

Opioid Prescribing Tool Kit

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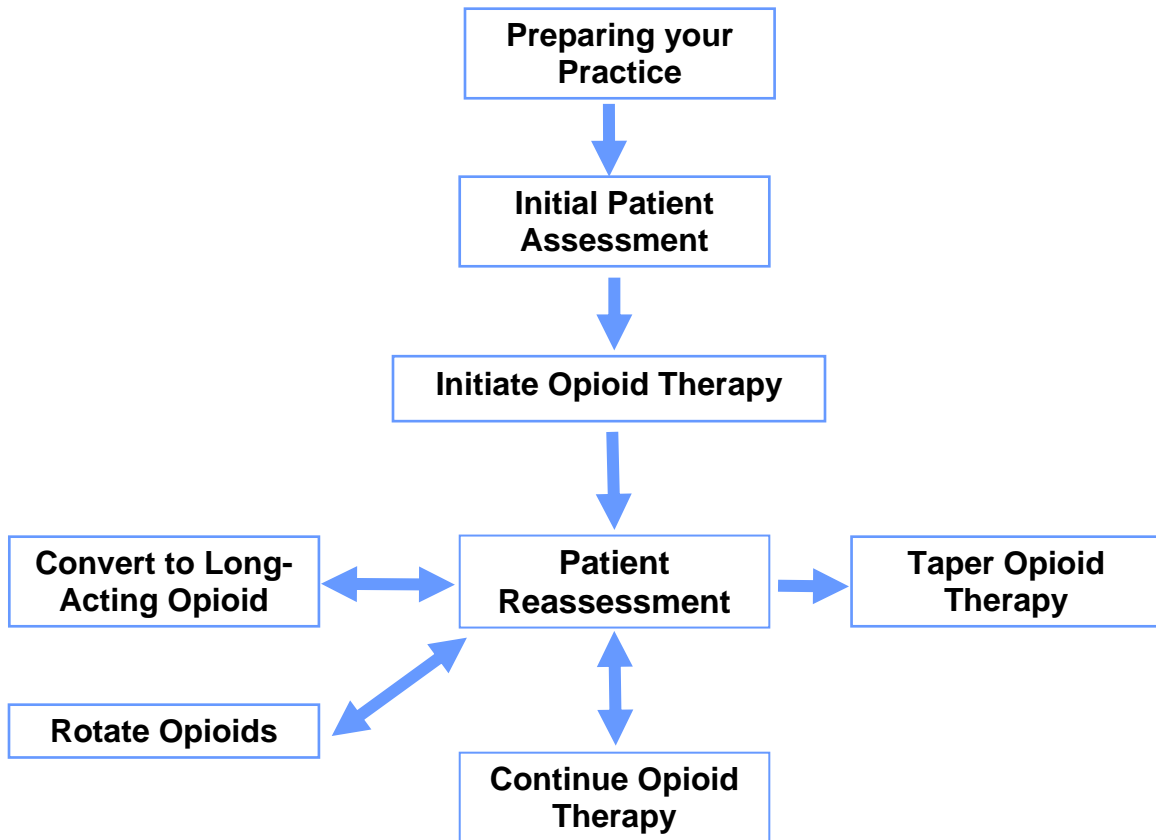
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ALGORITHM FOR OPIOID PRESCRIBING



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*Provided in this toolkit.

HOW TO PRESCRIBE OPIOIDS

- **If you are the clinician, read this page.**
- **If you are a member of the office staff, read the next document, “Instructions for Office Staff.”**

Instructions

- This toolkit will provide you with the information and tools to prescribe opioids safely and effectively to patients with chronic pain in a manner consistent with practice and regulatory guidelines.
- Read this section, “How to Prescribe Opioids,” for the necessary background information.
- Provide the document “Instructions for Office Staff” to your office manager. The office manager will need to implement certain systems to support opioid prescribing, which are detailed in that document.
- Then, when you are seeing a patient simply refer to the “Algorithm for Opioid prescribing” section.

Background

- Relief of pain is one of the most ancient and important obligations of the physician. Relieving both acute and chronic pain frequently requires the use of opioid analgesics. Like all medications, opioids are associated with complications; one of these is abuse and addiction. Unlike many other medications, not only the patient is at risk, but also the patient’s household and community.
- The purpose of this Tool Kit is to enable you and your staff to set up a system that supports safe and effective opioid prescribing for chronic pain. An additional purpose of this Tool Kit is to engage you and your staff in becoming public health advocates with respect to pain management and drug abuse. Read the Public Health Action Resource Kit when you are finished reading this background document.
- The risks and benefits of opioid therapy depend upon the patient, prescriber, practice setting, and community. Therefore, you should bear in mind that the general recommendations herein will often require some modifications based on your professional judgment and the realities of your practice.

Efficacy of Opioids

- Opioids have been shown to work for most kinds of pain, and most opioids have similar efficacy. However, like all other analgesics for chronic pain, they only work for a minority of patients long-term, and even then only relieve pain partially. It is important to have realistic expectations of the efficacy of long-term opioid therapy and to impart realistic expectations to patients and their family.
- It is an unwavering obligation of all physicians to treat pain aggressively, just like it is important to treat diabetes, asthma, or any other illness aggressively. However, there are many approaches to pain management, and there is no obligation to provide opioids when the risks would outweigh the benefits, or when a reasonable trial of opioid therapy has not produced a favorable risk-benefit balance.

- In general, patients requiring intermittent opioids do better with opioid combination products than with products that contain opioids alone – they get a better balance of pain relief and side effects.
- This illustrates the principle of “rational polypharmacy” – patients often do better on a rational combination of moderate doses of agents that work by different mechanisms, instead of high doses of a single agent.
- When patients have moderate or severe pain most of the time, they may do better on a long-acting opioid medication. This can be added to the short-acting medications, so the patient takes the long-acting medication on a fixed-dose basis, plus the short-acting medication as needed for “breakthrough pain.” However, patients on long-acting medications do not necessarily need to be on a short-acting medication. Alternatively, patients with fairly steady pain, or who have problems with short-acting medications, can just be on a fixed dose of a long-acting product.
- Some patients not doing well on one opioid may do well on another. The process of switching a patient from one opioid to another is called “opioid rotation.” Opioid rotation is safe when patients are on low doses but may be unsafe at high doses; specialty consultation is generally advisable under these circumstances, especially when converting to methadone.

Safety Issues

- The main side effects of opioids are nausea, vomiting, constipation, itching, sedation, dizziness, dysphoria, sweating, and urinary retention. A less well-known but very common side effect of opioids is endocrine disturbance, which take the form of central hypogonadism. Uncommon side effects include peripheral edema, mood disturbances, personality changes, insomnia, and headache. At high doses, or when ingested with other medications (notably benzodiazepines and alcohol), opioids can cause respiratory depression and death.
- Side effects can improve with continued therapy (i.e. tolerance to side effects develops), but many patients on long-term therapy still have persistent side effects.
- Patients will often not complain of side effects even if they are very bothersome; so you have to ask about them proactively; the enclosed tools will guide you.
- You can prevent side effects in a number of ways. Slow titration reduces side effects in general: start low and go slow. Flexible dosing (PRN) in general has fewer side effects than fixed dosing. In patients with previous problems with opioid-induced nausea/vomiting, prescribe an antiemetic (e.g. prochlorperazine 5 mg) with each opioid tablet for the first few days; when the patient is used to the opioid you can eliminate the antiemetic. Start all patients on long-term opioid therapy on a bowel regimen at the same time, such as senna/docusate 2 tablets at bedtime; if they don’t need it you can taper it off.
- Side effects are generally not self-reported; thus, you have to screen for them regularly by simply asking the patients or using testing tools. Side effects include endocrine effects, and substance abuse. Cognitive dysfunction or personality alterations, which occur occasionally, are not obvious to the patient and input from significant others is helpful.
- The treatment of side effects is dealt with at greater length in the “Algorithm for Opioid Prescription” tool and accompanying tools.

Definitions

Term	Definition
Addiction	A primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. Characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, craving, and continued use despite harm. Many still use the term “dependence” to mean addiction, which is different from “physical dependence.”
Physical Dependence	A state of adaptation that is manifested by a withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, or administration of an antagonist.
Tolerance	Loss of a drug’s effects over time, or need to increase the dose to maintain the effect.
Pseudoaddiction	Abuse-like behaviors that may develop in response to the undertreatment of pain. Examples include becoming focused on obtaining medications, "clock watching," and other "drug seeking" behaviors.
Withdrawal	A syndrome that occurs due to the cessation or reduction of prolonged use of a drug. Acute opioid withdrawal is characterized by dysphoria, nausea or vomiting, muscle aches, lacrimation, rhinorrhea, pupillary dilation, diarrhea, yawning, fever, or insomnia.
Psychoactive Substance Use	The use of a psychoactive drug in a socially accepted or medically sanctioned manner to modify or control mood or state of mind, in the absence of harmful consequences or a pattern of use likely to lead to harmful consequences. Examples include having a drink with a friend or taking an antianxiety agent for an acute anxiety state in accordance with a physician's prescription.
Abuse	The use of a substance to modify or control mood or state of mind in a manner that is illegal or harmful to oneself or others. Examples of the potential consequences of harmful use include accidents or injuries, blackouts, death by overdose, legal problems, and sexual behavior that increases the risk for HIV infection.
Misuse	The use of a substance in a manner not consistent with legal or medical guidelines, such as altering dosing or sharing medicines, which has harmful or potentially harmful consequences, exclusive of use for psychoactive purposes. Misuse can be intentional or unintentional.
Diversion	Redirecting the supply of legally obtainable drugs into illegal channels or obtaining a controlled substance by an illegal method.

Judging Outcomes

- Doing well on opioid therapy means getting meaningful pain relief, hopefully with improved ability to function, with little or no side effects, on steady doses, and with good compliance with the rules of opioid therapy (more on this later).
- It may take patients weeks, or even sometimes months, to stabilize on a steady dose. Patients with unbridled dose escalation beyond this point probably have opioid-unresponsive pain and will probably not benefit from long-term opioid therapy.
- A reasonable opioid trial means trying two or more agents, escalating the dose in a measured way to find the patient’s stable dose, and preventing and treating side effects proactively. Patients who are not doing well despite these efforts are not candidates for opioid therapy and should be taken off. This is one of the most important public health aspects of opioid prescribing (more on public health later).

Legal Issues

- Any licensed physician with a standard DEA number (federal and, if required, state) can prescribe any available opioid to treat any patient who suffers from pain. This still applies even if the patient has a drug addiction problem (although this is not always the best clinical course). However, physicians cannot prescribe any opioid for the maintenance treatment of addiction (even if the patient also has pain), except as indicated below. So, whether you can prescribe opioids depends on what you are prescribing them for.
- Only physicians working in a specially licensed methadone maintenance treatment center can prescribe methadone for the maintenance treatment of addiction. These patients frequently have co-morbid pain.
- Only physicians with a special waiver can prescribe buprenorphine for the treatment of opioid addiction. This is a growing area of responsibility for primary care doctors and is worth pursuing.
- It is illegal for patients to share their medications, use someone else's medications, or misrepresent themselves to obtain controlled substances, including failure to report significant information, such as a substance abuse history. Such events can generally be interpreted as crimes having been committed on the office premises, and the office staff has a right to report them to the police.
- HIPAA privacy rules do not apply when physicians need to exchange information with other health care providers to ensure the safety of patient care, or when a crime has been committed.

INSTRUCTIONS FOR OFFICE STAFF

How to Set Up an Opioid Prescribing System

1. Put this page in a visible place where only office staff can see it.
2. Inform your patients about your Controlled Substances Policy. Some practices choose to post a sign in the waiting room (see next page); others choose to provide this information in a Patient Treatment Agreement or Informed Consent Form.
3. Use only tamper- and copy-proof prescription pads; serialized pads are even better. Secure the pads as you would cash.
4. For electronic medical record systems, use a software that includes automatic dosing safeguards and alerts the physician when there are frequent opioid prescriptions for an individual patient.
5. Flag charts of all patients on long-term opioid therapy in a non-obvious way, such as with a colored sticker.
6. For all visits of patients on opioid therapy, follow these instructions:
 - a. Is there a completed **Initial Patient Assessment** form in the chart?
 - i. If not, put one on the chart for the clinician to fill out during the office visit. It will take about 10 minutes.
 - b. Is there a **Mental Health Screen** completed in the past year?
 - i. If not, have the patient fill it out prior to the visit, and put in on the chart for the clinician to review during the visit.
 - c. Is there a **Patient Treatment Agreement** signed by both patient and clinician on the chart?
 - i. If not, hand one to the patient to read before seeing the clinician, and to review and sign with the clinician during the visit.
 - d. Has the patient had **Endocrine Lab Tests** within the past year?
 - i. If not, set up the patient for the necessary blood tests.
 - e. Ask the patient whether he/she has received the **Patient Education Brochure**; if not, provide one.
 - f. For all follow-up visits for patients on opioid therapy, make sure the following are in the chart for the clinician to use for each visit:
 - i. **Patient Assessment and Documentation Tool (PADT)** for the clinician to fill out during the visit.
 - ii. **Triage & Exit Strategy Tool** for the prescriber to refer to during the visit.
 - iii. Results from the most recent urine toxicology screen (and all past ones)
 - iv. Latest **Prescription Monitoring Report** (where available)
 - v. **Medication Flow Chart**
 - vi. Set up a relationship with a urine toxicology screening provider. For all follow-up visits for patients on opioid therapy, have the patient provide a urine specimen before seeing the clinician. Patients should be advised prior to the visit to refrain from urinating for as long as possible prior to the visit and to arrive early for these procedures.

CONTROLLED SUBSTANCES POLICY SIGN

Regulations governing controlled substances vary by state and also include federal regulations. Following is a controlled substance policy statement/sign based on Massachusetts law. Review your state's regulations and develop an office policy regarding controlled substances; legal input is advisable.

NOTICE

It is a felony under state law, punishable by fine and imprisonment, to obtain or attempt to obtain possession of a controlled substance by means of forgery, fraud or deception, including forgery or falsification of a prescription or nondisclosure of a material fact in order to obtain a controlled substance from a practitioner.

“It is our policy to report this crime to the police.”

(NOTE: THIS NOTICE IS BASED ON MASSACHUSETTS STATUTES AND IS ONLY VALID FOR MASSACHUSETTS.)

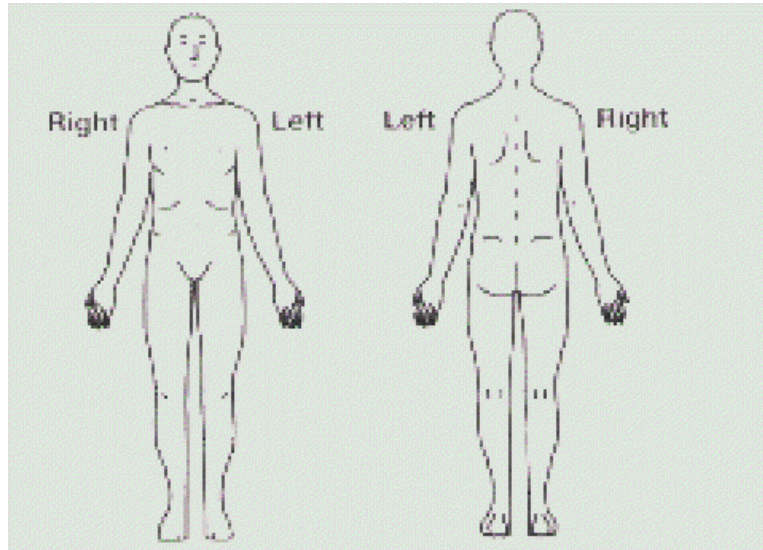
INITIAL PATIENT ASSESSMENT: SELF REPORT

Your Name _____ Today's Date _____

What type(s) of chronic pain do you have? (Check all that apply)

- Arthritis
- Low back pain
- Neck pain
- Fibromyalgia
(diffuse muscle pain)
- Reflex sympathetic dystrophy
- Neuropathy (nerve pain in limbs)
- Myofascial pain (face muscle pain)
- Muscle spasm
- Headache
- Migraine
- Pelvic pain
- Joint pain

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



For how long have you had your current chronic pain problem? (Check the best answer)

- Less than 3 months
- 3-6 months
- 6-12 months
- 1-2 years
- 2-5 years
- 5-10 years
- More than 10 years

Indicate the intensity of the pain by using the scale from 0 to 10, where 0 is no pain, and 10 is the worst pain

- What is the pain intensity today? (circle a number) 0 1 2 3 4 5 6 7 8 9 10

- What was the average pain intensity last week? 0 1 2 3 4 5 6 7 8 9 10

- What is the **lowest** and **highest** pain intensity you have had for this pain since the pain started? (circle two numbers) 0 1 2 3 4 5 6 7 8 9 10

- What makes the pain worse? _____

- What decreases the pain? _____

Describe the pain (Check all that apply)

- Sharp
- Dull
- Burning
- Throbbing

What is the effect of this pain on your life? (Check all that apply)

Affects your work, describe: _____

Affects your physical activities, describe: _____

Affects your daily functioning, describe: _____

Affects your mood, describe: _____

Indicate the treatments you have had for your pain problem (Check all that apply)

Surgery Results: _____

Infiltration Specify: _____
Results: _____

Medications

Non-steroidal anti-inflammatory drugs (e.g. ibuprofen, naproxen, aspirin)
Results: _____

Acetaminophen (e.g. Tylenol)
Results: _____

Opioids (e.g. Vicodin, Percocet, Oxycontin)
Results: _____

Gabapentin (e.g. Neurontin)

Results: _____

Other medications, specify: _____

Results: _____

Please indicate the medications you are currently taking for any reason:

<u>Medication</u>	<u>Strength</u>	<u>Frequency</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Please list any medications that you are allergic to and the reaction:

<u>Medication</u>	<u>Reaction</u>
_____	_____
_____	_____
_____	_____

Please indicate whether you have had any of the following issues:

- Depression
- Bipolar disorder
- Post-traumatic stress disorder
- Anxiety
- Other mood disorders, specify: _____

Please indicate whether you have ever had any problems with drugs or alcohol

- Yes
- No

If yes, please indicate which substances and when your last use was:

- Alcohol Last 30 days 1-3 months 3-6 months Over 6 months
- Marijuana Last 30 days 1-3 months 3-6 months Over 6 months
- Stimulants Last 30 days 1-3 months 3-6 months Over 6 months
- Heroin Last 30 days 1-3 months 3-6 months Over 6 months
- Pain meds Last 30 days 1-3 months 3-6 months Over 6 months
- Cocaine Last 30 days 1-3 months 3-6 months Over 6 months
- LSD Last 30 days 1-3 months 3-6 months Over 6 months
- Other, specify: _____
 Last 30 days 1-3 months 3-6 months Over 6 months

INITIAL PATIENT ASSESSMENT: CLINICIAN GUIDE

Use the Self-Report form completed by the patient (above) and the following Clinician Guide to complete the patient's initial assessment

Guide to Evaluation of Initial Medical History Information	
Category	Findings relevant to substance abuse risk
History of present illness	<ul style="list-style-type: none"> • <i>Assess risk at every visit (using the Triage Tool)</i> • Pain diagnosis • Previous pain treatments • Previous experience with opioid therapy <ul style="list-style-type: none"> ○ Effectiveness on pain and function ○ Compliance ○ Subjective experience (eg, euphoria) ○ Use of opioids for non-prescribed purposes
Past history	<ul style="list-style-type: none"> • Illnesses relevant to opioid therapy (eg, respiratory, hepatic, renal disease) • Medical illnesses suggestive of substance abuse <ul style="list-style-type: none"> ○ Hepatitis, HIV, TB, cellulitis, STDs, elevated LFTs, trauma, burns
Psychiatric history	<ul style="list-style-type: none"> • Current or past mental illness • History of substance abuse, including alcohol, tobacco: none, past in remission, current <ul style="list-style-type: none"> ○ Which substance(s); routes; prescription drugs
Social history	<ul style="list-style-type: none"> • Arrests • Motor vehicle accidents; driving under the influence • Domestic violence • Fires • Contact with substance abusers
Family history	<ul style="list-style-type: none"> • Substance abuse • Family support
Physical Signs Suggestive of Drug Abuse, by Body System (Swift)	
Skin	<ul style="list-style-type: none"> • Abscesses, cellulitis, and tissue necrosis—signs of drug use • Parallel needle marks; hyperpigmentation overlying a vein • Palpably sclerotic veins • Trauma to skin, e.g. abrasions, lacerations, cigarette burns
Head and neck	<ul style="list-style-type: none"> • Perforation of nasal septum, especially for individuals using stimulants • Poor dentition among opioid and stimulant abusers
Chest	<ul style="list-style-type: none"> • Cardiac disease in all types of drug users • Pulmonary disease due to smoking drugs (although most drug abusers are also heavy tobacco users) and in abusers of drugs that suppress respiration and the cough reflex
Abdomen	<ul style="list-style-type: none"> • Hepatomegaly and liver tenderness due to hepatitis • Splenomegaly in parenteral drug users
Lymphatic system	<ul style="list-style-type: none"> • Adenopathy, esp. in groin and axillae; common in injection drug users
Nervous system	<ul style="list-style-type: none"> • Peripheral neuropathies, sometimes secondary to tissue necrosis from injection, in alcohol and drug abusers

MENTAL HEALTH SCREENING TOOL

Patient Name _____ Today's Date _____

CIRCLE THE NUMBER THAT INDICATES THE BEST ANSWER.	
1. During the past month, how much of the time were you a happy person?*	
All of the time	5
Most of the time	4
Some of the time	3
A little of the time	2
None of the time	1
2. How much of the time during the past month, have you felt calm and peaceful?*	
All of the time	5
Most of the time	4
Some of the time	3
A little of the time	2
None of the time	1
3. How much of the time, during the past month, have you been a very nervous person?	
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5
4. How much of the time, during the past month, have you felt downhearted and blue?	
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5
5. How much of the time, during the past month, did you feel so down in the dumps that nothing could cheer you up?	
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5
Calculate: (<input type="text"/> - 5) / 20 = _____ X 100 = Final Score →	Final Score
CIRCLE THE LETTER BELOW THAT INDICATES THE BEST ANSWER	
1. In the past year, have you ever drunk or used drugs more than you meant to?	Y N
2. Have you felt you wanted or needed to cut down on your drinking or drug use in the past year?	Y N

*Reverse scored

Scoring Guide

Mental Health Screening Tool-5 (the first 5 questions):

1. Add up the numbers and write the total in the shaded box in the MHS tool (near bottom of page). Note that the first two items are already reversed scored for you.
2. To get the final score (FS), subtract 5 from the total. Divide by 20, and then multiply the result by 100. The formula is:
$$FS = [(Total - 5) / 20] \times 100$$
3. A final score less than 52 is clinically significant and should trigger a mental health referral to a practitioner experienced with chronic pain.

Two-item Conjoint Screening Test (last two items)

A “Yes” on either item should lead to further questioning about past and current drug abuse, should place the patient in at least the “medium” risk category, and in general should generate a referral for an addiction consultation.

URINE TOXICOLOGY

Practical Strategies

- Select a testing laboratory or Point of Care device supplier.
- Establish a routine urine drug test (UDT) immunoassay panel.
 - Recommended drugs/drug classes to screen for are:
 - Cocaine
 - Amphetamines (including ecstasy)
 - Opiates
 - Methadone
 - Marijuana
 - Benzodiazepines
 - Additional tests may be added as needed.
- Drug identification:
 - GC/MS or other chromatographic technique, identification for all patients prescribed opioids. Specify “no threshold” testing at the level of detection (LOD) to increase likelihood of detecting prescribed medications.
 - Many laboratories have a specific chromatographic pain panel that may include one or more of the following:
 - Codeine
 - Morphine
 - Hydrocodone
 - Hydromorphone
 - Oxycodone
 - Fentanyl
 - Buprenorphine
- Specimen collection:
 - Random collection is preferred;
 - Unobserved urine collection is usually acceptable;
 - If tampering is suspected, check urine temperature, pH, and creatinine concentration, and consider ordering an “adulteration panel” from your laboratory.
- UDT results:
 - Consult with laboratory regarding ANY unexpected results;
 - False positives: note that codeine is metabolized into morphine, and hydrocodone into hydromorphone. Thus, do not be alarmed if hydrocodone or hydromorphone are found in the urine of patients you are treating with codeine or hydrocodone. There are other causes of “false positives” as well.
 - Schedule an appointment to discuss abnormal/unexpected results with the patient; discuss in a positive, supportive fashion to enhance readiness to motivational enhancement therapy (MET) opportunities;
 - Use results to strengthen the healthcare professional-patient relationship and to support positive behavior change;
 - Chart results and interpretation.

Adapted from Gourlay D, Heit H, Caplan Y. Urine Drug Testing in Family Practice. California Academy of Family Physicians Monograph. Stamford, CT: Pharmacom Group, 2004.

PRESCRIPTION MONITORING REPORT

You have requested and obtained a prescription monitoring record for a patient. This guide will help you interpret these results and act accordingly. Do not forget to review prescription monitoring reports not only for your patients, but for individuals who may be receiving prescriptions in your name.

Interpreting Prescription Monitoring Data

- All tests have flaws. Prescription monitoring program reports (PMPRs) may have false positives (prescription attributed to one individual when it was actually filled by someone else), or false negatives (an individual did fill other prescriptions that are missing from the report). The rate of false positives and false negatives is unknown in most prescription monitoring systems.
- Different thresholds have different degrees of accuracy in predicting inappropriate behavior. Low thresholds (such as 2 doctors or 2 pharmacies) are likely to identify most doctor shoppers, but will reflect appropriate behavior in most cases (high sensitivity but low specificity). High thresholds (such as 10 prescribers or 10 pharmacies) are likely to reflect inappropriate behavior in all cases, but will probably miss cases of inappropriate behavior (high specificity, low sensitivity). The threshold of 4 or more doctors *and* 4 or more pharmacies is an acceptable indicator (according to experienced clinicians) for inappropriate behavior. However, the accuracy of any threshold for predicting actual inappropriate behavior is unknown. Therefore clinical judgment is required.
- The prescription monitoring report should be interpreted in the context of a complete patient assessment, not in isolation. Other important elements of a complete patient assessment include:
 - History and physical examination
 - Structured follow-up assessment (PADT)
 - Laboratory tests including urine toxicology screen
 - Reviewing a Medication Flow Chart for evidence of early refills
 - Documenting pill count (actual – expected) at every follow-up visit
 - Consultation reports from specialists when indicated
 - Review of outside medical records
 - Interviews with “significant others” (spouses, family, employers, etc.) as needed

Actions to Be Taken if Prescription Monitoring Data Suggest Drug Abuse and/or Diversion

- The goal of prescription monitoring is to eliminate doctor shopping, and to provide early identification of behaviors suggestive of drug abuse to trigger an early intervention.
- Actions taken in response to behaviors suggestive of drug abuse, from any of the above sources of information, should be taken for the benefit of the patient and the community, not to exert punishment or revenge, or to meet imagined but non-existent regulatory requirements.
- The appropriate response to a prescription monitoring report suggestive of doctor shopping or drug abuse is to bring the patient in for a conversation. The goals are:
 - To determine the “diagnosis” for the observed behavior. Possibilities include: (1) administrative (changed doctor, changed pharmacy, etc.); (2) under treatment of pain (“pseudoaddiction”); (3) misunderstanding of the Patient Treatment

- Agreement; (4) prescription opioid abuse; (5) frank criminal behavior (prescription rings, forgery, dealing opioids, etc.)
- Administer a “Brief Intervention.”
 - The Brief Intervention is a brief, several minute interview with the patient during which the physician expresses his/her concern over the patient’s pattern of behavior, discusses how drug abuse begins and emphasizes its negative consequences (health consequences, loss of employment, financial, friends, family, etc.)
 - Increase the intensity of patient monitoring and limit setting.
 - Reinforce the requirement for a single prescriber and single pharmacy. This will require coordination with other offices.
 - Options include: more frequent office visits, more frequent urine toxicology, smaller amounts of medication for each prescription, switching to a medication that the patient may be able to comply with more easily (e.g. fixed-doses of controlled-release medications), involving “significant others,” obtaining specialty consultation.
 - Patients who are disruptive to office staff, such as with frequent phone calls, unscheduled visits, calls to covering physicians, etc, should be reminded that such behaviors are not compatible with a continued doctor-patient relationship.
 - For patients who are unable to bring their behavior into compliance with office policies and the Patient Treatment Agreement, the benefits of continued opioid prescribing are likely to be outweighed by their risks. Options include:
 - Tapering opioid therapy over several weeks to avoid withdrawal, while continuing to work with the patient, with or without consultation, on non-opioid pain management strategies. Note that abandoning opioid therapy, which is not infrequently required, is not the same as abandoning the patient, which is rarely required.
 - Referring to specialists for consideration of continued opioid prescribing, since it is no longer safe in primary care practice.
 - Referring to addiction management, which may include opioid maintenance therapy for addiction.
 - Note that these options are not mutually exclusive, and will often be implemented in combination.
 - It is desirable for patients with addictive disorders and/or complex chronic pain problems to maintain a relationship with a primary care physician, even if the management of the pain and/or addiction will be conducted primarily by external specialists.
 - Discontinuing the doctor-patient relationship may be required when (1) patients are excessively disruptive or unable to comply with office policies, (2) frank criminal behavior precludes a working relationship.
 - If the physician believes that a crime has been committed on the office premises, such as misrepresenting oneself to obtain controlled substance prescriptions, it is the right of the physician or staff to contact law enforcement and/or other prescribers. HIPAA restrictions do not apply.

RECOGNIZING DRUG ABUSERS

Your Responsibilities

The abuse of prescription drugs —especially controlled substances— is a serious social and health problem in the United States today. As a healthcare professional, you share responsibility for solving the prescription drug abuse and diversion problem.

- You have a legal and ethical responsibility to uphold the law and to help protect society from drug abuse.
- You have a professional responsibility to prescribe controlled substances appropriately, guarding against abuse while ensuring that your patients have medication available when they need it.
- You have a personal responsibility to protect your practice from becoming an easy target for drug diversion. You must become aware of the potential situations where drug diversion can occur and safeguards that can be enacted to prevent this diversion.

This guide will help you meet these responsibilities.

Recognizing the Drug Abuser

Telling the difference between a legitimate patient and a drug abuser isn't easy. The drug-seeking individual may be unfamiliar to you. They could be a person who claims to be from out-of-town and has lost or forgotten a prescription of medication. Or the drug seeker may actually be familiar to you such as another practitioner, co-worker, friend or relative. Drug abusers or "doctor-shoppers" often possess similar traits and *modus operandi*. Recognizing these characteristics and *modus operandi* is the first step to identifying the drug-seeking patient who may be attempting to manipulate you in order to obtain desired medications.

Common Characteristics of the Drug Abuser

- Unusual behavior in the waiting room;
- Assertive personality, often demanding immediate action;
- Unusual appearance—extremes of either slovenliness or being over-dressed;
- May show unusual knowledge of controlled substances and/or gives medical history with textbook symptoms **OR** gives evasive or vague answers to questions regarding medical history;
- Reluctant or unwilling to provide reference information. Usually has no regular doctor and often no health insurance.;
- 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;
- May exaggerate medical problems and/or simulate symptoms;
- May exhibit mood disturbances, suicidal thoughts, lack of impulse control, thought disorders, and/or sexual dysfunction;
- Cutaneous signs of drug abuse: skin tracks and related scars on the neck, axilla, 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.

Modus Operandi Often Used by the Drug-Seeking Patient Include:

- Must be seen right away;
- Wants an appointment toward end of office hours;
- Calls or comes in after regular hours;
- States he/she's traveling through town, visiting friends or relatives (not a permanent resident);
- Feigns physical problems, such as abdominal or back pain, kidney stone, or migraine headache in an effort to obtain narcotic drugs;
- Feigns psychological problems, such as anxiety, insomnia, fatigue, or depression in an effort to obtain stimulants or antidepressants;
- States that specific non-narcotic analgesics do not work or that he/she is allergic to them;
- Contends to be a patient of a practitioner who is currently unavailable or will not give the name of a primary or reference physician;
- States that a prescription has been lost or stolen and needs replacing;
- Deceives the practitioner, such as by requesting refills more often than originally prescribed;
- Pressures the practitioner by eliciting sympathy or guilt or by direct threats;
- Utilizes a child or an elderly person when seeking methylphenidate or pain medication

What You Should Do When Confronted by a Suspected Drug Abuser**DO:**

- Perform a thorough examination appropriate to the condition;
- Document examination results and questions you asked the patient;
- Request picture I.D., or other I.D. and Social Security number. Photocopy these documents and include in the patient's record;
- Call a previous practitioner, pharmacist, or hospital to confirm patient's story;
- Confirm a telephone number, if provided by the patient;
- Confirm the current address at each visit;
- Write prescriptions for limited quantities;

DON'T:

- "Take the patient word for it" when you are suspicious;
- Dispense drugs just to get rid of drug-seeking patients;
- Prescribe, dispense, or administer controlled substances outside the scope of your professional practice or in the absence of a formal practitioner-patient relationship.

TRIAGE TOOL

The patient's risk level for substance abuse should be assessed at every visit and adjusted if necessary.

Risk Level	Characteristics	Management
Low	<ul style="list-style-type: none"> No history of substance abuse; minimal if any risk factors 	<ul style="list-style-type: none"> Can be managed by PCP If aberrant behaviors are observed, consider increasing risk category
Medium	<ul style="list-style-type: none"> Past history of substance abuse (not prescription opioid abuse); significant risk factors Patient previously assigned to low risk exhibiting aberrant behaviors 	<ul style="list-style-type: none"> PCP co-manages with addiction and/or pain specialists If aberrant behaviors are observed or persist, consider assigning to high-risk category
High	<ul style="list-style-type: none"> Active substance abuse problem; history of prescription opioid abuse Patient previously assigned to medium risk exhibiting aberrant behaviors 	<ul style="list-style-type: none"> Opioids may not be appropriate Refer treatment to specialists in management of patients with co-morbid pain and addictive disorders Continue to manage patient's medical care including pain relief and monitor specialized care

Adapted from: Gourlay D, *et al.* Universal precautions in pain medicine: a rational approach to the treatment of chronic pain. *Pain Med*; 2005 6:107-12.

CHOOSING AN ANALGESIC TREATMENT

This guide will help you choose the most appropriate treatment for the patient, taking into account the nature and intensity of the pain, as well as the patient's medical history and mental health status.

• Nonpharmacologic Treatment of Chronic Pain

In most cases, the treatment of pain should begin with nonpharmacologic measures:

- Ice
- Heat
- Corsets
- Exercise
- Rehabilitation
- Cognitive-behavioral therapy

If these measures are ineffective, a variety of nonopioid analgesic medications are also available, including those in the following tables. Potential side effects are noted.

• Nonopioid Analgesic Treatment of Chronic Pain

Drug	Potential Side Effects
Acetaminophen	Liver failure (rare, and most likely with overdose or history of alcohol abuse)
Aspirin	Abdominal pain, bleeding, constipation, edema, mental status change, nausea/vomiting, pruritus/rash
Nonselective NSAIDs	Abdominal pain, bleeding, constipation, edema, headache, nausea/vomiting, pruritus/rash
COX-2-selective NSAIDs	Abdominal pain, edema, headache, nausea/vomiting, pruritus/rash, cardiovascular, thrombosis

NSAIDs = nonsteroidal anti-inflammatory drugs

Medication	Usual Starting Dose and Interval	Common Dosage Range
Amitriptyline (Elavil®)	25 mg po hs (10 mg in frail, elderly)	50-150 mg po hs
Desipramine (Norpramin®, Petrofrane®)	25 mg po hs (10 mg in frail, elderly)	50-200 mg po hs
Nortriptyline (Aventyl®, Pamelor®)	25 mg po hs (10 mg in frail, elderly)	50-150 mg po hs
Anxiolytics – Azapirones		
Buspirone (Buspar®)	5 mg po tid	Max: 60 mg/day
Anxiolytics – Benzodiazepines (Note: all benzodiazepines cause additive sedation with opioids)		
Alprazolam (Xanax®)	0.25-0.5 mg po qd-tid	Minimum effective dose
Chlordiazepoxide (Librium®)	10-25 mg po qd-tid	Minimum effective dose
Diazepam (Valium®)	5-10 mg po qd-bid	Minimum effective dose
Lorazepam (Ativan®)	0.5-2 mg po qd-tid	Minimum effective dose
Midazolam (Versed®)	Doses vary depending on individual patient needs	
Psychostimulants		
Dextroamphetamine (Dexedrine®)	2.5-5 mg po qd or bid; last dose before 2 pm	5-20 mg in divided doses; last dose before 2 pm

Methylphenidate (Ritalin®)	2.5-5 mg po qd or bid; last dose before 2 pm	5-20 mg in divided doses; last dose before 2 pm
Anticonvulsants		
Carbamazepine (Tegretol®)	100 mg po bid	200 mg po bid-qid
Clonazepam (Klonopin®)	0.25-0.5 mg po tid	0.5-1 mg po tid
Duloxetine (Cymbalta®) For diabetic peripheral neuropathy	60 mg/day po; may increase to 60 mg po if tolerated but no response	120 mg/day
Gabapentin (Neurontin®)	100 mg po tid increase by 100 mg tid q 3 days	300-3600 mg/day in 3 divided doses
Phenytoin (Dilantin®)	300 mg po qd or 100 mg po tid	300-400 mg/day
Pregabalin (Lyrica®) For neuropathic pain; diabetic peripheral neuropathy	100 mg po tid; start 50 mg tid, increase to 300 mg/day over 7 days	Max: 300 mg/day
Valproic Acid (Depakene®) Divalproex (Depakote®)	125 mg po tid	500-1000 mg po tid
Corticosteroids		
Dexamethasone Methylprednisolone	Dexamethasone 40-100 mg IV or equivalent as loading doses or q 6h for first 24-72 hrs (if indications are acute spinal cord compression, increased ICP) Dexamethasone 4-8 mg po q 8-12 h Prednisone 20 - 40 mg po q 8-12 h (if indications are nerve compression, visceral distension, increased ICP, soft-tissue infiltration) Dexamethasone 4-12 mg/d Prednisone 5-10 mg tid (if indications are alleviation of nausea, anorexia, pain in palliative care)	Dexamethasone 10 – 20 mg IV q 6 h or Methylprednisolone 40 – 80 mg IV q 6 h Minimal effective dose
Miscellaneous Adjuvant Analgesic Agents		
Baclofen (Lioresal®, Atrofen®)	5-10 mg po tid-qid intrathecal infusions	Maximum oral dose: 80-120 mg/day Intrathecal: 300-800 µg/day
Clonidine (Duraclon®)	30 µg/hr (epidural)	Doses > 40 µg/hr not well studied
Mexilitene (Mexitil®)	150-300 mg po tid	150-300 mg po tid
Octreotide (Sandostatin®)	50-100 µg SC bid-tid	Varies
Pamidronate (Aredia®)	90 mg IV q 4 weeks	90 mg IV q 4 weeks proven effective
Strontium Chloride Sr 89 Samarium – 153 (Quadramet)	148 MBq, 4 mCi q 3 months 1.0 mCi/kg	148 MBq, 4 mCi q 3 months

bid = twice daily; hs = at bedtime; ICP = intracranial pressure; IV = intravenous; MBq - megabecquerel; mCi = millicuries; po = by mouth; qid = 4 times a day; q = every; qd = daily; SC = subcutaneous; tid = 3 times a day;

Adapted from Scott CJ, Griffin CB. Pain management table and guidelines. Boston: Dana- Farber Cancer Institute/Brigham & Women's Hospital; 2000.

- **Opioid Analgesics for Chronic Pain**

Drug	Recommended Starting Dose (adults > 50 kg)/Frequency		Recommended Starting Dose (child/adult < 50 kg)/Frequency		Duration (hours)	Comments
	Oral	Parental	Oral	Parenteral		
Codeine Phosphate/ Sulfate (Tylenol® with Codeine, Phenaphen® with Codeine)	15-60 mg/3-6 hrs	15-60 mg/4-6 hrs IM/SC	0.5-1 mg/kg/4-6 hrs	Not recommended	4-6	May be used for treatment of mild to moderate pain in conjunction with acetaminophen. (Analgesic and antitussive properties.) Available as a combination with Tylenol or Phenaphen.
Fentanyl Citrate IM: Sublimaze®, TD: Duragesic®, Ionsys®, PO: Actiq®, Fentora®	100-200 mcg; no more than 4 doses/day; transmucosal	50 mcg/hr/72 hrs TD 50-100 mCg/ 1 hr IM	--	2-3 mcg/kg/1 hr IM	1-2	
Hydrocodone HCL	2.5-10 mg/3-6 hrs	--	0.2 mg/kg/3-6 hrs	--	4-8	Available as a combination medication with acetaminophen (Lortab®, Lorcet®); aspirin (Lortab® ASA); ibuprofen (Vicoprofen®)
Hydromorphone HCL (Dilaudid®)	2-4 mg/3-4 hrs	1-2 mg SC; 1-2 mg IM/3-4 hrs	0.06 mg/kg/3-4 hrs	0.015 mg/kg IM/3-4 hrs	4-5	
Levorphanol Tartrate (Levo-Dromoran®)	2-4 mg/6-8 hrs	2-4 mg/6-8 hrs SC	0.04 mg/kg/6-8 hrs	0.02 mg/kg/6-8 hrs SC	6-8	
Meperidine HCL (Demerol®)	50-150 mg/3-4 hrs	100 mg SC; 100 mg IM/3-4 hrs	1.1-1.8 mg/kg/3-4 hrs	0.75 mg/kg SC/IM/3-4 hrs	2-4	
Methadone HCL (Dolophine®, others)	5-10 mg/6-8 hrs	10 mg SC; 10 mg IM/ 6-8 hrs	0.2 mg/kg/6-8 hrs	0.1 mg/kg SC/IM/6-8 hrs	4-6	Extra potent when used chronically; specialty consultation is advised when converting patients to methadone. Wait 1 week between dose increases
Morphine Sulfate (MS Contin®,	30 mg/3-4 hrs	10 mg SC; 10 mg IM;	0.3 mg/kg/4-6 hrs	0.1 mg/kg SC/IM/4-8 hrs	3-6	Main alkaloid of opium. Prototype of opiate agonists.

Duramorph®, Astramorph®)		2-4 mg IV/ 3-4 hrs				
Morphine Sulfate (MS Contin®, Duramorph®, Astramorph®)	30 mg/3-4 hrs	10 mg SC; 10 mg IM; 2-4 mg IV/ 3-4 hrs	0.3 mg/kg/4-6 hrs	0.1 mg/kg SC/IM/4-8 hrs	3-6	Main alkaloid of opium. Prototype of opiate agonists.
Oxycodone HCL (OxyContin®, Roxicodone®)	5-10 mg/3-4 hrs	--	0.2 mg/kg/3-4 hrs	--	4-6	Available as a combination medication with acetaminophen (Percocet®, Roxicet™, Tylox®); aspirin (Percodan®)
Oxymorphone HCL (Numorphan®)	Not available	1-1.5 mg SC; 1-1.5 mg IM; 0.5 mg IV/ 3-6 hrs	Not recommended	Not recommended	3-6	
Oxymorphone HCL (Opana®)	10 mg/4-6 hrs	--	Not recommended	--	3-6	
Oxymorphone (Opana ER®)	5-10 mg/12 hrs	--	Not recommended	--	3-6	
Propoxyphene HCL (Darvon®)	65-100 mg/4 hrs	--	No recommended	--	4-6	Weak analgesic; not recommended as first line opioid. Available as a combination medication with acetaminophen (Darvocet-N, Wygesic®); aspirin (Darvocet-N with ASA); aspirin and caffeine (Darvon-N compound).
Tramadol HCL (Ultracet®, Ultram®, Ultram® ER)	50-100 mg/4-6 hrs	--	No recommended	--	24	

Note: Published tables vary in the suggested doses. Clinical response is the criterion that must be applied for each patient; titration to clinical response is necessary. Because there is not complete cross-tolerance among these drugs, it is usually necessary to use a lower dose when changing drugs and to retitrate to response. Long-acting or extended-release (ER) medications typically are designed with a coating, shell, or capsule that acts to delay the release of active medication. Patients should therefore always be cautioned not to chew such medications but rather to swallow them whole.

Caution: Doses listed for patients with body weight less than 50 kg cannot be used as initial starting doses in babies less than 6 months of age.

Ag = agonist; IM = intramuscular; IV = intravenous; PO = oral; SC = subcutaneous

PATIENT TREATMENT AGREEMENT

Patient Name: _____ MRN#: _____

Doctor: _____

Goals for taking opioid medications:

1. _____
2. _____
3. _____

Medication and proposed duration of use: _____

Background

- There are many types of treatments for pain. Opioid medications are one type of pain treatment.
- When used appropriately, opioids can be very safe and effective to treat pain, even long-term. When used inappropriately, opioids can be dangerous for both the person prescribed the medication, as well as their family and their community.
- Therefore to protect you and others we have implemented the following policies around opioid medications. The purpose of these policies is to protect you and your community, so that patients who need opioid medications can continue to receive them.
- Not all pain conditions respond to opioids. Some pain may only be partially responsive to opioid therapy. Total elimination of pain is an unrealistic goal.

Your Responsibilities

- Only the following primary prescribing doctor will prescribe opioid medications for you:

- You agree not to ask for opioid medications from any other doctor without the knowledge and assent of your primary prescribing doctor.
- You agree to keep all scheduled appointments, not just with your physician, but also with recommended therapists and psychological counselors. Three or more missed appointments or same day cancellations may lead to tapering off of opioid medications.
- You agree to provide samples for drug screens, on a regular basis or upon request of your doctor. Positive tests for any illegal substances, or medications not prescribed by your pain doctor, may result in tapering off of opioid therapy, and possibly referral elsewhere for substance abuse evaluation and management.
- No prescriptions will be refilled early.
- No prescriptions will be refilled if you lose, destroy, or have any of your medication stolen.
- Prescription refills will be authorized only during regular office hours. If you want the prescription mailed to you, contact our office seven working days prior to the refill date. If you want to pick up the prescription in person, call two working days in advance of renewal date. You may be required to provide postage-paid self-addressed envelopes in advance for mailed prescriptions.
- You agree to comply fully with all aspects of your treatment program including behavioral medicine (psychology/psychiatry) and physical therapy, if recommended. Failure to do so may lead to discontinuation of your medication and referral to another provider or treatment center.
- Successful pain management entails employing multiple interventions, including active participation in regular physical exercise and the use of psychological coping strategies. A pattern of passive reliance on medications, resistance to more active physical treatments, and repeated

failure to demonstrate the implementation of psychologically based coping strategies that have been taught to you may lead to discontinuation of medications and/or referral to another provider or treatment center.

- You will secure your medications as you would cash, in a lockbox or other similar device.
- You will not share your medications with anyone, even if they appear to have legitimate need, or take someone else's medications – this is a crime punishable by arrest and possible imprisonment.
- You will tell your doctor any information that he/she needs to know to provide you the best treatment. This includes past or present problems with drugs or alcohol, especially prescription drugs.
- You will report any side effects or other problems you are having with your medications so we can help you through them.

We understand that emergencies can occur and under some circumstances, exceptions to these guidelines may be made. Emergencies will be considered on an individual basis.

Our Responsibilities

- We will provide you the highest quality pain management based on our professional judgment, or refer you elsewhere if this is in your best interest.
- We will provide you opioid medications if that appears to be in your best interest, or provide you other pain treatments if those appear to be best for you.
- We will taper off and stop your opioid medications if: (1) You are not getting significant pain relief, (2) you are not achieving your goals for improved function, (3) the dose needs to go higher and higher to achieve pain relief, or (4) you are not able to follow the rules indicated above for compliance with opioid therapy. This does not mean we will abandon you. We will continue to work with you to find better treatments for your pain.
- We will treat you with respect and dignity.

Possible Side Effects of Opioid Medications

- Opioids may cause drowsiness that can be worsened with alcohol, benzodiazepines (Valium and similar medications), and other sedating medications. Use care when driving or operating machinery.
- An overdose can cause severe side effects, even death.
- Other common, usually temporary, side effects include nausea, itching, and sweating. Psychological depression and lowered testosterone levels (in men) may also occur. Sleep apnea, if present, may be worsened by opioids. Constipation commonly occurs, and often does not improve with time. It is impossible to predict opioid side effects in any individual patient. Having side effects on one opioid does not necessarily mean there will be side effects on another opioid.
- You must take opioids only as directed. Tampering with the dosage is dangerous and potentially fatal.
- Physical dependence will develop with regular use. This means that if you stop the medication suddenly you will feel sick for a few days (withdrawal syndrome). Important: this does not by itself indicate addiction. You need to plan ahead to not run out of your medications.
- Tolerance may develop to the pain relieving effects of opioids; this means that the pain relief may decrease over time, but in chronic pain states this usually occurs slowly, if at all.

I, the undersigned, agree to follow these guidelines that have been fully explained to me. All of my questions and concerns regarding treatment have been adequately answered.

I give permission to my pain doctor to contact my other healthcare providers, for the purposes of sharing information concerning my situation, as is deemed necessary for coordinated, high quality care.

If I do not follow these guidelines fully, my doctor may taper and stop opioid treatment and refer me elsewhere for care.

A copy of this document has been given to me.

Patient signature: _____

Date: _____

Clinician signature: _____

Date: _____

Witness signature: _____

Date: _____

PATIENT EDUCATION BROCHURE

- **What is an opioid?**

An opioid is a powerful pain medication available only by prescription. Classified as narcotics, opioids include morphine, heroin, oxycodone, oxymorphone, methadone, and codeine. Opioids are associated with a significant potential for addiction and abuse.

- **What is opioid abuse?**

Opioid abuse is a pattern of overuse of opioid medication(s) that leads to social, work, and health problems. Relationships with family, friends, and coworkers may be impaired by an individual's dependence and need to obtain increasing amounts of opioids.

- **What are the signs of opioid abuse?**

- Family history of substance abuse, including alcohol abuse
- Deterioration of personal appearance and hygiene
- Appearing intoxicated or sedated or confused
- Increasingly negative moods and mood swings
- Over-the-top reactions to criticism or compliments
- Increasing complaints about coworkers, family, or friends
- Carelessness; making frequent mistakes and showing poor judgment
- Involvement in a car accident (3.6 times more likely to have an accident at work and 9 times more likely to have a car accident or accident at home)
- Frequent and recurring financial problems
- Frequent tardiness at work
- Requests for early dismissal (2.2 times more often)
- Frequent use of sick time (3 times more often)
- Frequent filing of worker compensation claims (5 times more likely)
- Purposeful oversedation
- Use of pain medication in response to stress
- Use of more medication than prescribed
- Reporting lost/stolen prescriptions
- Requesting frequent early renewals/running out of medications early
- Attempting to obtain prescriptions from other doctors
- Buying medication on the streets
- Legal problems: arrests; driving under the influence; domestic violence
- Contact with substance abusers

- **Medication Dos and Don'ts**

- Do secure your meds in a lockbox or other secure manner.
- Do communicate with your doctor if medications aren't working or you have side effects.
- Do tell your doctor if you've had a problem with drugs or alcohol in the past so that he/she can prescribe the best pain medication possible for you.
- Don't share your opioid medications with others.
- Don't hoard your medications; if you are concerned you will not get the treatment you need in the future, share those concerns with your doctor.

- Don't drink alcohol or take other narcotic or sedative medications together with your current opioid treatment without your doctor's approval.
- Dispose of leftover medications when you are done with them.
- Do tell your physician if you are pregnant.

- **When beginning opioid therapy, you may be asked to sign a Patient Treatment Agreement which states that:**
 - You will receive opioid prescriptions only from your primary care physician.
 - You agree not to ask for opioid medications from any other doctor without the knowledge and assent of your primary care physician.
 - You agree to keep all scheduled medical appointments.
 - You agree to provide regular urine samples for drug screens.
 - No prescriptions will be refilled early.
 - No prescriptions will be refilled if lost or destroyed, or if any of your medication has been stolen.
 - Prescription refills will be authorized only during regular office hours.
 - You agree to comply fully with all aspects of your treatment program including behavioral medicine (psychology/psychiatry) and physical therapy, if recommended.

For More Information

- Specific drug information: see www.drugs.com, www.pdrhealth.com/drug_info or www.webmd.com/drugs.

- Common opioid medication side effects and practical measures to minimize them: see www.painaction.org/painaction/Article.aspx?channelId=2&contentId=117.

- **Constipation?** None Mild Moderate Severe
- **Itching?** None Mild Moderate Severe
- **Mental cloudiness?** None Mild Moderate Severe
- **Sweating?** None Mild Moderate Severe
- **Fatigue?** None Mild Moderate Severe
- **Drowsiness?** None Mild Moderate Severe
- **Reduced sex drive?** None Mild Moderate Severe
- **Other:** _____ None Mild Moderate Severe

○ Endocrine blood test results:

- **Total testosterone** N/A Normal <LLN >LLN
- **Free testosterone** N/A Normal <LLN >LLN
- **SHBG** N/A Normal <LLN >LLN
- **LH** N/A Normal <LLN >LLN
- **FSH** N/A Normal <LLN >LLN
- **Prolactin** N/A Normal <LLN >LLN
- **DHEAS** N/A Normal <LLN >LLN
- **Free cortisol** N/A Normal <LLN >LLN

▪ **CBC, abnormal findings:** _____

▪ **Lipid panel, abnormal findings:** _____

▪ **Pregnancy test** N/A Negative Positive

Patient sex: M F

Female patient status: (check all that apply)

- Pre-menopausal
- Post-menopausal
- Taking hormonal contraceptive
- Taking estrogen therapy

Conclusions: endocrine adverse events are: _____

● **Questionable Behavior Assessment**

Since the last visit, have you:

- Used illicit drugs or had a drinking problem?
- Hoarded medications?
- Used more opioid than prescribed?
- Ran out of meds early?
- Increased the use of opioids?
- Used analgesics PRN when the prescription is for time-contingent use?
- Received opioids from another doctor?
- Bought medications on the streets?

Also, note the following regarding the patient:

- Appears sedated or confused (eg, slurred speech, unresponsive)
- Expresses worries about addiction
- Expresses a strong preference for a specific type of analgesic or a specific route
- Expresses concern about future availability of opioid
- Reports worsened relationships with family
- Misrepresented analgesic prescription or use
- Indicated she or he “needs” or “must have” analgesic medications
- Requested office visit primarily to discuss analgesic medication
- Exhibited lack of interest in rehab or self-management
- Reports minimal/inadequate relief from opioid
- Indicated difficulty with using patient medication agreement
- Significant others express concern over the patient’s use of analgesics

o Urine toxicology tests:

Negative Positive for: _____

o Prescription monitoring report (if available):

Since [fill in date] ___/___/___, patient used/had:

_____ (number of) doctors prescribing opioids

_____ (number of) pharmacies dispensing opioids

_____ (number of) prescriptions for opioids

_____ (number of) refills for opioids

the following opioids dispensed: _____ dose: _____

_____ dose: _____

_____ dose: _____

• **Patient Risk Assessment**

o Assess the patient risk for opioid drug abuse using the Triage Tool:

Low risk Medium risk High risk Unsure

o The patient risk category since the last visit has Decreased Increased

• **Patient Overall Assessment**

Is your overall impression that this patient is benefiting from opioid analgesic therapy?

Yes No Unsure

Comments: _____

- **Action Plan**

(Check all that apply)

- Continue present opioid regimen, recheck patient in _____ days/months
- Increase/decrease the current opioid, specify new dose: _____
- Adjust/switch to a modified-release opioid, specify: _____
- Adjust/switch to non-opioid analgesic, specify: _____
- Taper off opioids, specify tapering schedule: _____
- Refer to: _____

Comments: _____

ENDOCRINE LAB TESTS

Several blood tests should be considered to detect suppression of gonadotropins or other hormones by some opioids. In the absence of evidence-based guidelines, a reasonable standard is annual screening. Depending on clinical presentation, the tests listed below may be indicated:

- **Blood Sampling:**
 - Blood samples for men and women should be obtained between 7 AM and noon for standardization.
 - In women on hormonal contraceptives or estrogen therapy, samples can be obtained at any time during the cycle, in the morning.
 - In premenopausal women NOT on hormonal contraceptives who are on their period, collect blood sample between Day 3 and 8.

- **Screening for Men:**
 - Total testosterone
 - Sex hormone binding globulin (SHBG)
 - Luteinizing hormone (LH)
 - Follicle stimulating hormone [FSH], optional
 - Free testosterone
 - Prolactin
 - Complete blood count (CBC)
 - Lipid panel

- **Screening for Women:**
 - Total testosterone
 - Sex hormone binding globulin (SHBG)
 - Luteinizing hormone (LH)
 - Follicle stimulating hormone (FSH)
 - Free testosterone
 - Prolactin
 - Dehydroepiandrosterone sulfate (DHEAS)
 - Free cortisol (serum)
 - Pregnancy test for pre-menopausal women not on oral or transdermal contraceptives and who are not having menstrual cycles

- **Results:**
 - In men, the following values may be low due to opioid therapy:
 - Free and total testosterone
 - FSH or LH
 - In women, the following values may be low due to opioid therapy:
 - FSH
 - Free testosterone
 - Prolactin
 - DHEAS
 - Free cortisol

- In women on hormonal contraceptives or estrogen therapy:
 - SHBG levels may be elevated from estrogen administration
 - LH/ FSH levels may additionally be lowered from estrogen therapy.
 - Free testosterone levels may be lower than in postmenopausal women not on estrogen therapy or than in premenopausal women not on hormonal contraceptives.

BRIEF INTERVENTION

As a primary care physician, you will have an opportunity to identify early signs of opioid abuse. A brief intervention delivered by a physician with whom the patient has a comfortable relationship can be particularly effective.

QUESTIONS	YES / NO	NOTES
Has any one in your family ever had a drug problem?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
In the past year,		
Have you used drugs other than those required for medical reasons?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you felt you wanted or needed to cut down on your drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you used pot, coke, heroin or other opioids, uppers, downers, hallucinogens, or inhalants?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you taken a larger or more frequent dose of a prescribed medication?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you ever used drugs more than you meant to?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you use more than one drug at a time?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you feel you need to use more and more drugs to get the effect you want?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Can you get through the week without using drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Are you always able to stop using drugs when you want to?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you had “blackouts” or “flashbacks” as a result of drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Does your family ever complain about your involvement with drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Has your drug use created problems between you and your family?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you lost friends because of your use of drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you neglected your family because of your use of drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you been in trouble at work or school because of drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you lost a job because of drug abuse?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Do you ever feel bad or guilty about your drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have people annoyed you by criticizing your drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Have you gotten into fights when under the influence of drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you engaged in illegal activities in order to obtain drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you been arrested for possession of illegal drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you felt sick, shaky, or depressed when you stopped using drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you had hepatitis, convulsions, bleeding, etc, as a result of your drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you gone to anyone for help for a drug problem?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Have you been involved in a treatment program specifically related to drug use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Thanks for answering these questions.

Results

“Yes” responses should be a “red flag:” they should heighten your vigilance for prescription opioid misuse, but not necessarily contraindicate opioid therapy. Categorize the patient into a low, medium, or high risk for opioid dependence or substance abuse; then use the **Triage Tool** to make a decision on how to manage the patient. According to your clinical judgement, chose one of the following solutions:

- **Give a warning** if there is a possibility of an emerging substance abuse
- **Start opioid tapering** if the patient has already had a warning and is clearly unable to remain compliant
- **Refer the patient to an addiction specialist** if there are clear signs of addiction to the prescription opioid medication

1- Warning

When there is a possibility of an emerging substance abuse, you could say the following:
 “I am concerned that your use of _____ is not medically safe. I am especially concerned that you might be developing a problem with your use of this medication. Other who have used this medication the way you are using it have had serious medical problems that have, in some cases, lead to death. If not already a problem, you may begin to have 1 or more of the following difficulties:

- Mood swings that affect your relationships with family and friends
- Worsening of your personal appearance and hygiene, and increasing carelessness, which can cause problems at work, at school, and at home
- Car accidents or accidents at home

It is my duty to warn you of the potential disastrous effects of abusing this drug. You need to make sure you are using this medication in a medically safe way, ie stay compliant with the prescription schedule and alert me if any difficulty I mention earlier start to develop.

2- Opioid tapering

For patients who have been unable to remain compliant with medication despite a clear warning, you could say the following to explain the rationale for an exit strategy:

“I recommend that we begin to gradually withdraw your opioid pain medication. We will accomplish this by reducing the dose of _____, which you are currently taking, by half every ____ days until you are completely off the medication. In its place, I recommend that we begin treating your pain with _____. This is a non-narcotic pain medication that should be effective at no risk of addiction.”

Then use the **Exit Strategy Tool**.

3- Referring a patient to a pain medication specialist

For patients who have clear signs of addiction, you could say:

“I will arrange for you to see Dr. _____, an addiction specialist I trust, who will help evaluate your situation and provide recommendations for treatment. I also recommend that you join a support group for people who have problems with prescription medication or other substances. The nearest one to your home is located at the following address, and meetings are held every _____ at _____. I am going to continue to work with you through this process and have arranged a follow-up appointment to see you again in 2 weeks.”

When referring the patient,

- Ask the addiction specialist to provide summary reports on the patient’s progress
- Retest the patient annually for substance abuse

OPIOID ROTATION TOOL

This tool will help you evaluate whether to change the type of opioid prescribed and how to do it properly.

Clinical Reasons for Changing Opioids

- **Lack of Efficacy**
 - Worsening of existing pain or underlying disease process
 - Development of opioid analgesic tolerance
 - Inability to tolerate effective dose
 - Dose required to produce analgesia exceeds maximum daily dose recommendations

- **Development of intolerable side effects**
 - Gastrointestinal (eg, constipation, nausea, vomiting)
 - CNS (eg, sedation, somnolence, dysphoria, hallucinations, myoclonus)
 - Vascular (eg, orthostatic hypotension due to histamine release)
 - Cardiac (eg, direct effects on cardiac tissue)

- **Change in patient status**
 - Inability to swallow
 - Poor peripheral vascular status/poor absorption of transdermal medications
 - Requirement of high-dose opioids that cannot be practically administered by oral, rectal, or transdermal routes
 - Worsening of disease
 - Development of a new pain

- **Practical considerations**
 - Availability in local pharmacies
 - Cost
 - Amount of opioid needed
 - Route of administration
 - Patient preference

4-Step Approach to Opioid Conversion

A few important tips before you start:

- Globally assess the patient to determine if the uncontrolled pain is secondary to worsening of disease or development of a new type of pain.
- Opioid rotation for patients on high doses is not straight forward and may require consultation and possibly hospitalization, especially when switching to methadone.
- Use only 1 conversion table.
- Start conservatively; then titrate to effect.
- Know the drugs you are using.
- Get help.

1. Determine the total daily dose of the current opioid

- Calculate doses based on a 24-hour usage.
- Include all long-acting and short-acting opioid doses.
- Don't forget rescue opioid doses.
- Dose changes for patients on high doses of opioids should be accomplished in stages by first implementing a partial conversion in order to minimize the risks of serious miscalculation (e.g., withdrawal, severe pain, overdose). For example, a patient being changed from an intravenous to an oral opioid preparation should have his/her infusion decreased by 50%, with the remaining 50% of the opioid provided by an oral formulation. Reassessment of this strategy can be made after 24 hours.

2. Decide which new opioid analgesic will be used and determine the new opioid dose using the Opioid Conversion Table below

- Doses listed are just *estimates* and can vary between patients; the optimal dose for an individual patient is always determined by careful titration and appropriate monitoring (see Step 3).
- Comparisons between IM and IV doses of different opioids are not always clear. It is recommended that IV doses be based on 2 assumptions:
 - Half the IV dose will give the same peak effect as a single IM dose.
 - IV and IM total doses should be equal when calculating the 24-hour requirements since IM doses are eventually fully absorbed.
- If switching to any opioid other than methadone or fentanyl, decrease the dose by 25% to 50%.
- If switching to methadone, reduce the dose by 75% to 90%.
- If switching to transdermal fentanyl, do not reduce the dose.

3. Individualize the new opioid dose

- It is always safer to convert on the low side, providing that rescue analgesia is needed, and be prepared to titrate upwards with the background dose.
- If you are concerned about undertreating severe pain or overestimating the conversion dose, especially for patients on high opioid doses, hospitalization during dose conversion may be appropriate.

4. Follow-up with the patient and adjust the new opioid dose

- Continually reassess the patient, especially during the first 7 to 14 days
- Fine-tune the total daily dose (long-acting plus short-acting) by increasing/decreasing the around-the-clock long-acting dose accordingly.

Opioid Conversion Table

Drug	Equianalgesic Dosage
Codeine	IM/IV/SC: 120 mg PO: 200 mg
Fentanyl	0.1-0.2 mg
Hydrocodone	20-30 mg
Hydromorphone	IM/IV/SC: 1.3-1.5 mg PO: 7.5 mg
Levorphanol	IM/IV/SC: 2 mg PO: 4 mg
Meperidine*	IM/IV/SC: 75 mg PO: 300 mg
Methadone	IM/IV/SC: 1-10 mg [†] Short term: 5-10 mg Chronic use: 1-4 mg (2 mg) PO: 2 - 20 mg [†] Short term use: 20 mg Chronic dosing: 2-4 mg (3 mg)
Morphine	IM/IV/SC: 10 mg PO: 30-60 mg [‡]
Oxycodone	15-30 mg (20 mg)
Oxymorphone	IM/IV/SC: 1 mg PO: 10 mg
Propoxyphene	130-200 mg [§]

*Meperidine should be used for acute dosing only and not used for chronic pain management (meperidine has a short half-life and a toxic metabolite: normeperidine). Its use should also be avoided in patients with renal insufficiency, chronic heart failure, hepatic insufficiency, or the elderly because of the potential for toxicity due to accumulation of the metabolite normeperidine. Seizures, confusion, tremors, or mood alterations may be seen.

[†]Many equianalgesic tables underestimate methadone potency—more studies are needed. Parenteral: Program utilizes 10 mg for short-term dosing and 2 mg for chronic dosing. Oral: Program utilizes 20 mg for short-term dosing and 3 mg for chronic dosing.

[‡]Acute dosing (opiate naive): 60 mg. Chronic dosing: 30 mg.

[§]Propoxyphene HCL: 130 mg; Napsylate: 200 mg (not recommended for chronic pain management and therefore not listed above).

Adapted with permission from D. McAuley, GlobalRPh, Inc. www.globalrph.com/narcoticonv.htm

EXIT STRATEGY TOOL

This tool will help you determine the best exit option for a patient who needs to be taken off opioid therapy.

