Comments
				Drug Screen	Y/N	
Family Hx of Substance Abuse				DOPL Screen	Y/N	
Alcohol	[ ]	1	3	Risk of Obstructive Sleep Disorder	Y/N	
Illeg Drugs	[ ]	2	3			
Prescrp	[ ]	4	4			
Personal Hx of Substance Abuse				Obesity Y/N	BMI =	
Alcohol	[ ]	3	3	Hx of Sleep Apnea	Y/N	
Illeg Drugs	[ ]	4	4			
Prescrp	[ ]	5	5			
Hx of Preadolescent Sexual abuse	[ ]	3	0	**Baseline Measures**		**Comments**
				Analgesia[2] (Pain 0-10)		
Age 16-45 yrs	[ ]	1	1	Activity[3] (Function 0-10)		
Depression	[ ]	1	1	Adverse Events	Y/N	
Psychiatric Disease				Aberrant Behavior	Identify	
ADD	[ ]	2	2			
OCD	[ ]	2	2			
Bipolar	[ ]	2	2			
Skiz	[ ]	2	2			
Total	[ ]					

Consultation/Referral:				**Comments**
If receiving Morphine equivalent ≥ 120 mg/day or Methadone ≥ 50 mg/day	**then**	Sleep Apnea Test	Y/N	
If receiving Methadone ≥ 50 mg	**then**	EKG (Qt)	Y/N	

Treatment agreement discussed and signed by patient	**Date**

Patient Goals			Identify aberrant behavior which indicates discontinuation
Analgesia Pain[2] (0-10)	Activity - Function[3] (0-10)	Adverse Events - #	

[1] Opioid Risk Tool (Webster & Dove, 2007 - low risk (routine care), moderate risk (increased monitoring frequency) high risk (consider referral to Substance Abuse and/or Pain Management specialists)
[2] Pain Intensity 0 = no pain, 5 = moderate pain, 10 = worst pain imaginable
[3] Activity Function 0= no limitations, 5 = limitations (difficulty working, lifting,exercising, or conducting daily living activities) 10 = severe limitations (unable to work, conduct daily living activities, lift, or exercise)

Produced by Utah Department of Health, Prescription Pain Medication Program, 2008

Pain Management and Evaluation Tool

Pain Management Follow-Up

Name	ID#	Date
Pain Dxs:		DOB
		Gender M/F

Initation of Trial			Start Date			Review Date	
Visit Frequency [1] Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation Change (Date)

Titration - Visit = 2 - 4 weeks							
Visit Frequency [1] Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation Change (Date)

Maintenance - Visit = Quarterly							
Visit Frequency [1] Date	Analgesia - Pain (0-10)	Activity - Function (0-10)	Adverse Events - #	Aberrant Behavior - Identify	DOPL Check	Random Drug Screen	Comments (Date)
							Discontinuation Change (Date)

[1] Webster 2008 Monitoring Frequencies
Low Risk (0-3) Routine
Mod Risk 4-7 Bi-Weekly
High Risk ≥ 8 Weekly

TOOLS

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TOOLS

Patient Pain and Medication Tracking Chart

Patient Pain and Medication Tracking Chart

Name	ID#	Date
Pain Dxs:		DOB
		Gender M/F

Directions: At the end of each day use this log to record your function, pain, sleep and alcohol/drug use. This will be used by your provider to properly adjust your medications to obtain optimal benefit and to minimize risk to your health and safety.

Date	Medications	# Pills/day	Pain [1] (0-10)	Function [2] (0-10)	# Hours Slept	Alcohol or Drugs used

[1] Pain Scale: 0 = no pain, 5 = moderate pain, 10 = worst pain imaginable
[2] Function Scale: 0 = no limitations, 5 = limitations (difficulty working, lifting, exercising, or conducting daily living activities, 10 = severe limitations (unable to work, conduct daily living activities, lift or exercise)

Produced by Utah Department of Health, Prescription Pain Medication Program, 2008

Sheehan Disability Scale

SHEEHAN DISABILITY SCALE

A BRIEF, PATIENT RATED, MEASURE OF DISABILITY AND IMPAIRMENT

Please mark ONE circle for each scale.

WORK* / SCHOOL

The symptoms have disrupted your work / school work:

Not at all — Mildly — Moderately — Markedly — Extremely

0 ◄ 1 2 3 4 5 6 7 8 9 ► 10

☐ I have not worked /studied at all during the past week for reasons unrelated to the disorder.

* Work includes paid, unpaid volunteer work or training

SOCIAL LIFE

The symptoms have disrupted your social life / leisure activities:

Not at all — Mildly — Moderately — Markedly — Extremely

0 ◄ 1 2 3 4 5 6 7 8 9 ► 10

FAMILY LIFE / HOME RESPONSIBILITIES

The symptoms have disrupted your family life / home responsibilities:

Not at all — Mildly — Moderately — Markedly — Extremely

0 ◄ 1 2 3 4 5 6 7 8 9 ► 10

DAYS LOST

On how many days in the last week did your symptoms cause you to miss school or work or leave you unable to carry out your normal daily responsibilities? _____

DAYS UNDERPRODUCTIVE

On how many days in the last week did you feel so impaired by your symptoms, that even though you went to school or work, your productivity was reduced? _____

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TOOLS

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Brief Pain Inventory Form

Brief Pain Inventory (Short Form)©

Study ID#_____ Hospital#_____

Do not write above this line

Date:____/____/____

Time:_____

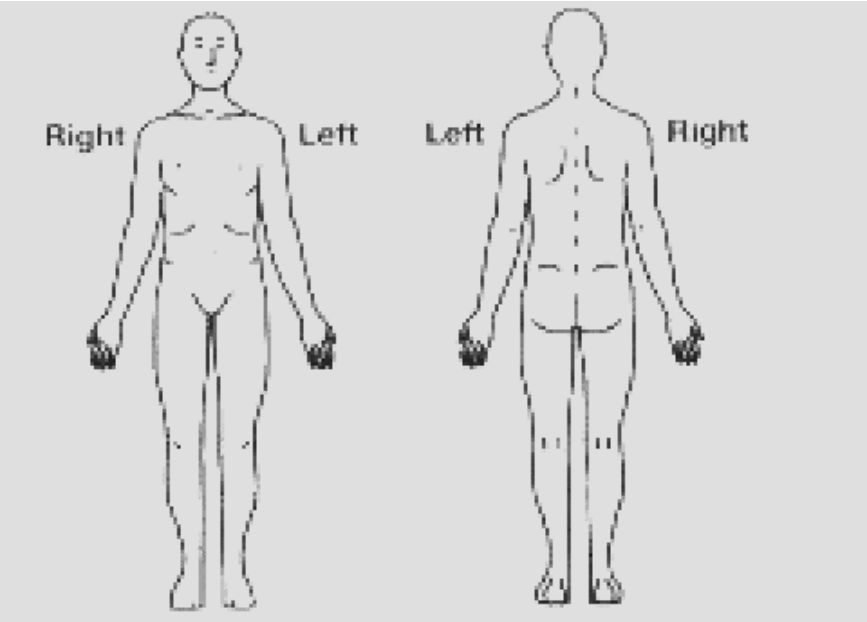
Name:_____

Last First Middle Initial

1) Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

1. yes 2. no

2) On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3) Please rate your pain by circling the one number that best describes your pain at its **WORST** in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No pain								Pain as bad as you can imagine		

Brief Pain Inventory Form

4) Please rate your pain by circling the one number that best describes your pain at its **LEAST** in the past 24 hours.

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

5) Please rate your pain by circling the one number that best describes your pain on the **AVERAGE.**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

6) Please rate your pain by circling the one number that tells how much pain you have **RIGHT NOW.**

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

7) What treatments or medications are you receiving for your pain?

_____

8) In the past 24 hours, how much **RELIEF** have pain treatments or medications provided? Please circle the one percentage that most shows how much.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
No relief										Complete relief

9) Circle the one number that describes how, during the past 24 hours, **PAIN HAS INTERFERED** with your:

A. General Activity:

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

B. Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

TOOLS

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Brief Pain Inventory Form

C. Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

D. Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

E. Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

F. Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

G. Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

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Source: Dr. Charles Cleeland, Anderson Cancer Center, Pain Research Group, 1100 Holcombe, Houston, TX 77030.

Sample Treatment Plan for Prescribing Opioids

Treatment Plan Using Prescription Opioids

Patient name: _____

Prescriber name: _____

THE PURPOSE OF THIS AGREEMENT IS TO STRUCTURE OUR PLAN TO WORK TOGETHER TO TREAT YOUR CHRONIC PAIN. THIS WILL PROTECT YOUR ACCESS TO CONTROLLED SUBSTANCES AND OUR ABILITY TO PRESCRIBE THEM TO YOU.

I (patient) understand the following (initial each):

_____ Opioids have been prescribed to me on a trial basis. One of the goals of this treatment is to improve my ability to perform various functions, including return to work. If significant demonstrable improvement in my functional capabilities does not result from this trial of treatment, my prescriber may determine to end the trial.

Goal for improved function: _____

_____ Opioids are being prescribed to make my pain tolerable but may not cause it to disappear entirely. If that goal is not reached, my physician may end the trial.

Goal for reduction of pain: _____

_____ Drowsiness and slowed reflexes can be a temporary side effect of opioids, especially during dosage adjustments. If I am experiencing drowsiness while taking opioids, I agree not to drive a vehicle nor perform other tasks that could involve danger to myself or others.

_____ Using opioids to treat chronic pain will result in the development of a physical dependence on this medication, and sudden decreases or discontinuation of the medication will lead to symptoms of opioid withdrawal. These symptoms can include: runny nose, yawning, large pupils, goose bumps, abdominal pain and cramping, diarrhea, vomiting, irritability, aches and flu-like symptoms. I understand that opioid withdrawal is uncomfortable but not physically life threatening.

_____ There is a small risk that opioid addiction can occur. Almost always, this occurs in patients with a personal or family history of other drug or alcohol abuse. If it appears that I may be developing addiction, my physician may determine to end the trial.

Continued on other side.

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Sample Treatment Plan for Prescribing Opioids

I agree to the following (initial each):

_____ I agree not to take more medication than prescribed and not to take doses more frequently than prescribed.

_____ I agree to keep the prescribed medication in a safe and secure place, and that lost, damaged, or stolen medication will not be replaced.

_____ I agree not to share, sell, or in any way provide my medication to any other person.

_____ I agree to obtain prescription medication from one designated licensed pharmacist. I understand that my doctor may check the Utah Controlled Substance Database at any time to check my compliance.

_____ I agree not to seek or obtain **ANY** mood-modifying medication, including pain relievers or tranquilizers from **ANY** other prescriber without first discussing this with my prescriber. If a situation arises in which I have no alternative but to obtain my necessary prescription from another prescriber, I will advise that prescriber of this agreement. I will then immediately advise my prescriber that I obtained a prescription from another prescriber.

_____ I agree to refrain from the use of **ALL** other mood-modifying drugs, including alcohol, unless agreed to by my prescriber. The moderate use of nicotine and caffeine are an exception to this restriction.

_____ I agree to submit to random urine, blood or saliva testing, at my prescriber's request, to verify compliance with this, and to be seen by an addiction specialist if requested.

_____ I agree to attend and participate fully in any other assessments of pain treatment programs which may be recommended by the prescriber at any time.

I understand that ANY deviation from the above agreement may be grounds for the prescriber to stop prescribing opioid therapy at any time.

_____ _____
Patient Signature Date

_____ _____
Prescriber Signature Date

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SF-12

Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

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(SF12v2 Standard, US Version 2.0)

SAMPLE

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SF-12

3. During the past 4 weeks, how much of the time have you had any of the result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

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SAMPLE

COMM

The Current Opioid Misuse Measure (COMM)® is a brief paper and pencil self-administered patient questionnaire to help monitor chronic pain patients who are on chronic opioid therapy. The COMM helps clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with the misuse or abuse of opioid medications. Validated in 2006 and unlike other available predictive measures, the objective was to provide clinicians with an assessment tool to periodically monitor misuse of medication for patients who have been prescribed opioids for an extended period of time over the course of treatment. Additionally, the COMM serves as an ideal way to help document risk assessment over the continuum of care with opioid treatment.

The COMM tool, instructions for administration, and scoring information guide are available for download for individual clinician use at http://www.painedu.org/registration.asp?target=terms.

COMM

Current Opioid Misuse Measure (COMM)®

The Current Opioid Misuse Measure (COMM)® is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM is for clinician use only. The tool is not meant for commercial distribution.
- The COMM is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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COMM

Current Opioid Misuse Measure (COMM)®

Please answer each question as honestly as possible. Keep in mind that we are only asking about the **past 30 days**. There are no right or wrong answers. If you are unsure about how to answer the question, please give the best answer you can.

Please answer the questions using the following scale:	**Never**	**Seldom**	**Sometimes**	**Often**	**Very Often**
	0	1	2	3	4
1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems?	O	O	O	O	O
2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (i.e., doing things that need to be done, such as going to class, work or appointments)	O	O	O	O	O
3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (i.e., another doctor, the Emergency Room, friends, street sources)	O	O	O	O	O
4. In the past 30 days, how often have you taken your medications differently from how they are prescribed?	O	O	O	O	O
5. In the past 30 days, how often have you seriously thought about hurting yourself?	O	O	O	O	O
6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)?	O	O	O	O	O

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COMM

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)?	O	O	O	O	O

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COMM

Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
17. In the past 30 days, how often have you had to visit the Emergency Room?	O	O	O	O	O

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COMM

Scoring Instructions for the Current Opioid Misuse Measure (COMM)®

To score the COMM, simply add the rating of all the questions. A score of 9 or higher is considered a positive

Sum of Questions	COMM Indication
> or = 9	+
< 9	-

As for any scale, the results depend on what cutoff score is chosen. A score that is sensitive in detecting patients who are abusing or misusing their opioid medication will necessarily include a number of patients that are not really abusing or misusing their medication. The COMM was intended to over-identify misuse, rather than to mislabel someone as responsible when they are not. This is why a low cut-off score was accepted. We believe that it is more important to identify patients who have only a possibility of misusing their medications than to fail to identify those who are actually abusing their medication. Thus, it is possible that the COMM will result in false positives – patients identified as misusing their medication when they were not.

The table below presents several statistics that describe how effective the COMM is at different cutoff values. These values suggest that the COMM is a sensitive test. This confirms that the COMM is better at identifying who is misusing their medication than identifying who is not misusing. Clinically, a score of 9 or higher will identify 77% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 9 is .95, which means that most people who have a negative COMM are likely not misusing their medication. Finally, the Positive likelihood ratio suggests that a positive COMM score (at a cutoff of 9) is over 2 times (2.26 times) as likely to come from someone who is actually misusing their medication (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 9 will ensure that the provider is least likely to miss someone who is really misusing their prescription opioids. However, one should remember that a low COMM score suggests the patient is really at low-risk, while a high COMM score will contain a larger percentage of false positives (about 34%), while at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

COMM Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 9 or above	.77	.66	.66	.95	2.26	.35

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TOOLS

TOOLS

SOAPP-R

The *Screener and Opioid Assessment for Patients with Pain- Revised Version (SOAPP®-R)* is a brief paper and pencil self-administered patient questionnaire that was developed for clinicians to help them better assess and determine how much monitoring a patient on long-term opioid therapy might require prior to prescription. The SOAPP®-R was validated in 2008, and is an updated and revised version of SOAPP V.1 originally released in 2003. The use of opioid medications sometimes includes concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Since long-term opioid therapy may carry significant risk in certain patients, the SOAPP®-R is intended to play a role as a quick and easy-to-use tool that can help clinicians identify and mitigate that risk, document risk assessment prior to opioid prescription.

The SOAPP®-R tool, instructions for administration, and scoring information guide are available for download for individual clinician use at http://www.painedu.org/registration.asp?target=terms.
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SOAPP-R

2007 Release

Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R)

The Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®-R) is a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require. This is an updated and revised version of SOAPP V.1 released in 2003.

Physicians remain reluctant to prescribe opioid medication because of concerns about addiction, misuse, and other aberrant medication-related behaviors, as well as liability and censure concerns. Despite recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems, physicians often express a lack of confidence in their ability to distinguish patients likely to have few problems on long-term opioid therapy from those requiring more monitoring.

SOAPP-R is a quick and easy-to-use questionnaire designed to help providers evaluate the patients' relative risk for developing problems when placed on long-term opioid therapy. SOAPP-R is:

- A brief paper and pencil questionnaire
- Developed based on expert consensus regarding important concepts likely to predict which patients will require more or less monitoring on long-term opioid therapy (content and face valid)
- Validated with 500 chronic pain patients
- Simple to score
- 24 items
- <10 minutes to complete
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The SOAPP-R is for clinician use only. The tool is not meant for commercial distribution.
- The SOAPP-R is **NOT** a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with SOAPP-R scores to decide on a particular patient's treatment.
- The SOAPP-R is **NOT** intended for all patients. The SOAPP-R should be completed by chronic pain patients being considered for opioid therapy.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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SOAPP-R

SOAPP®-R

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	○	○	○	○	○
2. How often have you felt a need for higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impatient with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often have you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

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SOAPP-R

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
13. How often have any of your close friends had a problem with alcohol or drugs?	○	○	○	○	○
14. How often have others told you that you had a bad temper?	○	○	○	○	○
15. How often have you felt consumed by the need to get pain medication?	○	○	○	○	○
16. How often have you run out of pain medication early?	○	○	○	○	○
17. How often have others kept you from getting what you deserve?	○	○	○	○	○
18. How often, in your lifetime, have you had legal problems or been arrested?	○	○	○	○	○
19. How often have you attended an AA or NA meeting?	○	○	○	○	○
20. How often have you been in an argument that was so out of control that someone got hurt?	○	○	○	○	○
21. How often have you been sexually abused?	○	○	○	○	○
22. How often have others suggested that you have a drug or alcohol problem?	○	○	○	○	○
23. How often have you had to borrow pain medications from your family or friends?	○	○	○	○	○
24. How often have you been treated for an alcohol or drug problem?	○	○	○	○	○

Please include any additional information you wish about the above answers.
Thank you.

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SOAPP-R

Scoring Instructions for the SOAPP®-R®

All 24 questions contained in the SOAPP®-R have been empirically identified as predicting aberrant medication-related behavior six months after initial testing.

To score the SOAPP, add the ratings of all the questions. A score of 18 or higher is considered positive.

Sum of Questions	SOAPP-R Indication
> or = 18	+
< 18	-

What does the Cutoff Score Mean?

For any screening test, the results depend on what cutoff score is chosen. A score that is good at detecting patients at-risk will necessarily include a number of patients that are not really at risk. A score that is good at identifying those at low risk will, in turn, miss a number of patients at risk. A screening measure like the SOAPP-R generally endeavors to minimize the chances of missing high-risk patients. This means that patients who are truly at low risk may still get a score above the cutoff. The table below presents several statistics that describe how effective the SOAPP-R is at different cutoff values. These values suggest that the SOAPP-R is a sensitive test. This confirms that the SOAPP-R is better at identifying who is at high risk than identifying who is at low risk. Clinically, a score of 18 or higher will identify 81% of those who actually turn out to be at high risk. The Negative Predictive Values for a cutoff score of 18 is .87, which means that most people who have a negative SOAPP-R are likely at low-risk. Finally, the Positive likelihood ratio suggests that a positive SOAPP-R score (at a cutoff of 18) is nearly 4 times (3.80 times) as likely to come from someone who is actually at high risk (note that, of these statistics, the likelihood ratio is least affected by prevalence rates). All this implies that by using a cutoff score of 18 will ensure that the provider is least likely to miss someone who is really at high risk. However, one should remember that a low SOAPP-R score suggests the patient is very likely at low-risk, while a high SOAPP-R score will contain a larger percentage of false positives (about 30%); at the same time retaining a large percentage of true positives. This could be improved, so that a positive score has a lower false positive rate, but only at the risk of missing more of those who actually do show aberrant behavior.

SOAPP-R Cutoff Score	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Positive Likelihood Ratio	Negative Likelihood Ration
Score 17 or above	.83	.65	.56	.88	2.38	.26
Score 18 or above	.81	.68	.57	.87	3.80	.29
Score 19 or above	.77	.75	.62	.86	3.03	.31

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SOAPP-R

How does the SOAPP-R help determine appropriate treatment?
The SOAPP-R should only be one step in the assessment process to determine which patients are high-risk for opioid misuse. The following discussion examines the assessment and treatment options for chronic pain patients who are at risk (high risk or medium risk) and those who are likely not at risk.

Who is at a high risk for opioid misuse? (SOAPP-R score = 22 or greater*)

Patients in this category are judged to be at a high risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at a higher risk for opioid misuse. Some examples of these behaviors or beliefs include a current or recent history of alcohol or drug abuse, being discharged from another physician' care because of his/her behavior, and regular noncompliance with physicians' orders. These patients may have misused other prescription medications in the past. It is a good idea to review the SOAPP-R questions with the patient, especially those items the patient endorsed. This will help flesh out the clinical picture, so the provider can be in the best position to design an effective, workable treatment plan.

Careful and thoughtful planning will be necessary for patients in this category. Some patients in this category are probably best suited for other therapies or need to exhaust other interventions prior to entering a treatment plan that includes chronic opioid therapy. Others may need to have psychological or psychiatric treatment prior to or concomitant with any treatment involving opioids. Patients in this category who receive opioid therapy should be required to follow a strict protocol, such as regular urine drug screens, opioid compliance checklists, and counseling.

Specific treatment considerations for patients in this high-risk category:

- Past medical records should be obtained and contact with previous and current providers should be maintained.
- Patients should also be told that they would be expected to initially give a urine sample for a toxicology screen during every clinic visit. They should also initially be given medication for limited periods of time (e.g., every 2-weeks).
- Ideally, family members should be interviewed and involvement with an addiction medicine specialist and/or mental health professional should be sought.
- Less abusable formulations should be considered (e.g., long-acting versus short-acting opioids, transdermal versus oral preparation, tamper-resistant medications).
- Early signs of aberrant behavior and a violation of the opioid agreement should result in a change in treatment plan. Depending on the degree of violation, one might consider more restricted monitoring, or, if resources are limited, referring the patient to a program where opioids can be prescribed under stricter conditions. If violations or aberrant behaviors persist, it may be necessary to discontinue opioid therapy.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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SOAPP-R

Who is at a moderate risk for opioid misuse? (SOAPP-R score = 10 to 21*)

Patients in this category are judged to be at a medium or moderate risk for opioid misuse. These patients have indicated a history of behaviors or beliefs that are thought to place them at some risk for misuse. Some examples of these behaviors or beliefs are family history of drug abuse, history of psychological issues such as depression or anxiety, a strong belief that medications are the only treatments that will reduce pain and a history of noncompliance with other prescription medications. It is a good idea to review the SOAPP-R items the patient endorsed with the patient present.

Some of these patients are probably best treated by concomitant psychological interventions in which they can learn to increase their pain-coping skills, decrease depression and anxiety, and have more frequent monitoring of their compliance. They may need to be closely monitored until proven reliable by not running out of their medications early and having appropriate urine drug screens.

Additional treatment considerations for patients in this category:

- Periodic urine screens are recommended.
- After a period in which no signs of aberrant behavior are observed, less frequent clinic visits may be indicated. If there are any violations of the opioid agreement, then regular urine screens and frequent clinic visits would be recommended.
- After two or more violations of the opioid agreement, an assessment by an addiction medicine specialist and/or mental health professional should be mandated.
- After repeat violations referral to a substance abuse program would be recommended. A recurrent history of violations would also be grounds for tapering and discontinuing opioid therapy

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

Who is at a low risk for opioid misuse? (SOAPP-R score < 9*)

Patients in this category are judged to be at a low risk for opioid misuse. These patients have likely tried and been compliant with many other types of therapies. They should be able to handle their medication safely with minimal monitoring. They are apt to be responsible in their use of alcohol, not smoke cigarettes, and have no history of previous difficulties with alcohol, prescription drugs, or illegal substances. This patient probably reports few symptoms of affective distress, such as depression or anxiety.

As noted previously, the SOAPP-R is not a lie detector. The provider should be alert to inconsistencies in the patient report or a collateral report. Any sense that the patient's story "doesn't add up" should lead the provider to take a more cautious approach until experience suggests that the person is reliable.

Patients in this category would be likely to have no violations of the opioid treatment agreement. These patients are least likely to develop a substance abuse disorder. Additionally, they may not require special monitoring or concomitant psychological treatment.

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SOAPP-R

Additional treatment considerations for patients in this category:

- Review of SOAPP-R questions is not necessary, unless the provider is aware of inconsistencies or other anomaly in patient history/report.
- Frequent urine screens are not indicated.
- Less worry is needed about the type of opioid to be prescribed and the frequency of clinic visits.
- Efficacy of opioid therapy should be re-assessed every six months, and urine toxicology screens and update of the opioid therapy agreement would be recommended annually.

** Note these are general ranges. Clinicians should also complement SOAPP scores with other clinical data such as urine screens and psychological evaluations.*

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TOOLS

Opioid Risk Tool

Date _____

Patient Name _____

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. Family History of Substance Abuse	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. Personal History of Substance Abuse	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. Age (Mark box if 16 – 45)		[ ]	1	1
4. History of Preadolescent Sexual Abuse		[ ]	3	0
5. Psychological Disease	Attention Deficit Disorder Obsessive Compulsive Disorder Bipolar Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
TOTAL		**[ ]**		

Total Score Risk Category Low Risk 0 – 3 Moderate Risk 4 – 7 High Risk $\geq$ 8

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Opioid Risk Tool

Low-risk patients should be monitored at a level that could be described as routing. This does not mean these individuals are not monitored with vigilance and care, only that no extraordinary measures are required.

- Explain the standard treatment agreement; both provider and patient should sign it.
- Schedule regular follow-up visits (monthly at first).
- Set the frequency of medication refills (monthly for the first 6 months).
- Perform initial urine (or other) drug screening.
- Communicate with pharmacies or obtain initial reports from prescription-monitoring programs (where available) and prior medical providers.
- Document every patient and clinician interaction.
- Continually review the Four A's during return visits.
- Consultations with specialists are not required.
- Medication type: adequate analgesia, no restrictions.

Moderate risk for drug abuse calls for another layer of vigilance in addition to the routine monitoring established for low-risk patients:

- Regular follow-up visits and prescriptions refills should occur every 2 weeks initially.
- Observe patients for signs of complicating co morbid diagnoses, such as anxiety, depression, or a sleep disorder.
- Consider referring the patient for evaluation by pain management and psychiatric specialists.
- Conduct regular checks (every 6-12 months) of your state's prescription monitoring database, if available, or consult with the patient's pharmacist.
- Visit with the patient's family members or other third parties to verify the patient's accounts and for evidence of environmental influences.
- Institute random urinalysis (or another screening method) to confirm compliance with medication levels.
- Consider checking leftover medications to verify their quantity.
- Consider limiting the use of rapid-onset analgesics.

High-risk patients require the following measures of intense monitoring in addition to those required by the low-risk and moderate-risk groups:

- Schedule regular follow-up visits more frequently than usual. If problems develop, shorten the treatment interval to weekly.
- Prescribe just enough medication to last until the next appointment and ensure that prescription refills are contingent upon attendance.
- Typically, psychiatric and addiction-medicine consultations are required. Consider consultation with a pain management specialist. Coordinate treatment.
- Conduct regular urine (or other) drug screenings in addition to some unexpected screenings.
- Consider using blood screenings.
- During every visit, count the patient's leftover medication.
- Consult a prescription database (if available) more frequently.
- Strongly enforce the treatment agreement.
- Avoid prescribing rapid-onset analgesics and consider limiting short-acting analgesics.

Webster & Dove, 2007

Opioid Risk Tool

The 3 risk categories help make treatment decisions easier but should not be used to label patients. Remember that the need to monitor for aberrant behavior is ongoing, and patients can move from 1 risk group to another throughout the course of treatment. For example, a patient initially assessed as low risk may later display multiple aberrant behaviors in response to a deteriorating physical condition or life stresses.

In general, exhibiting more than 3 mildly aberrant behaviors during 1 year or exhibiting 1 egregious behavior should cause a patient to move to a higher risk category and to be monitored more closely. If patients remain in the low-risk category for 6 months, the interval between visits and refills of medication can be increased. Eventually, when patients have remained in the low-risk category for 1 year, refills that last for 3 months are common.

Webster & Dove, 2007

Urine Drug Testing Devices

Urine Drug Testing Devices

To the best of our knowledge, this is a comprehensive list of CLIA waived office drug testing devices that test for specific prescription drugs and are under $10.

Test Name	Analytes that are Tested	Approx. Price
Alfa Scientific Designs, Inc. Instant Verdict Multi-Drug of Abuse Urine Test	Methadone, Morphine-Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	$8.50
American Bio Medica Rapid TOX	Buprenorphine, Methadone, Opiates, Oxycodone, Propoxyphene- Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	$4.15
BTNX Inc. Know Multi-Drug One Step Screen Test Panel (Urine)	Methadone, Morphine-Amphetamines, Barbiturates, Benzos, Cocaine, MDMA, Methamphetamines, PCP, THC, Tricyclic Antidepressants	$6.80

Search for CLIA approved tests
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm
CLIA waived tests
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm
CLIA waived analytes
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

TOOLS

Signs of Substance Misuse

Features of presentation that may alert practitioner to the possibility of substance misuse

- Cutaneous signs of drug abuse - skin tracks and related scars on the neck, axilla, groin, neck, forearm, wrist, foot and ankle. Such marks are usually multiple, hyper-pigmented and linear. New lesions may be inflamed. Shows signs of “pop” scars from subcutaneous injections.
- Being assertive, aggressive or emotionally labile
- Current intoxication/withdrawal
- May show unusual knowledge of controlled substances.
- Gives medical history with textbook symptoms or gives evasive or vague answers to questions regarding medical history.
- Reluctant or unwilling to provide reference information. May have no General Practitioner.
- Will often request a specific controlled drug and is reluctant to try a different drug.
- Generally has no interest in diagnosis - fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation.

British Pain Society, 2007

Checklist for Adverse Effects, Function, and Opioid Dependence

Checklist for adverse effects

- Constipation, sweating, nausea
- Exacerbation of sleep apnea, COPD
- Opioid bowel syndrome
- Rebound headaches
- Fatigue and confusion (particularly in the elderly)
- Reproductive effects (impotence in men and menstrual irregularities in women)
- Sensitization to pain (higher opioid doses may be required in acute pain compared to stable chronic pain)
- Neurotoxicity, seizures and hallucinations (for example with repeated administration of Demerol)

Checklist for function that should be assessed

- Sleep
- Mood
- Libido
- Time out of bed, ability to sit, ability to stand
- Activities within the house and outside (e.g., household chores, shopping, etc.)
- Activities at work (return to work, modified duties, trial employment, etc.)

Checklist for signs of opioid dependence

- On high and escalating doses of opioids
- Frequently runs out of medicine early observed to be intoxicated or in withdrawal
- Alters, borrows, steals, or sells prescriptions
- Accesses multiple sources of opioids, including from ERs, other prescribers, friends, acquaintances, or on the street *
- Injects oral medications
- Threatens or harasses staff to get immediate appointment
- Reluctant to try alternatives
- Angry, demanding, or tearful if not given drug of choice
- Deterioration of functional status while in receipt of opioid
- Concurrent abuse of alcohol or other illicit drugs
- Multiple dose escalations or other noncompliance with therapy despite warnings
- Multiple episodes of prescription loss

College of Physicians and Surgeons of Ontario, 2000

Federal Guidelines on Proper Disposal of Prescriptions

Proper Disposal of Prescription Drugs

Federal Guidelines:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription drugs down the toilet *only* if the label or accompanying patient information specifically instructs doing so (see box).
- Take advantage of community pharmaceutical take-back programs that allow the public to bring unused drugs to a central location for proper **disposal**. Some communities have pharmaceutical take-back programs or community solid-waste programs that allow the public to bring unused drugs to a central location for proper disposal. Where these exist, they are a good way to dispose of unused pharmaceuticals.

The FDA advises that the following drugs be flushed down the toilet instead of thrown in the trash:
Actiq (fentanyl citrate)
Daytrana Transdermal Patch (methylphenidate)
Duragesic Transdermal System (fentanyl)
OxyContin Tablets (oxycodone)
Avinza Capsules (morphine sulfate)
Baraclude Tablets (entecavir)
Reyataz Capsules (atazanavir sulfate)
Tequin Tablets (gatifloxacin)
Zerit for Oral Solution (stavudine)
Meperidine HCl TabletsPercocet (Oxycodone and Acetaminophen)
Xyrem (Sodium Oxybate)
Fentora (fentanyl buccal tablet)
Note: Patients should always refer to printed material accompanying their medication for specific instructions.

Office of National Drug Control Policy
ONDCP, Washington, D.C. 20503p (202) 395-6618 f (202) 395-6730

www.WhiteHouseDrugPolicy.gov

TOOLS

Non-Opioid Pain Management Tool

Non-Opioid Pain Management Tool

Area/Type of Pain	Treatment Options (Strongest Recommendations listed first)	When to Initiate	Population	Duration/Indication of Treatment	Cautions/MISC
Back Pain <4 weeks	Directed Exercise Program (1, 2, 3, 4, 5, 6)	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss (2)	Immediately	All ages	Life long	Consider co morbidities
	Ice/Heat (2, 4, 6, 7)	During the first 1-4 days	All ages	Most effective in first 1-3 days	Consider co morbidities
	Acetaminophen up to 4 g/day (1, 2, 4, 6, 8, 9)	Immediately	Adults	Can be long term	Consider co morbidities
	Physical therapy (4, 6, 10, 11)	After 3 weeks of conservative therapy	Adults	1-2 visits	Consider co morbidities
	NSAIDs (2, 4, 6, 9, 12)	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers (4, 9, 13)	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing
	Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and failed Acetaminophen therapy	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors
	Back School (14, 15)	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain.
	Tramadol/acetaminophen (2)	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol (2)	After initial acetaminophen trail	Adults	Can be long term	Consider co morbidities
	Manipulation (1, 4, 6, 16, 17, 18, 19)	Most effective when used for pain <6 weeks of duration without radiculopathy	Adults	3-4 weeks of treatment has been studied. Up to 8 treatments.	Consider co morbidities, not shown to be better than other therapies. Not to be used with herniated disks
Back Pain >4 weeks	Directed Exercise Program (1, 2, 3, 4, 5, 8, 18, 19)	Immediately	Adults	Life Long	Consider co morbidities
	Yoga exercises (viniyoga) (20)	Immediately	Adults	Life Long, studies for 12 weekly sessions	Has been shown to be as or more beneficial than exercise in some studies.
	Controlled Weight Loss (2)	Immediately	Adults	Life Long	Consider co morbidities
	Acetaminophen up to 4 g/day (1, 2, 4, 8)	Immediately	Adults	Can be long term	Consider co morbidities

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	NSAIDs (2, 4, 12)	Immediately, recommend acetaminophen trial first. Some evidence that NSAIDs are equal with acetaminophen in chronic low back pain (21) Some evidence that it is superior at pain control. (22)	Adults with no CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
	Muscle Relaxers (4, 13)	Immediately	Adults	Short term treatment	Significant side effects profile, use cautions in prescribing, some studies did not show any benefit after 3-4 weeks of injury
	Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and no CV risk factors	Adults with no CV risk factors	Short term	Consider co morbidities, no CV risk factors
	Back School (14, 15, 18)	After 1-2 weeks of conservative therapy	Adults	For length of program	This has shown to speed return to work, but not any significance in lowering of pain scores or duration of pain. Swedish Back School program was studied.
	Tricyclic antidepressants (9, 23)	After 3-4 weeks and failing conservative therapy, acetaminophen	Adults	As long as deemed beneficial	Have significant side effects profile, consider co morbidities
	Tramadol/acetaminophen (2)	After failing acetaminophen for 1-2 weeks	Adults	Can be long term	Consider co morbidities
	Tramadol (2)	After failing acetaminophen trial, co administration with acetaminophen has been shown to have more favorable results	Adults	Can be long term	Consider co morbidities
	Injections, epidural/facet joints (24, 25)	After failing conservative treatment	Adults	As long as beneficial, if effective often last 1-4 months in duration, can be used to help diagnosis and evaluate for additional treatment options	Choose population according to guidelines. There are conflicting opinions on efficacy
	Physical Therapy (10, 11)	Recommend starting immediately	Adults	1-2 visits	Consider co morbidities
	Message Therapy (26, 27, 28)	Recommended in conjunction exercise and education	Adults	As long as beneficial has been shown to effective for up to one year, >5 visits shows better results, most studies showed results in 6-10 treatments	Some disagreement in literature, but done by licensed therapist found to be more effective
	Neuroreflexotherapy (29)	Only in Chronic LBP	Adults	Undetermined	Preliminarily this has shown some effect.

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					Requires lengthy training of practitioner to be considered effective
Neck Pain	Directed Exercise Program (1, 2, 3, 6, 30)	Within 7-10 days of injury	All ages	Life long	Consider co morbidities, can add mechanical manipulation to an exercise program
	Acetaminophen 4g/day maximum (2, 6, 31)	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs (6, 12, 31)	Immediately (recommended to try Acetaminophen first)	Younger adults, without any CV, Renal or GI risk factors	Short term treatment	Consider co morbidities, no CV, renal or GI risk factors
	Physical Therapy (6)	After 2 weeks of conservative treatment	Adults	1-2 visits for education, counseling of home exercise	Consider co morbidities
	Manipulation (6)	Once more conservative measures fail	Adults	Best when combined with exercise	Consider co morbidities, rare instances of CVA
	IV methylprednisolone (31)	Within 8 hours of injury for acute whiplash	Adults	One time treatment	Any contraindications to IV steroids.
	IM Lidocaine (31)	Chronic neck pain with arm symptoms	Adults	Only a few treatments indicated	Consider co morbidities
	Muscle Relaxers (31)	Immediately	Adults	Short term	Consider co morbidities
	Acupuncture (32)	After failing exercise and/or acetaminophen/NSAIDs	Adults	Ideally 6 or more treatments, effects have been shown for short-term pain relief	Consider co morbidities
Headache	Directed exercise program (33)	Immediately	Adults	When the HA is a result of a mechanical neck disorder	Consider co morbidities
	Acetaminophen 4g/day maximum (34)	Immediately	Adults	Long term, has not been shown to be effective in migraines	Consider co morbidities
	NSAIDS (12, 35, 36)	Immediately	Adults	Short term, shown to be effective in both migraine and non-migraine HAs	Consider co morbidities, not to be used with CV, renal or GI risk factors
	Triptans (36, 37)	Use if unable to control HA with NSAIDs and or acetaminophen	Adults	Beneficial for migraine headaches. IM has been shown to be more effective than oral, but both are superior to placebo. Sumatriptan most studied	Consider co morbidities
	Excedrin (36)	Immediately	Adults	Shown to be beneficial in Acute migraines	Consider co morbidities
	Amitriptyline (35)	Immediately	Adults	Best for migraine headaches, can be started immediately	Monitor for side effects and complications of medication, can cause drowsiness
	Antidepressants (other TCAs, SNRIs,	After failing conservative	Adults	Migraine, tension, and mixed.	Independent of depression,

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	SSRIs) (38, 39)	therapy		Studies lasted 4-27 weeks	SSRI least effective
	Antiemetics (36)	With migraine associated nausea	Adults	Has been shown to help with pain and nausea with migraines	Consider co morbidities
	Anticonvulsants (40)	After failing other therapies, for prevention	Adults	For prevention of migraine headache	Sodium valproate/divalproex sodium and topiramate are the best studied
	NSAIDS combined with metoclopromide (41)	After failing acetaminophen	Adults	Migraine	Consider co morbidities, metoclopromide can cause dystonia. NNT 3.5
	DHE IM/SC/IV (36)	After failing more conservative therapies	Adults	Have shown to help migraines, more effective in combination with antiemetics	Consider co morbidities
	Isometheptene (36)	After failing more conservative therapies	Adults	Found effective for mild-moderate migraine	Consider co morbidities
	Normal barometric oxygen therapy (42)	Immediately	Adults	For use in Cluster Headaches	Unknown
	TENS (35)	Immediately	Adults	Best for cervical tension headaches, mildly affective in some migraine headaches	Do not use in patients with pacemakers, cardiac conduction abnormalities, or over the carotid body or sinus
	Manipulation (35)	Immediately	Adults	Best for tension, post-traumatic headache. Can be helpful in some migraine headaches	Choose population according to literature
	Acupuncture (43)	As adjuvant treatment	Adults	Shown to be effective for both tension and migraine	Choose population according to literature, not effective for all
Osteoarthritis	Directed Exercise Program (1, 2, 3, 6, 44)	Within 7-10 days of injury	All ages	Life long	Consider co morbidities
	Controlled Weight Loss (2)	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen 4g/day maximum (2, 8)	Immediately first line	Adults	Can be long term	Consider co morbidities
	NSAIDs (2, 12)	Immediately	Younger adults, without any CV, Renal or GI risk factors	Short term	Consider co morbidities, no CV, renal or GI risk factors
	Non-acetylated salicylates (2)	Immediately	Adults	Short term	Consider co morbidities, watch for ototoxicity
	Topical capsaicin (2)	Immediately	Adults	Short term	Consider co morbidities
	Intra-articular steroid injection (2, 45)	Immediately	Adults	Can be long term, but if too long can consider joint replacement.	This should be considered first-line therapeutic intervention if OA is confined to a single joint.
	Cox-2 Inhibitors (1, 2)	If unable to tolerate NSAIDs and failed Acetaminophen	Adults , not to be used in people with any CV risk factors	Short term treatment	Consider co morbidities, no CV risk factors

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		therapy			
	Diacerein (46, 47)	After failing other therapies	Adults	Studies lasted 2 months to 3 years	Consider co morbidities, shown to have minimal pain relief
Acute Sports Injury	Ice/Heat (2)	Immediately for first 1-4 days	All ages	For first 1-4 days	Instruct on timing to not cause tissue damage
	Acetaminophen 4g/day maximum (2)	Immediately	Adults	Can be long term	Consider co morbidities
	NSAIDs (2, 12)	Immediately, recommended to try acetaminophen first	Adults	Short term	Consider co morbidities
Neuropathic Pain	Acetaminophen 4g/day maximum (48)	Immediately	Adults	Can be long term	Consider co morbidities
	Anticonvulsants (49, 50)	After failing acetaminophen	Adults	Can be long term	Have a side effect profile that must be monitored. Carbamezapine and gabapentin found to most effective, some showing crabamezapine to be more effective with lower NNT and higher NNH
	Systemic administration of local anesthetics (51)	After failing acetaminophen	Adults	Undetermined	Can be as effective as anticonvulsants. Monitor for side effects
	Antidepressants (34, 52)	After failing acetaminophen.	Adults	Can be long term, TCAs (amitriptyline) and Venlafaxine shown to be most effective. Not shown to be effective in HIV neuropathies	Monitor for side effects, follow black box warnings. Newer SSRIs have less evidence supporting their use in neuropathic pain
Post-Herpetic Pain	Anticonvulsants (49)	Immediately	Adults	While symptoms last	Can cause drowsiness
Fibromyalgia	Supervised Aerobic/Strength training exercise (53, 54, 55)	Immediately, for at least 20 minutes a day 3 times a week	All ages	Life long, most studies were conducted on average for 12 weeks, 3-24 weeks.	Consider co morbidities
	Cognitive Behavioral Therapy (54, 56)	Immediately	Adults	Data showed results from 6-30 months	Works best as a multidisciplinary approach
	Amitriptyline (54, 57, 58)	Immediately	Adults	While beneficial	Does have side effect profile, tolerance to effect can occur
	Cyclobenzaprine (54, 57)	Typically is after exercise, acetaminophen and amitriptyline	Adults	While beneficial	Significant side effects
	Acupuncture (54, 59, 60)	After exercise and	Adults	While beneficial	Mild/weak evidence

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		amitriptyline			
	Deep tissue message (54)	Immediately	Adults	While beneficial	Mild/weak evidence
	Fluoxetine (54)	Typically start with exercise, acetaminophen, and amitriptyline first	Adults	While beneficial	Secondary to amitriptyline, can be used in conjunction with tricyclics
	Dual-reuptake inhibitors (SNRIs): (54)	Immediately	Adults	While beneficial	Weaker evidence than previous medications
	Gabapentin (61)	Immediately	Adults	While beneficial, studied over a 12 week period	Consider co morbidities
	Pregabalin (54, 62, 63)	Immediately	Adults	While beneficial	Still under investigation, one study showing positive results
Dental Pain	Acetaminophen (64, 65)	Immediately	All ages	As needed	Consider co morbidities
	NSAIDs (65)	Immediately	Adults	As needed	Consider co morbidities
	Acupuncture (57, 66)	Immediately post-op	Adults	1-4 sessions	
Pelvic Pain (dysmenorrheal)	Directed exercise program (67)	Immediately	All ages	Life long	Consider co morbidities
	Acetaminophen (68)	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	NSAIDs (68, 69)	During first 3 days of menstruation	Adults	While beneficial	Consider co morbidities
	Oral contraceptives (70)	Immediately	Adults/Adolescents	While beneficial	Consider co morbidities, can be traditional or extended continuous cycle
	Acupuncture (71)	Immediately	Adults	10 visits over 3 months	Consider co morbidities
	Chinese herbal medication (72)	After other interventions	Adults	While beneficial	Not all interactions known with other medications
Pelvic Pain (chronic pelvic pain)	Directed exercise program (73)	Immediately	All ages	Life long	Consider co morbidities
	Medroxyprogesterone acetate (73)	Immediately	Adults	Not found to be effected after 9 months	Consider co morbidities
	Goserelin (73)	After failing more conservative therapies	Adults	As long as beneficial, cannot be taken longer than six months	Consider co morbidities, extensive side effects
Pelvic Pain (Endometriosis)	Danazol (74)	After failing conservative therapy	Adults	For up to 6 months	Consider co morbidities, extensive side effects
	OCPs (75)	Immediately	Adults	While beneficial	Consider co morbidities
	Goserelin (75)	After failing more conservative therapies	Adults	While beneficial, cannot be taken for longer than six months	Consider co morbidities, extensive side effects

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TOOLS

Absolute Contraindications to Opioid Prescribing

Absolute Contraindications to Opioid Prescribing: Discussion

1. Allergy to opioid agents
Morphine causes the release of histamine, frequently resulting in itching, but this is not an allergic reaction. True allergy to opioid agents (e.g. anaphylaxis) is not common but does occur. Generally, allergy to one opioid agent does not mean the patient is allergic to other opioids; also switching to an agent in another opioid drug class may be effective. For example, if a patient has a hypersensitivity to a phenanthrene, then a diphenylheptane drug may be tried. (See table below.) When patients report an "allergy" to all but one agent (such as meperidine), the presence of a substance use disorder should be considered. Consultation with an allergist may be helpful to resolve these issues.

Classes of Opioid Medications

Phenanthrenes	Diphenyleptanes	Phenylpiperidine
Codeine	Methadone	Fentanyl
Hydrocodone	Propoxyphene	Meperidine
Hydromorphone		
Levorphanol		
Morphine		**Other**
Oxycodone		Tramadol

[a] Meperidine is not recommended for chronic pain because of the potential for accumulation of the neurotoxic metabolite, normeperidine, and a potentially fatal drug interaction with monoamine oxidase inhibitors (MAOIs).

2. Co-administration of a drug capable of inducing life limiting drug-drug interaction
Providers should carefully evaluate potential drug interactions prior to initiating opioid therapy, (such as MAOI with concurrent meperidine use, or propoxyphene and alcohol and other CNS depressants). (Note: meperidine is not recommended for chronic pain because of this potentially fatal drug interaction and the potential for accumulation of the neurotoxic metabolite, normeperidine, with regular dosing.)

3. Active diversion of controlled substances
Diversion should be suspected when there are frequent requests for early refills, atypically large quantities are required, when purposeful misrepresentation of the pain disorder is suspected, or when a urine drug screen (UDS) is negative for the substance being prescribed, in the absence of withdrawal symptoms. Routine UDS often does not detect synthetic and semi-synthetic opioids (methadone, oxycodone, fentanyl, hydrocodone, meperidine or hydromorphone). Verified diversion is a crime and constitutes a strong contraindication to prescribing additional medications, and consultation with a pain specialist, psychiatrist, or addiction specialist may be warranted.

Strategies for Tapering & Weaning

Strategies for tapering:

From a medical standpoint, weaning from opioids can be done safely by slowly tapering the opioid dose and taking into account the following issues:

- A decrease by 10% of the original dose per week is usually well tolerated with minimal physiological adverse effects. Some patients can be tapered more rapidly without problems (over 6 to 8 weeks).
- If opioid abstinence syndrome is encountered, it is rarely medically serious although symptoms may be unpleasant.
- Symptoms of an abstinence syndrome, such as nausea, diarrhea, muscle pain and myoclonus can be managed with clonidine 0.1 – 0.2 mg orally every 6 hours or clonidine transdermal patch 0.1mg/24hrs (Catapres TTS-1™) weekly during the taper while monitoring for often significant hypotension and anticholinergic side effects. In some patients it may be necessary to slow the taper timeline to monthly, rather than weekly dosage adjustments.
- Symptoms of mild opioid withdrawal may persist for six months after opioids have been discontinued.
- Consider using adjuvant agents, such as antidepressants to manage irritability, sleep disturbance or antiepileptics for neuropathic pain.
- Do not treat withdrawal symptoms with opioids or benzodiazepines after discontinuing opioids.
- Referral for counseling or other support during this period is recommended if there are significant behavioral issues.
- Referral to a pain specialist or chemical dependency center should be made for complicated withdrawal symptoms.

Recognizing and managing behavioral issues during opioid weaning:

Opioid tapers can be done safely and do not pose significant health risks to the patient. In contrast, extremely challenging behavioral issues may emerge during an opioid taper.

Behavioral challenges frequently arise in the setting of a prescriber who is tapering the opioid dose and a patient who places great value on the opioid he/she is receiving. In this setting, some patients will use a wide range of interpersonal strategies to derail the opioid taper. These may include:

- Guilt provocation (“You are indifferent to my suffering”)
- Threats of various kinds
- Exaggeration of their actual suffering in order to disrupt the progress of a scheduled taper

There are no fool-proof methods for preventing behavioral issues during an opioid taper, but strategies implemented at the beginning of the opioid therapy are most likely to prevent later behavioral problems if an opioid taper becomes necessary.

Washington State Agency Medical Directors’ Group, 2007

Information for Patients—Opioid Analgesics for Non-Cancer Pain

Photocopy for use by clinician

Information for Patients - Opioid (Narcotic) Analgesics for Non-Cancer Pain

FOR:

FROM: **Dr.**

DATE:

Making Pain Tolerable

The main reason for using an opioid (narcotic) analgesic for chronic non-cancer pain is to make the pain tolerable - not to eliminate it. This treatment is usually only considered after more standard treatments such as anti-inflammatory drugs have failed. If you are agreeable, your physician will prescribe an opioid analgesic for you in gradually increasing doses to minimize side effects. It is extremely important that you follow the directions exactly. Your physician will be the only one prescribing this medication to you. If you increase the dose without your physician's permission, give the medication to another person or obtain this medication from another physician without the consent of your primary physician, the physician may stop prescribing the opioid analgesic for you.

Pain medication is only part of your chronic pain treatment program. Equally important is a gradual exercise program that will increase your activity level despite ongoing pain. You and your physician should agree on specific ongoing treatment goals.

What is My Risk of Addiction?

There is increasing scientific evidence that strong painkillers can relieve some pain in selected patients without causing addiction. It is important to be careful, however, when defining what "addiction" is. Addiction, or psychological dependence, is a pattern of drug use in which the patient craves a drug for its ability to produce a "high" rather than for its pain-relieving properties. This can lead to the selling and injection of drugs and attempts to obtain drugs from multiple physicians - activities generally referred to as "drug abuse". Studies have shown that if a person has no past history of drug abuse and the pain is physical in origin, the risk of addiction is extremely low. If you are placed on an opioid analgesic for a period of weeks, however, and then are suddenly taken off the medication, it is possible to experience a short withdrawal reaction. Although this can be prevented by withdrawing the drug slowly, it does not mean that you have developed a craving for the drug or developed a drug addiction.

Information for Patients—Opioid Analgesics for Non-Cancer Pain

What are the Side Effects?

Although opioid analgesics can produce side effects (drowsiness, confusion, nausea, constipation), these can be minimized by slowly increasing the dose of the drug and by using anti-nausea drugs and bowel stimulants. Pain medication as prescribed will not depress your respiration or prevent you from breathing normally.

Remember Your Follow-up

If you seem to benefit from the pain medications, your physician will see you about every 4 to 6 weeks for the first few months and about every two to three months thereafter. During each visit, you and your physician will assess pain relief, any side effects from the pain medication and your ability to meet your established activity goals.

Other Instructions: _____

_____

_____

The Role of Methadone in the Management of Chronic Non-Malignant Pain

TOOLS

The Role of Methadone in the Management of Chronic Non-Malignant Pain: Specific Considerations

Overview

Although the literature on methadone for non-malignant pain is scanty and based on case studies, the increasing use of methadone for this purpose requires recommendations to guide practice. There is extensive literature on the use of methadone as a potent analgesic agent for cancer pain and therefore recommendations for the use of methadone in the management of chronic non-malignant pain must be extrapolated from the cancer pain literature.

Methadone is a synthetic opioid analgesic with excellent oral bioavailability, a side effect profile similar to other opioid analgesics and a duration of action of at least eight hours with repetitive dosing. These qualities make it an attractive drug for outpatient pain management. Methadone also has an opioid receptor profile different from that of morphine and has N-methyl-D-aspartate (NMDA) antagonist activity that may confer advantages over morphine. However, experience in the use of methadone for cancer pain has revealed that methadone is far more potent as an analgesic agent than has been suggested by equianalgesic tables derived from single dose studies. With repetitive dosing, methadone is approximately ten times more potent than indicated in these standard tables. The main reason for this is probably the long elimination half-life of methadone (24-36 hours) which allows for much higher drug levels to be reached than could be predicted from single dose studies. This has obvious clinical implications since methadone takes 5-7 days to reach steady state at any particular dose. Therefore, the use of methadone as an analgesic agent requires the same pain assessment skills as for any other opioid drug, but even greater scrutiny in patient monitoring of analgesic and side effects.

Methadone use in the Management of Chronic Non-Malignant Pain

In Canada, methadone is available at low cost as an elixir which is usually made up at a concentration of 1 mg/ml. In opioid-naive patients or patients taking codeine preparations, methadone 2.5 mg q8h is safe and usually well-tolerated. For patients already on a major opioid analgesic like oxycodone or morphine, a reasonable starting dose of methadone is 5 mg q8h with dose increments of 5 mg q8h every 5-7 days. A general rule is to provide careful dose titration until adequate pain relief is achieved or side effects limit further dose escalation. However, one should look for a graded analgesic response to incremental dosing. The absence of a graded analgesic response may mean that the patient is not

The Role of Methadone in the Management of Chronic Non-Malignant Pain

'opioid-responsive. Patients should be seen weekly during the titration phase and every month or two during the maintenance phase.

For patients being switched from relatively large doses of an opioid analgesic (> 200 mg oral morphine or morphine equivalents daily), the table below should be used to calculate equianalgesic doses. For patients taking more than 500 mg oral morphine or morphine equivalents daily, the conversion to methadone should be staged with a third of the anticipated methadone dose being introduced every five days so that the entire conversion takes fifteen days. The dose of the previous opioid is decreased by a third every five days in inverse fashion.

Equianalgesic Doses of Common Opioid Analgesics Relative to Oral Methadone with Repetitive Dosing

Drug	Per Os (PO)	Intramuscular/Subcutaneous
Methadone	2 mg	
Morphine	30 mg	10 mg
Hydromorphone	8 mg	2 mg
Oxycodone	15 mg	

Patients and co-habitants should be warned about potential side effects (especially drowsiness and respiratory depression) and the possibility that side effects can continue to evolve for five to seven days after each dose adjustment. The spouse or significant other should be available at least twice daily to monitor for toxicity. Since drowsiness commonly precedes respiratory depression, they should be instructed to call the prescribing physician if drowsiness develops to obtain advice about further dosing. This obviously requires physician availability 24 hours a day during the titration phase. Elderly patients (over the age of 65), patients with severe lung disease and patients who cannot be adequately monitored at home should be considered for inpatient initiation of methadone treatment.

Note: *The CPSO involvement in the opioid dependence program mentioned is unrelated to the use of Methadone for analgesic purposes. If a physician wishes to obtain a permit to prescribe Methadone for analgesic purposes, he or she needs to apply to the* ***Office of Controlled Substances in Ottawa (613) 946-5139***

TOOLS

Dosing Guidelines

Starting Methadone Dose

Morphine Equivalent	Healthy adult <70 yrs	Adult w/ chronic illness or >70 yrs
Opioid naïve	5mg tid	2.5 mg bid
60 mg - 100 mg	5 mg tid	5 mg bid
>100mg	5 mg qid	5 mg bid

*Webster, 2005

MED for Selected Opioids

Opioid	Approximate Equianalgesic Dose (oral & transdermal)*
Morphine (reference)	30mg
Codeine	200mg
Fentanyl transdermal	12.5mcg/hr
Hydrocodone	30mg
Hydromorphone	7.5mg
Oxycodone	20mg
Oxymorphone	10mg

*Adapted from Washington 2007 Guidelines

Dosing Threshold for Selected Opioids*

Opioid	Recommended dose threshold for pain consult (not Equianalgesic)	Recommended starting dose for opioid-naïve patients	Considerations
Codeine	800mg per 24 hours	30mg q 4-6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Fentanyl Transdermal	50mcg/hour (q 72 hr)		Use only in opioid-tolerant patients who have been taking ≥ 60mg MED daily for a week or longer
Hydrocodone	30mg per 24 hours	5-10mg q 4-6 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Hydromorphone	30mg per 24 hours	2mg q 4-6 hours	

*the Utah guidelines do not specifically recommend a pain consult

Produced by Utah Department of Health, 2009 adapted from Washington State Agency Medical Director's Group, 2007 and Webster, 2005

Dosing Guidelines

Opioid	Recommended dose threshold for pain consult (not Equianalgesic)	Recommended starting dose for opioid-naïve patients	Considerations
Methadone**	*See table above*		Methadone is difficult to titrate due to its half-life variability. It may take a long time to reach a stable level in the body. Methadone dose should not be increased more frequently than every 7 days. Do not use as PRN or combine with other long-acting (LA) opioids.
Morphine	120mg per 24 hours	Immediate- release: 10mg q 4 hours Sustained-release: 15mg q 12 hours	Adjust dose for renal impairment.
Oxycodone	80mg per 24 hours	Immediate-release: 5 mg q 4-6 hours Sustained-release: 10mg q 12 hours	See individual product labeling for maximum dosing of combination products. Avoid concurrent use of any OTC products containing same ingredient. See acetaminophen warning, below.
Oxymorphone	40mg per 24 hours	Immediate-release: 5-10mg q 4-6 hours	Use with extreme caution due to potential fatal interaction with alcohol or medications containing alcohol

*the Utah guidelines do not specifically recommend a pain consult

Acetaminophen warning with combination products

Hepatotoxicity can result from prolonged use or doses in excess of recommended maximum total daily dose of acetaminophen including over-the-counter products.

- Short-term use (<10 days) – 4000 mg/day
- Long-term use – 2500mg/day

Key considerations in dosing long acting opioids

- Monitoring for adequate analgesia and use of “rescue” medications (at least until the long-acting opioid dose is stabilized). All new dosage calculations should include consideration for concurrent utilization of short-acting opioids.
- If the patient is more debilitated, frail and/or has significant metabolic impairments (e.g. renal or hepatic dysfunction), consider starting at the lower end of the conversion dose range.
- Always monitor for adverse effects (nausea, constipation, over-sedation, itching, etc.)

Equianalgesic dose table for converting opioid doses

All conversions between opioids are estimates generally based on “equianalgesic dosing” or ED. Patient variability in response to these EDs can be large, due primarily to genetic factors and incomplete cross-tolerance. **It is recommended that, after calculating the appropriate conversion dose, it be reduced by 25–50% to assure patient safety.**

Produced by Utah Department of Health, 2009 adapted from Washington State Agency Medical Director’s Group, 2007 and Webster, 2005

Directory of Resources

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Utah Directory of Resources

Consultation and Referral

Identifying Pain Management, Mental Health, and Substance Abuse Providers

1) The 211 Information and Referral Bank
http://www.informationandreferral.org
The 211 Info Bank strives to ease the process of locating available and appropriate resources.

2) Utah Cares: State Online Services
https://utahcares.utah.gov/erepucpub/en/ServiceSupplier_searchPage.do?__o3rpu=ScreenReferralHomePage.do
This site allows you to do a search on providers by type and county.

3) Utah Resources Hotline: 2-1-1
Dial 2-1-1 and someone can direct you to providers by specialty in any county in Utah.

4) Utah Medicaid Pain Management Providers
http://health.utah.gov/medicaid/pharmacy/documents/chronic.php

5) Utah Mental health providers
http://mentalhealth.samhsa.gov/databases/facility-search.aspx?state=UT&fullname=Utah

6) Substance Abuse Providers
http://www.dsamh.utah.gov/locationsmap.htm
This link allows you to seek providers by location using an interactive map.

Referral Services

8) Substance Abuse Hotline: 1-866-633-HOPE (4673)

5) Utah Medicaid Restriction Program
http://health.utah.gov/medicaid/pharmacy/Restriction/restriction.php

9) University of Utah Assessment & Referral Services
Assessment & Referral Services is a University of Utah Clinic within the Department of Psychiatry that provides high-quality, objective substance abuse assessments and referrals for individuals with possible substance abuse problems.

Laws Governing Use of Controlled Substances

Federal/DEA laws – www.dea.gov

1) Practitioner Manual
http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf
This manual has been prepared by the Drug Enforcement Administration to assist practitioners and other registrants authorized to prescribe, dispense, and

Directory of Resources

administer controlled substances. A summary of the act can be found below in Appendix C.
2) Schedules of Controlled Substances
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr1308_01.html
Schedules of controlled substances can be found in Title 21, Chapter II.
3) Prescriptions
http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr1306_01.html
Contains the rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829)
4) Administering and Dispensing of Controlled Substances
http://edocket.access.gpo.gov/cfr_2001/aprqtr/pdf/21cfr1306.07.pdf
Persons who are entitled to fill prescriptions are described in this document found at the link above.

State of Utah Laws – State legislation and regulations

1) Utah Medical Practice Act Rules
http://www.dopl.utah.gov/laws/R156-67.pdf
2) Utah Controlled Substance Act 58-37
http://www.dopl.utah.gov/laws/58-37.pdf
3) Utah Controlled Substance Rules R156-37
http://www.dopl.utah.gov/laws/R156-37.pdf
4) Reporting Prescription Fraud and/or Prescription Related Crime
http://www.urxnet.org/ or http://www.urxnet.org/tip/addtip.asp
5) Division of Occupational and Professional Licensure
http://dopl.utah.gov/
6) Utah Controlled Substance Database
https://csdb.utah.gov/
7) Model Policy for the Use of Controlled Substances for the Treatment of Pain—Federation of State Medical Boards
http://www.fsmb.org/pdf/2004_grpol_Controlled_Substances.pdf
The Model Policy, which was adopted by the Utah Medical Board of Examiners, is designed to communicate certain messages to licensees: that the state medical board views pain management to be important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. This policy is not meant to constrain or dictate medical decision making.

*If there are legal or workplace concerns, it is recommended that patients go to the industrial clinic

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Utah's Tamper Resistant Requirements

Tamper Resistant Prescription Pad/Paper Mandate
Effective April 1, 2008

Effective April 1, 2008, all non-electronic prescriptions must be written on tamper-resistant pads/paper in order to be eligible for reimbursement by Medicaid. The tamper resistant prescription pads/paper requirement applies to all outpatient drugs, including over-the-counter drugs. It also applies whether DOM is the primary or secondary payer of the prescription being filled. This new provision impacts all DOM prescribers: physicians, dentists, optometrists, nurse practitioners and other providers who prescribe outpatient drugs.

The Centers for Medicare & Medicaid Services (CMS) has issued guidance to the States in implementing the new federal requirement. This guidance allows for compliance with the tamper-resistant prescription pad/paper requirement to occur in two phases. For the first phase, a prescription must contain at least one of the three features outlined below by April 1, 2008, in order to be considered "tamper-resistant." All three features are required on the prescription pads by October 1, 2008.

DOM encourages providers to implement all security features by April 1, 2008 to be in compliance with all program requirements. Note that computer generated prescriptions are not exempt from the CMS mandate.

The features listed below are recommended as best practice tamper resistant features by a national taskforce including representatives from CMS, State Medicaid agencies, and national medical and pharmacy organizations. Features listed in bold tend to be less costly and easier for prescribers to implement.

Category 1 – One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form.	
Feature	**Description**
"Void" or "Illegal" Pantograph	**The word "Void" appears when the prescription is photocopied. Due to the word "Void" on faxed prescriptions, this feature requires the pharmacy to document if the prescription was faxed.**
Reverse "RX" or White Area on prescription	"Rx" symbol or white area disappears when photocopied at light setting. This feature is normally paired with the "Void" pantograph to prohibit copying on a light setting.
Coin-reactive ink	Ink that changes color when rubbed by a coin – Can be expensive and is not recommended.
Security Back print	Printed on the back of prescription form. The most popular wording for the security back print is "Security Prescription" or the security back print can include the states name.
Watermarking (forderiner)	Special paper containing "watermarking".
Diagonal lines (patented "Void")	Diagonal lines with the word "void" or "copy". Can be distracting or expensive.
Micro printing	Very small font writing, perhaps acting as a signature line. This is difficult to photocopy and difficult to implement if using computer printer. It is also difficult for a pharmacist to see.

Utah's Tamper Resistant Requirements

Category 2 - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.	
Feature	**Description**
Uniform non-white background color	**Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase or copy, the consistent background color will look altered and show the color of the underlying paper.**
Quantity check off boxes	**In addition to the written quantity on the prescription, Quantities are indicated in ranges. It is recommended that ranges be 25's with the highest being "151 and over". The range box corresponding to the quantity prescribed MUST be checked for the prescription to be valid. See illustration in Appendix 1.**
Refill Indicator (circle or check number of refills or "NR")	**Indicates the number of refills on the prescription. Refill number must be used to be a valid prescription.**
Pre-print "Rx is void if more than___ Rx's on paper" on prescription paper	**Reduces the ability to add medications to the prescription. - Line must be completed for this feature to be valid. Computer printer paper can accommodate this feature by printing "This space intentionally left blank" in an empty space or quadrant.**
Quantity Border and Fill (for computer generated prescriptions on paper only)	**Quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional)**
Refill Border and Fill (for computer generated prescriptions on paper only)	**Refill quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **5** Value may also be expressed as text, e.g. (FIVE), (optional)**
Chemically reactive paper	**If exposed to chemical solvents, oxidants, acids, or alkalis to alter, the prescription paper will react and leave a mark visible to the pharmacist.**
Paper toner fuser	Special printer toner that establishes strong bond to prescription paper and is difficult to tamper.
Safety or security paper with colored pattern	White (or some other color) mark appears when erased. This is expensive paper.

Category 3 – One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.	
Feature	**Description**
Security features and descriptions listed on prescriptions	**Complete list of the security features on the prescription paper for compliance purposes. This is strongly recommended to aid pharmacists in identification of features implemented on prescription.**
Encoding techniques (bar codes)	Bar codes on prescription. Serial number or Batch number is encoded in a bar code.
Logos	Sometimes used as part of the background color or pantograph.
Metal stripe security	Metal stripe on paper, difficult to counterfeit.
Heat sensing imprint	By touching the imprint or design, the imprint will disappear.
Invisible fluorescent fibers/ink	*Visible only under black light.*
Thermo chromic ink	*Ink changes color with temperature change. This is expensive paper and problematic for storage in areas not climate controlled.*
Holograms that interfere with photocopying	*May interfere with photocopying or scanning.*

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Utah's Tamper Resistant Requirements

Per CMS guidance, pharmacies that are presented with a prescription on a non-tamper-resistant prescription pad/paper may satisfy the federal requirement by calling the provider's office and verbally confirming the prescription with the physician or prescriber. The pharmacy shall document through placement on the original non-compliant prescription form that such communication and confirmation has taken place.

Prescriptions that the federal requirement does not apply to:

- E-prescriptions transmitted to the pharmacy;
- Prescriptions faxed to the pharmacy;
- Prescriptions communicated to the pharmacy by telephone by a prescriber;
- Transfer of a prescription between two pharmacies, provided that the receiving pharmacy is able to confirm by facsimile or phone call the authenticity of the tamper-resistant prescription with the original pharmacy;
- Written orders prepared in an institutional setting (which include Intermediate Care Facilities and Nursing Facilities), provided that the beneficiary never has the opportunity to handle the written order and the order is given by licensed staff directly to the dispensing pharmacy;
- Drugs dispensed or administered directly to the beneficiary in the physician's office or clinic;
- Written prescriptions dispensed to MS Medicaid beneficiaries s who become retroactively eligible after April 1, 2008, provided the prescription was filled on or after April 1, 2008, and before the beneficiary became retroactively eligible for MS Medicaid;
- Emergency fills, provided that the prescriber provides a verbal, faxed, electronic or compliant written prescription within 72 hours;
- Refills of written prescriptions presented at a pharmacy before April 1, 2008;
- Written prescriptions paid for by Medicare, a Medicare Part D plan or Medicare Advantage Plan, unless MS Medicaid fee-for-service is a secondary payer. Part D excluded drugs paid for by Medicaid must be executed on tamper-resistant pad/paper[1].

[1] Prescriber may not know when Medicaid is the primary or secondary payer for MS Medicaid beneficiaries; therefore, the Division of Medicaid (DOM) recommends that prescribers use tamper-resistant prescription pads/paper for all DOM beneficiaries.

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Appendix A: Guideline Rating Scale

10/10	• Extremely explicit evidence-based guidelines The “gold standard” • Evidence has been analyzed thoroughly through an explicit rating system • Recommendations are based on the evidence with the highest rating of quality • Expert consensus creates the recommendations, • Recommendations verified through a peer review
9/10	• Very explicit evidence-based guidelines • Evidence has been analyzed thoroughly through an explicit rating system • Recommendations are based on the evidence with the highest rating of quality • Expert consensus creates the recommendations
8/1	• Explicit evidence-based guidelines • Evidence has been analyzed thoroughly through an explicit rating system • Expert consensus
7/10	• Evidence-based guidelines • No record of the evidence from which the guidelines have been created is present • No rating system of the evidence is present either
6/10	• Evidence-based guidelines • Limited details to how they were created • No record of the evidence from which the guidelines have been created is present • No rating system of the evidence is present either
5/10	• Expert consensus statement only • Very detailed explanation of how the consensus was formed • Reviewed thoroughly by pain experts
4/10	• Expert consensus statement only • Detailed explanation of how the consensus was formed
3/10	• Expert consensus statement only • Little explanation of how the consensus was reached
2/10	• Expert consensus statement only • No explanation of how the consensus was reached
1/10	• No explanation of how guidelines were created

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