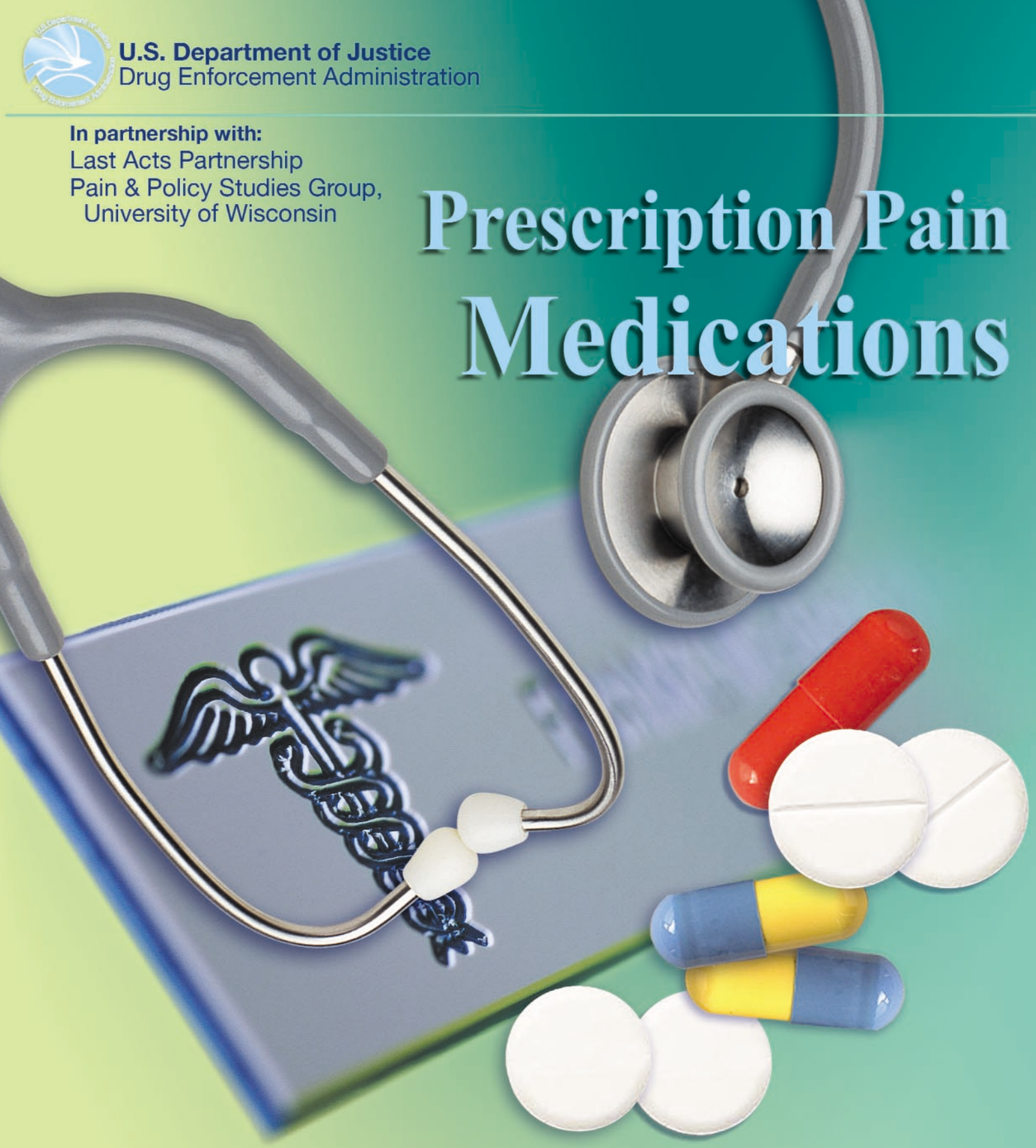
PAIN & POLICY STUDIES GROUP
University Of Wisconsin-Madison Medical School

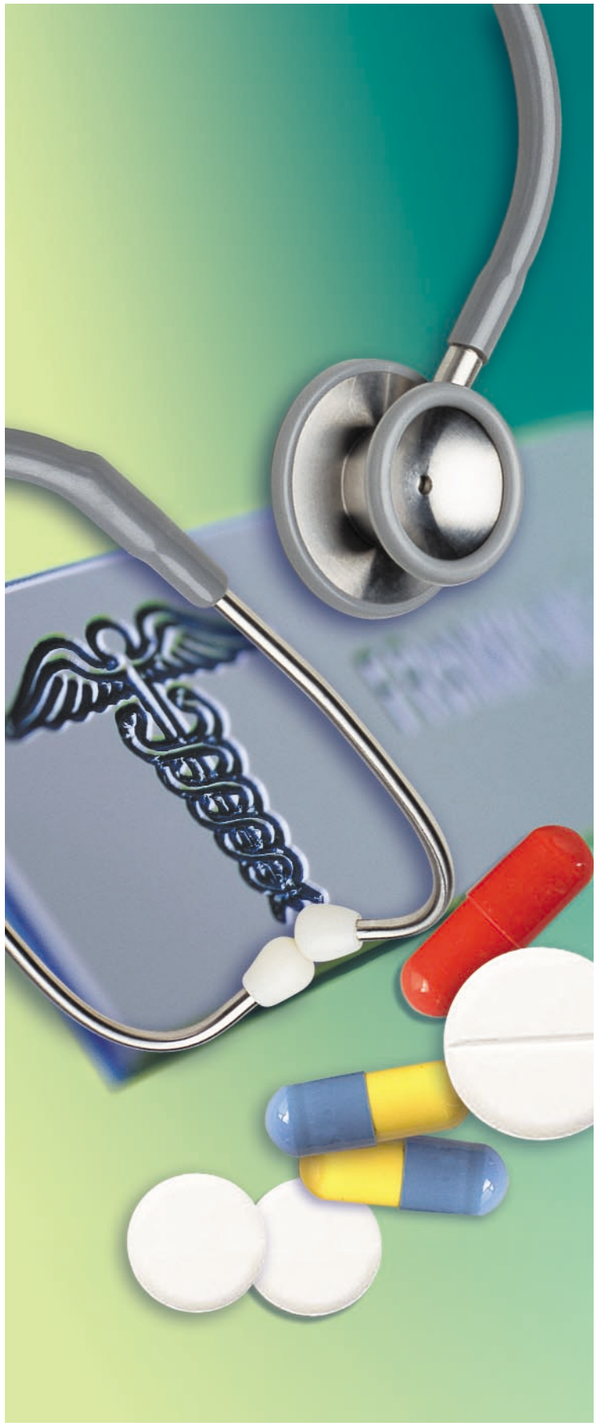


**U.S. Department of Justice**
Drug Enforcement Administration

**In partnership with:**
Last Acts Partnership
Pain & Policy Studies Group,
University of Wisconsin

# Prescription Pain Medications

## Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel



# PRESCRIPTION PAIN MEDICATIONS:

***Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel***


**Supported by**

**Drug Enforcement Administration**

**Last Acts Partnership**

**Pain & Policy Studies Group, University of Wisconsin**

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## Preface

The Drug Enforcement Administration, Last Acts Partnership, and the Pain & Policy Studies Group at the University of Wisconsin joined forces in 2001 to develop a consensus statement, "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act" (the statement can be found on www.lastacts.org). This consensus statement, which was joined by numerous other health care organizations, called for a balanced policy addressing both the necessity of medical access to prescription pain medications and active approaches to stem abuse, addiction and diversion. After the statement was released, the group met to discuss the need for education of both the health care community, and the law enforcement and regulatory community. Although educational programs that promoted the philosophy, science and practical issues surrounding the policy of balance had begun to appear, there was a compelling need for a clear and concise educational product, which would be targeted to both health care professionals and professionals in the law enforcement and regulatory communities. The group met several times during the last year to review existing educational material and ultimately decided to produce a highly readable "Frequently Asked Questions" that would cover the clinical and regulatory issues surrounding the prescribing of controlled drugs.

These Frequently Asked Questions (FAQs) were produced by a Principal Working Group, which included the experts who developed the consensus statement, and a Review Committee, which included experts from the fields of nursing, neurology, psychiatry, pharmacology, pharmacy and addiction medicine. The material represents a consensus, supported by the available literature and by the laws and regulations that govern the use of controlled prescription drugs.

***Important Disclaimer***

Although the FAQs reflect a consensus view of an expert panel, lack of strict adherence to these suggestions does not imply that a particular practice is outside the scope of legitimate medical practice. The FAQ is not intended to be used as medical practice guidelines or standards or as legal advice with regard to specific practices or cases for which clarification should be obtained by consulting relevant practice guidelines, laws, and regulations; the agencies that administer them; and experts in law and in pain and addiction medicine. Practitioners, law enforcement, and regulators should always keep abreast of changes in federal and state statutes, in regulations, and in other policies relevant to pain management.

***Relevant Resources:***

Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group, et al. (2000). *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act.* Washington, DC: Last Acts. (Available at http://www.medsch.wisc.edu/painpolicy/dea01.htm)

Research America. (2003). *Chronic Pain Pervasive in All Age Groups, New Study Shows.* Alexandria, VA, September 4. (Available at http://www.researchamerica.org/opinions/pain.html)

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# SECTION I INTRODUCTION

The purpose of this document is to provide information to health care professionals and professionals in the law enforcement and regulatory communities about the medical treatment of pain. The goal is to achieve a better balance in addressing the treatment of pain while preventing abuse and diversion of pain medications. The authors of this document stand committed to the core principle of balance that was expressed in the 2001 joint consensus statement by the U.S. Drug Enforcement Administration and numerous health care organizations:

> Both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical (DEA et al., 2001).

Controlled substances that are prescription drugs, such as opioids, are essential for the care of patients but carry a risk that goes beyond the usual clinical concern about toxicity. These drugs can become the object of abuse and addiction or be a target for diversion to an illicit market. This potential for abuse, addiction, and diversion raises concern among all clinicians, including physicians and pharmacists, and those in law enforcement, drug regulation, and policy makers.

When potentially abusable drugs are also necessary medicines, assessment and management of drug-related problems can be complex. The parameters of acceptable medical practice include patterns of drug prescription—such as long-term administration of an opioid drug at escalating doses and administration of more than one controlled prescription drug—that may raise a "red flag" for both clinicians and regulators. Problematic drug-related behavior takes many forms and has many causes in the clinical setting. Even relatively severe drug-seeking behaviors in the context of a legitimate medical need, such as uncontrolled pain, cannot immediately be ascribed to addiction. The desperate search for pain relief, and the complex psychosocial disturbances accompanying chronic pain, may influence the phenomenology of drug use and greatly complicates the assessment of drug-related problems.

At the same time, however, even patients with severe pain can develop patterns of abuse or addiction, or engage in criminal activity. Physicians who encounter such patients must control the behaviors, diagnose the comorbidities, and react in a way that is both medically appropriate and consistent with the laws and regulations that apply to the medical use of controlled drugs. Although physicians have expressed concern about criminal prosecution when treating such patients, the arrest and indictment of a physician cannot occur unless he or she can be shown to have knowingly and intentionally distributed or prescribed controlled substances to a person outside the scope of legitimate practice.

Drug abuse exacts a huge social cost, and some have been tempted to address prescription drug abuse by greatly limiting access. When drugs are needed for legitimate medical purposes, such as pain management, this action may have unintended consequences that could be just as harmful to the public. Surveys have found that chronic pain is highly prevalent and exacts a huge toll in terms of lost productivity, health care costs, and human suffering. As the U.S. population ages, people will live longer with chronic, often painful, diseases. Even if opioids are appropriate for only a small proportion of these patients, nothing should be done to limit access to the drugs when they are needed, or to increase the reluctance of prescribers to recommend them.

Society has a compelling interest in ensuring ***both*** the ready access to controlled prescription drugs when medically needed ***and*** ongoing efforts to minimize their abuse and diversion. These two goals are not in conflict; they coexist and must be balanced. Those who are licensed to prescribe, dispense and administer these drugs, and those in the law enforcement or regulatory communities need continual education to improve their ability to balance these goals. There should be an ongoing dialogue between practitioners and those in law enforcement and regulation.

The FAQs in this document support the need for dialogue and reflect an effort to answer basic questions about the appropriate use of opioids given their unquestioned medical value, as well as their potential for abuse, addiction, and diversion. The goal is to provide medically and legally sound and balanced education to practitioners, law enforcement, and regulators. Clinical items have been drafted by experts in pain management, and the items addressing regulatory issues have been drafted by members of law enforcement and experts in the regulation of controlled substances. All responses derive from the fundamental view that practitioners must try to relieve pain, but also must obey laws and regulations, and avoid contributing to diversion, while law enforcement personnel and regulators must address the sources of diversion, but do so in a manner that never interferes in clinical pain management.

# SECTION II
# TERMS

### 1. What are the key addiction-related terms used in discussing pain medications and risk management?

It is imperative to use clear terminology when discussing medical matters. Terms such as abuse, addiction, physical dependence, pseudoaddiction, and tolerance are often used incorrectly by researchers, clinicians, regulators, the media, and patients. This contributes to misunderstandings about the risk of addiction when opioids are used to manage pain. Definitions of these and other terms are provided in Appendix A to:

- encourage accurate and consistent use of addiction-related terms,
- promote communication and better care of patients with pain and other conditions when the use of controlled prescription drugs is appropriate, and
- encourage controlled substances regulatory policies and enforcement strategies that do not confuse the necessary treatment of pain with abuse or addiction.

# SECTION III
# PAIN AND ITS TREATMENT

### 2. Why is pain management important?

Uncontrolled pain is an enormous public health problem in the United States. Already accounting for many tens of billions of dollars of needed health care and lost productivity, it is expected that the costs will grow dramatically as the population ages and people live longer with chronic diseases. Equally important, unrelieved pain has a devastating impact on the physical, emotional, social, and economic well-being of patients and their families. Diagnosing and treating pain is, therefore, fundamental to the public health. Many medical and regulatory organizations have recognized the imperative to relieve pain in official statements and guidelines.

***Relevant Resources:***


American Geriatrics Society Panel on Persistent Pain in Older Persons. (2002). The management of persistent pain in older persons. *Journal of the American Geriatric Society* 50 (6 suppl): S205-S224. (Available at http://www.americangeriatrics.org/education/manage_pers_pain.shtml)

American Pain Society. (1999). *Guideline for the Management of Acute and Chronic Pain in Sickle Cell Disease. Clinical Practice Guideline Number 1*. Glenview, IL: American Pain Society.

American Pain Society. (2002). *Guideline for the Management of Pain in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Chronic Arthritis. Clinical Practice Guideline Number 2.* Glenview, IL: American Pain Society.

Arnold R, Berger A, Billings JA, et al. (2004) *Clinical Practice Guidelines for Quality Palliative Care*. Brooklyn, NY: National Consensus Project for Quality Palliative Care. (Available at http://www.nationalconsensusproject.org/guideline.pdf)

Cancer Pain Management Policy Review Group.(2001). *American Cancer Society Policy Statement on Cancer Pain Management*. National Government Relations Department, American Cancer Society.

Federation of State Medical Boards of the United States Inc. (2004). *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Dallas, TX: Federation of State Medical Boards of the United States Inc. (Available at http://www.fsmb.org)

Foley, K. M., and H. Gelband (eds). (2001). *Improving Palliative Care for Cancer*. Washington, DC: National Academy Press. (Available at http://www.nap.edu/catalog/10149.html)

Institute of Medicine Committee on Care at the End of Life. (1997). *Approaching Death: Improving Care at the End of Life*. Washington, DC: National Academy Press. (Available at http://books.nap.edu/catalog/5801.html)

National Institutes of Health Consensus Development Program. (2002). *Symptom Management in Cancer: Pain, Depression and Fatigue*. Statement prepared following a National Institutes of Health State-of-the-Science Conference on Symptom Management in Cancer; Bethesda, MD, July 15–17. (Available at http://consensus.nih.gov/ta/022/022_intro.htm)

Research America. (2003). *Chronic Pain Pervasive in All Age Groups, New Study Shows*. Alexandria, VA, September 4. (Available at http://www.researchamerica.org/opinions/pain.html)

Rich, B. A. (2001). Physicians' legal duty to relieve suffering. *Western Journal of Medicine* 175:151–152.

Tucker, K. L. (2001). A new risk emerges: Provider accountability for inadequate treatment of pain. *Annals of Long-Term Care* 9 (4): 52–56.

Tucker, K. L. (2002). Anatomy of a claim for failure to treat pain adequately: $1.5M jury verdict in first case to be tried. *Progress in Palliative Care* 10 (1): 14-15.

### *3. What are the goals of pain management?*

The goals of pain treatment are to reduce pain and suffering, enhance quality of life, and increase the ability to function—all while minimizing the risk of adverse effects. These goals are the same for all pain patients regardless of addiction history. To accomplish these goals, pain management may involve any of a broad array of interventions, one of which is drug therapy. There are numerous options for analgesic drug therapy, including opioids. When drug therapy is one of the strategies used to address pain, the primary goal is to reduce pain without causing distressing side effects or other drug-related problems. Functional restoration may be another important goal and clinical decisions about the ongoing use of analgesic drugs typically require a careful assessment of all outcomes.

### *4. How can a clinician assess a patient's pain?*

Pain assessment is a critically important component of pain treatment because it can yield a pain diagnosis (usually described in terms of etiology, pathophysiology and/or syndrome) that may clarify the need for further evaluation, guide the selection of treatments, suggest prognosis, and indicate the status of coexisting diseases. A documented pain assessment provides a clinical basis for prescribing controlled substances and a recorded baseline against which to measure progress during treatment. The measurement of pain intensity is an important aspect of the pain assessment. Self-report is the "gold standard" for pain measurement. This should be done with a tool appropriate for the patient's cognitive development, language, culture, and preferences; the same tool should be used in subsequent assessments to allow for reliable evaluation of change. Pain measurement tools include numeric scales, visual analog scales, and verbal rating scales. In addition to pain measurement, the assessment should describe the pain in terms of location, temporal characteristics (onset, duration, course, and fluctuation), quality, and factors that increase and decrease pain. The assessment also should evaluate the impact of the pain on physical and psychosocial functioning. Other tools, such as body maps, daily diary records, and multidimensional pain scales, may be used to capture some of this additional information.

A comprehensive pain assessment also includes a physical examination, which can help define the etiology and pathophysiology of the pain. The need for a physical examination is most compelling when a patient with pain is initially evaluated. The extent of this examination is considered to be a matter of clinical judgment and is determined by the nature of the clinical problem; the physician's discipline; and the availability of previously documented examinations, imaging, and laboratory findings relevant to the pain problem. At the end of an examination, the physician should have sufficient information about the physical status of the patient to support a reasonable diagnostic formulation and decide on next steps. Whether further physical examination is required on subsequent visits also is a matter of clinical judgment, based on the need to confirm or monitor specific findings, track specific treatment effects, or assess comorbidities.

***Relevant Resources:***


Miaskowski C, Cleary J, Burney R, Coyne,P.; Finley,R.; Foster,R.; Grossman,S.; Janjan,N.; Ray,J.; Syrjala,K.; Weissman,S.; Zahrbock,C. (2004) *Guideline for the Management of Cancer Pain in Adults and Children*. Glenview, IL: American Pain Society.

Simon, L.S., AG Liman, and A Jacox et al. (2002). *Guideline for the Management of Pain in Osteoarthritis, Rheumatoid Arthritis, and Juvenile Chronic Arthritis. Clinical Practice Guideline Number 2*. Glenview, IL: American Pain Society.


### *5. When should a primary care physician turn to a pain medicine specialist to manage a patient's pain?*

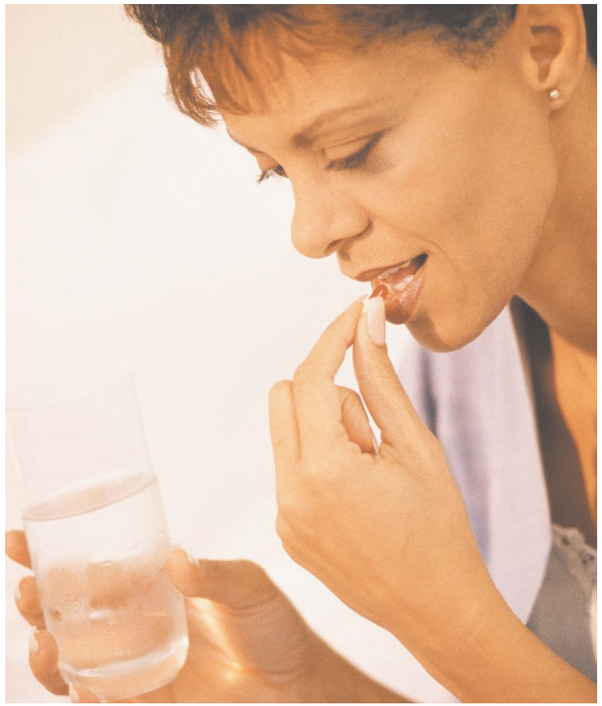
Treatment of pain is an expected part of good medical practice, and all physicians should address the problem to the best of their abilities. Physicians have an obligation to 1) know about the range of therapies used to manage acute and chronic pain; 2) recognize their own level of expertise in pain assessment, treatment selection, and management; 3) understand the nature of the consultative resources in the community; and 4) refer appropriately. Consultation may be needed to obtain a more comprehensive evaluation, to clarify the optimal therapeutic strategy, to implement a therapy that is outside of the referring physician's expertise, or to respond to the patient's desire for another opinion.

If the use of a controlled prescription drug, such as an opioid, is considered to be a potentially useful element in the therapeutic strategy, the physician may consider consultation for any of a variety of specific reasons. Consultation is considered part of good medical practice and is encouraged by the Federation of State Medical Boards' "Model Policy for the Use of Controlled Substances for the Treatment of Pain" (available at http://www.fsmb.org). Specialist input may be helpful to clarify the appropriateness of therapy; define the optimal regimen or monitoring approach; assist in the evaluation of problematic behavior, or evaluate specific recommendations, such as a switch from "PRN" to fixed scheduled dosing, or from a short-acting to a long-acting drug.

In all cases, the decision to request a consultation should be based on both a critical self-evaluation on the part of the physician and an assessment of the clinical challenges posed by the patient. The physician's self-evaluation should define which types of patients or therapies can be implemented without additional help, which can be implemented with guidance through consultation, and which are better left to a specialist. Where these lines are drawn depends on existing knowledge and skills, and the availability of support systems for monitoring. Ideally, most patients who undergo evaluation by the specialist will then return to the primary physician for ongoing treatment.

In some situations, consultation prior to, or during, opioid therapy may be requested solely to address the concern that specialist review would be reassuring to a regulator should the therapy ever be questioned. Although this is not a medical justification per se, it may be appropriate given the evolving nature of opioid therapy in medical care. Consultation is not required under federal law, but some states do require consultation when treating patients with pain (see http://www.medsch.wisc.edu/painpolicy/2003_balance for examples). Some states have done away with this requirement.

If the patient is referred to a specialist or pain treatment center to receive treatment, the referring physician should understand whether the expertise needed is in fact available. Not all pain specialists are knowledgeable or experienced in opioid therapy, for example, and not all provide access to psychological or rehabilitative treatments. The referring physician should understand the nature of the consultative services in the community before sending a patient for evaluation or care. A searchable list of credentialed pain specialists can be found at the American Academy of Pain Medicine's website: http://www.painmed.org/membership; a searchable list of pain clinics can be found at http://www.pain.com/frameindex.cfm.



# SECTION IV
# MEDICAL USE OF OPIOID ANALGESICS

### 6. How are opioids used to manage chronic pain?

There are many approaches to treating chronic pain that should be considered based on a comprehensive assessment of the pain syndrome and its impact, the level of disability, and the existence of medical and psychiatric comorbidities. In some cases, specific treatment targeting the cause of the pain is available and appropriate. For example, good glycemic control is central to the treatment of painful diabetic neuropathy and joint replacement can eliminate pain due to severe osteoarthropathy. When pain becomes chronic, there are numerous specific therapies that may be appropriate to lessen discomfort or address the need for functional restoration. On the basis of the assessment, pain treatment may emphasize or de-emphasize pharmacotherapy and incorporate any of a variety of non-drug treatments. These may include physical therapy or other rehabilitative approaches; cognitive and behavioral strategies; interventional treatments such as injections or implantation of spinal cord stimulators and pumps; or numerous complementary approaches such as acupuncture and massage.

Drug treatments include nonopioid medications, such as acetaminophen, aspirin and the nonsteroidal anti-inflammatory drugs (NSAIDs); numerous drugs known collectively as the adjuvant medications (including antidepressants, antiseizure medications, and others); and opioid analgesics. Like the decision to use any other treatment, the decision to try an opioid, or to continue opioid therapy on a long-term basis, should be based on a careful evaluation of the issues specific to this approach.

Opioid therapy is accepted around the world as the most important approach to managing severe, acute pain (such as pain after surgery), moderate to severe chronic cancer pain, and moderate to severe chronic pain caused by other life-threatening diseases (such as AIDS). The use of opioid therapy to treat chronic nonmalignant pain has been more controversial and is still being actively discussed by medical experts. The consensus now is that some patients with chronic pain should be considered as candidates for long-term opioid therapy, and some will gain great benefit from this approach.

The controversy over the use of opioid drugs to treat chronic pain is multifaceted. To some extent, it is related to limited scientific literature that does not yet clearly define the most appropriate patient subpopulations, best treatments, and range of outcomes. More research is seriously needed to address these questions.

The controversy also stems from a lack of education about these drugs on the part of clinicians, regulators, law enforcement, policy makers, patients and the public at large. The scientific literature that does exist is often poorly recognized. This literature is generally viewed by pain specialists as having established the effectiveness of opioid therapy in selected patients. It also has helped define the risks and range of benefits that are associated with the approach.

There also is substantial confusion about the meaning of, and the true risks associated with, drug-related phenomena such as physical dependence, tolerance, and addiction (see Appendix A for definitions). This confusion can lead to the withholding of opioid medication because of a mistaken belief a patient is addicted when he or she is merely physically dependent. It can lead to inappropriate targeting of practitioners and patients for investigation and prosecution, and to excessive and unfounded fear of opioid use among patients and the public. This confusion must be resolved to settle the important medical questions relating to patient selection, treatment goals, dosing, and monitoring. The answers to these questions should be informed by research.

Ideally, the clinician's decision about how to treat a patient's pain is based on a full understanding of the likelihood of both benefit and harm from reasonable treatment alternatives. However, there are few data on risks and benefits for many treatments, including the long-term use of opioids. Nevertheless, it is widely agreed that opioids are an option for long-term pain treatment and that a trial may be a reasonable step for patients who have moderate to severe chronic pain. To make this decision, the assessment should attempt to answer the following questions:

- *What is conventional medical practice in the treatment of this type of pain?* If there is widespread acceptance of an approach, such as trials of nonsteroidal anti-inflammatory drugs in painful osteoarthropathy, then the decision to use an opioid may require documentation that the accepted approach has been tried and failed, or carries an unacceptably high risk in the specific patient.

- *Are there other treatments that may be effective and feasible, and have a risk-to-benefit profile as good as, or better than, the opioids?* This question is difficult to resolve, given the lack of comparative data from clinical trials. Nonetheless, the clinician who is considering the administration of an opioid, particularly long-term administration, should carefully consider whether there are other treatment options that are likely to work as well in the specific case, at the level of risk associated with opioid therapy.

- *Is the patient particularly vulnerable to opioid side effects?* The analysis of risk-to-benefits shifts in those who are predisposed to severe opioid side effects.
- *Is the patient likely to take medications responsibly or, if problems seem likely, could a plan for structuring the therapy and monitoring it be successful?* Risk assessment and management should be considered a fundamental aspect to long-term opioid therapy. An assessment that reveals characteristics, such as a history of substance abuse in the recent past, that suggests a relatively high risk of problematic drug-related behaviors may influence the decision to initiate treatment or lead to more intensive monitoring if opioid therapy is still indicated.

Based on the answers to these questions, the clinician should be able to make an informed judgment about the potential value of an opioid trial in a particular patient.

Opioid treatment options include short-acting opioids, such as codeine, hydrocodone, hydromorphone, morphine, or oxycodone. Some of these drugs are available in combination with aspirin, acetaminophen or ibuprofen; in this case, caution is needed to avoid toxicity from the nonopioid component. Long-acting opioids, such as one of the modified-release opioids (e.g., fentanyl, morphine, or oxycodone) or the long half-life drug methadone (see Question 26) are preferred for chronic pain because they are more convenient and may provide more consistent pain relief. Less frequent dosing with long-acting or controlled-release opioids also can improve adherence to the therapy (fewer missed doses). In appropriate patients, a short-acting opioid may be prescribed on a "PRN" basis in combination with fixed scheduled administration of a long-acting drug to assist in the management of "breakthrough" pain.

For more information on the use of opioids in the management of pain, see:

- American Academy of Pain Management
  http://www.aapainmanage.org/education/Education.php
- American Academy of Pain Medicine
  http://www.painmed.org/cme
- American Academy of Physician Assistants
  http://www.mecgeducation.com/jaapa/pain_management/default.asp
- American Board of Pain Medicine
  http://www.abpm.org/index.htm
- American Headache Society
  http://www.ahsnet.org
- American Medical Association
  http://www.ama-assn.org/ama/pub/category/10171.html
- American Pain Society
  http://www.ampainsoc.org
- Beth Israel Department of Pain Medicine and Palliative Care
  http://www.stoppain.org
- California Academy of Family Physicians
  http://www.familydocs.org
- National Pain Education Council
  http://www.npecweb.org

***Relevant Resources:***


American Society of Addiction Medicine. (1997). *Rights and Responsibilities of Physicians in the Use of Opioids for the Treatment of Pain*. Chevy Chase, MD: American Society of Addiction Medicine. (Available at http://www.asam.org/ppol/opioids.htm)

Gourlay, G. K. (2002). Clinical pharmacology of opioids in the treatment of pain. In M. A. Giamberadino (ed.), *Pain 2002—An Updated Review: Refresher Course Syllabus*. Seattle: IASP Press, pp. 381–394.

Graven, S., H. C. W. deVet, M. van Kleef, and W. E. J. Weber (2000). Opioids in chronic nonmalignant pain: a criteria-based review of the literature. In M. Devor, M. C. Rowbotham, and Z. Wiesenfeld-Hallin (eds.), *Proceedings of the 9th World Congress in Pain Research and Management* 16, Seattle: IASP Press.

Kalso, E. (2000). Opioids for chronic noncancer pain. In J. O. Dostrovsky, D. B. Carr, and M. Koltzenburg (eds.), *Proceedings of the 10th World Congress on Pain*, Seattle: IASP Press, pp. 751–765.

Passik, S. D., and H. J. Weinreb Managing chronic nonmalignant pain; Overcoming obstacles to the use of opioids. *Advances in Therapy* 17: 70–80.

Savage, S. R. (2003). Opioid medications in the management of pain. In A. W. Graham, T. K. Schultz, M. F. Mayo-Smith et al. (eds.). *Principles of Addiction Medicine* (3rd ed.). Chevy Chase, MD: American Society of Addiction Medicine, Inc., pp.1451–1463.

Zacny, J., G. Bigelow, P. Compton et al. (2003). College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: Position statement. *Drug and Alcohol Dependence* 69: 215–232.

### 7. What outcomes should be assessed when judging whether opioid therapy is successful?

Opioid analgesics have the ability to relieve pain. Improved comfort may be associated with better physical and psychosocial functioning, and enhanced quality of life. Opioids also have the potential for side effects and adverse effects (including abuse or addiction). Given the variation in the responses associated with this therapy, the management of opioid therapy should include ongoing evaluation of a range of outcomes. The relevant categories include:

- pain relief;
- side effects;
- functioning, both physical and psychosocial (and overall quality of life); and
- problematic drug-related behaviors (which may suggest misuse, abuse, addiction, or even diversion).

Pain intensity, or the extent of pain relief, should be measured over time and documented in the medical record. This may involve questions using a simple verbal rating scale (none, mild, moderate, severe), a numeric scale ("0 to 10"), or some other type of measure. Documentation in the medical record that pain is being followed over time is important evidence of the appropriateness of therapy.

Although opioids can provide pain relief, complete pain relief is uncommon during the treatment of chronic pain. Pain measurements during the treatment of chronic pain are seldom "zero," and in some cases, can fluctuate at relatively high levels. In the clinical setting, the overall benefit, or success, of opioid therapy often cannot be determined by pain scores alone. Although clinical studies have suggested that meaningful pain relief is associated with defined reductions in pain scores (e.g., two points on a 0 to 10 scale or 30% on a visual analogue scale), these values are helpful in research but do not capture the complexity of the clinical situation. For some patients, pain relief may be "meaningful" when specific tasks can be performed, mood improves, sleep is better, or relationships with others can occur. The monitoring of pain intensity is important but the clinician should be prepared to assess all these outcomes in an effort to understand the overall effects of therapy.

Side effects are common during opioid therapy. The potential for side effects should be explained to the patient and anticipated, assessed, and managed. With the exception of constipation, side effects are usually of short duration and can be expected to lessen with time as the body adapts to the opioid (see Question 9 for more information on side effects.)

Although a large clinical experience suggests that most patients use opioid drugs responsibly—following instructions, communicating with the clinician, and avoiding actions that would be worrisome to the prescriber—some patients engage in problematic drug-related behaviors. These problematic behaviors are very diverse and may reflect any of a wide array of clinical disorders (including addiction); they could potentially reflect diversion as well. Practitioners who prescribe controlled prescription drugs, such as the opioids, should monitor drug-related behavior. This may be done through history-taking, or if indicated, through more structured plan that includes behavioral assessments. Such a structured approach is most clearly indicated if the patient has a known history of addiction or significant substance abuse (see Question 23).

In summary, pain treatment with opioids should be evaluated over time by assessing improvement in pain and the extent to which this outcome is associated with side effects, gains in function and quality of life, and the occurrence of any problematic behaviors. These outcomes are important to assess in all cases, regardless of their history.

***Relevant Resources:***


Gourlay, G. K. (2002).Clinical pharmacology of opioids in the treatment of pain. In M. Giamberadino (ed.), *Pain 2002—An Updated Review: Refresher Course Syllabus*.Seattle: IASP Press, pp. 381–394.

McQuay, H. J. (1999). How should we measure the outcome? Opioid Sensitivity of Chronic Noncancer Pain. In E. Kalso, H. J. McQuay, and Z. Weisenfeld-Hallin (eds.), *Progress in Pain Research and Management* 14. Seattle: IASP Press, pp. 371–383.

Rowbotham, M. C. (2001). Editorial: What is a "clinically meaningful" reduction in pain? *Pain* 94: 131–132.


### 8. Where can clinicians find educational material on prescribing opioid analgesics?

- American Academy of Pain Management
  http://www.aapainmanage.org/education/Education.php
- American Academy of Pain Medicine
  http://www.painmed.org/cme
- American Academy of Physician Assistants
  http://www.mecgeducation.com/jaapa/pain_management/default.asp
- American Geriatrics Society
  http://www.americangeriatrics.org/education/manage_pers_pain.shtml
- American Medical Association
  http://www.ama-assn.org/ama/pub/category/10171.html
- Beth Israel Department of Pain Medicine and Palliative Care
  http://www.stoppain.org
- California Academy of Family Physicians
  http://www.familydocs.org
- National Pain Education Council
  http://www.npecweb.org

### 9. What are the common side effects associated with opioid therapy, and how can they be managed?

It is very important that physicians anticipate, recognize, and treat side effects when patients are receiving opioids for pain. Common side effects at the start of therapy or after dose escalation include somnolence or mental clouding, nausea, and constipation. Uncommon side effects include fatigue; itching; adverse mood change; dry mouth, loss of appetite, bloating, or heartburn; urinary hesitancy; sweating; sexual dysfunction; and headache. Although any side effect can persist, the most common long-term side effect is constipation. With overdose, opioids can cause serious respiratory depression, the risk of which is again highest in the setting of limited or no ongoing opioid therapy.

Physicians should periodically inquire about side effects. If side effects are present and are not tolerated well, treatment should be adjusted. The drug or how it is administered can be changed, or a specific treatment can be given for the side effect. Typically, successful therapy depends on achieving and maintaining a favorable balance between analgesic effects and side effects.

Constipation is very common during opioid therapy, particularly among those patients who are predisposed (the elderly, patients taking other constipating drugs, patients with diseases that affect the gastrointestinal track). Tolerance may not develop to opioid-induced constipation, and laxative therapy may be needed throughout the course of treatment.

Somnolence and mental clouding are common when therapy is initiated or the dose is increased. Although these effects typically decline over time, some patients experience persistent impairment. The risk presumably is higher among those who are concurrently using other CNS depressants and those with diseases associated with encephalopathy. Selected patients with analgesia compromised by somnolence or mental clouding may be candidates for specific therapy with a psychostimulant drug.

Nausea and vomiting may be treated with antiemetics such as phenothiazines, butyrophenones, or metoclopramide. When nausea is due to motion-related vestibular effects, a trial of an antihistamine, such as meclizine or scopolamine, should be considered. If opioid-induced gastroparesis is suspected (postprandial nausea, bloating, reflux symptoms), metoclopramide is a preferred drug because of its positive effects on gastrointestinal motility. To help manage nausea, it may be worthwhile to consider switching to a nonoral route of administration, at least for a time.

Itching, which results at least in part from the release of histamines triggered by opioids, usually resolves within a few days. If itching persists, it may be treated with an antihistamine. Among the commonly used opioids, and fentanyl and oxymorphone have a relatively low propensity to release histamine.

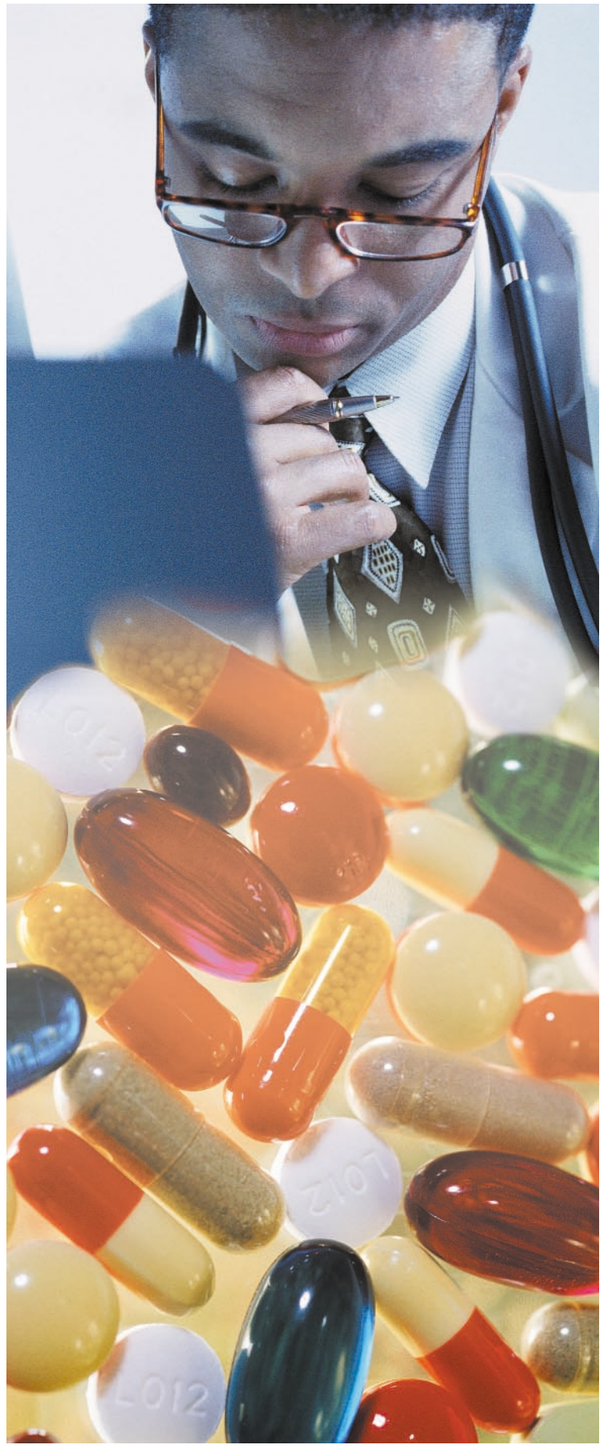
Respiratory depression is a rare adverse effect during chronic opioid treatment. Respiratory depression is possible if dose escalation occurs very quickly, beyond the ability of compensatory mechanisms to adjust; if some intercurrent cardiopulmonary event occurs (for example, pulmonary embolism or pneumonia), or if something happens to eliminate the source of the pain (for example, a nerve block). Except in rare circumstances, respiratory depression is preceded by somnolence and slowed breathing. Respiratory depression that occurs from some intercurrent cardiopulmonary event may be partially reversed by naloxone. Accordingly, a response to naloxone does not mean that the opioid was the primary problem. When patients develop respiratory depression in the setting of stable dosing, a prompt search for another cause usually is indicated, even if the patient improves with naloxone.

Because the administration of naloxone carries substantial risks in the physically dependent patient (severe withdrawal), it should not be used unless clinically significant respiratory depression is feared. Naloxone should not be given for somnolence in the absence of existing or impending respiratory effects. If the time of peak effect of the drug has passed, and the patient has adequate respirations, it is safer to observe for a period of hours than to treat with naloxone. If naloxone must be given, it is safer to give small doses repeatedly and monitor effects.

***Relevant Resources:***


American Pain Society. (2003). *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain* (5th ed.). Glenview, IL: American Pain Society.

Fohr, S. A. (1998). The double effect of pain medication: Separating myth from reality. *Journal of Palliative Medicine* 1 (4): 315–328.

### *10. What information do patients need about using opioids for chronic pain?*

Informing patients about issues surrounding pain management and the use of opioid analgesics is good medical practice. Sometimes, this is accomplished as part of informed consent, which is recommended and, in fact, required in some states (to see if your state requires informed consent, refer to http://www.medsch.wisc.edu/painpolicy/matrix.htm).

Physicians can provide information through discussions with the patient or by distributing a handout, booklet, or medication agreement. Patients and their caregivers also can gain access to valuable information by using the Internet to reach a number of organizations (see links provided below).

Although not a complete list, patients should understand this information:

- Patients' rights
  - Patients have the right to have their pain assessed and treated.
  - Accredited medical facilities should recognize this right.
- Diagnosis and treatment plan
  Patients should:
  - know the diagnosis and as much as possible about reasons for the pain.
  - know the goals of treatment and how the physician will measure progress to achieve the goals.
  - know why opioid analgesics are part of the treatment plan and how and when to take them.
  - know the realistic expectations for sustained pain relief and improved functioning, and that it may not be possible to relieve all their pain.
  - realize that opioids are only one part of a treatment plan that may include other treatments such as physical therapy or psychological techniques.
  - recognize that decisions about starting, changing, or stopping opioid treatment should be made with patient input.
  - know that they can ask for changes in treatment or a consultation with a specialist if pain relief is not adequate.
- Side effects
  Patients should:
  - know what side effects to expect and how to manage them.
  - understand that most side effects are transitory, but any effect can persist and potentially compromise the long-term value of the treatment.
  - recognize that concurrent therapies for side effects may be recommended.
  - know that the occurrence of intolerable and untreatable side effects means that the treatment is not appropriate and must be changed.
  - know that opioids may impair thinking and alertness at first and, if this occurs, the patient should avoid driving or other similar activities until these effects dissipate.
- Abuse, addiction, physical dependence, and tolerance
  Patients should:
  - know the definitions of physical dependence, tolerance, and addiction.
  - understand that the use of an opioid in a manner different from what is instructed is a form of drug abuse, and that the clinician must continually assess whether this is occurring and take steps to prevent it or, should it be identified, stop it.
  - know that the use of alcohol and any other prescribed drugs during opioid therapy must be assessed by the clinician, and should the use of these substances be perceived to be problematic, the clinician must assess the situation and take appropriate actions.
  - recognize that the use of illicit drugs can be a significant problem, and that the clinician must monitor the patient for this occurrence and act appropriately if it is discovered.
  - know that addiction is a serious illness, and that the clinician must monitor drug-related behaviors in part to make sure that this problem is not developing; if there is a possibility that problematic behaviors surrounding medicines are due to an addiction, the physician must treat this.
  - know that true addiction is believed to be a rare occurrence in patients who receive opioids for a medical reason and have no history of drug abuse or addiction; clinicians must monitor drug-related behaviors in all patients, however, have accurate and balanced information about addiction and how it is assessed.
  - know that physical dependence, which is the capacity for withdrawal, is normal during opioid therapy, does not prevent discontinuation of the therapy if the pain stops, and, most important, is not addiction.
  - know that analgesic tolerance occurs when a stable dose of pain medication has a decreasing effect over time and does not indicate addiction.

- Some "Dos" and One "Don't" for Patients
  - Do talk to the doctor and other health care professionals involved in your pain care about the pain; keep notes and write down questions to ask about the pain.
  - Do talk to the doctor if the medication is not working.
  - Do talk to the doctor if there are problems with side effects.

- Do talk to the pharmacist openly about this therapy if he or she could potentially help with information about the pain or the management of side effects.
- Do keep the medications in a safe place and out of children's reach.
- Do look for another physician, or request referral to a specialist, if the pain is not taken seriously.
- Do use the medication only as it is prescribed and handle the therapy with a high level of responsibility.
- Do notify the physician if you are planning to become pregnant or are already pregnant.
- Don't allow others to use the prescription medication; the patient is the only person who is legally permitted to have the prescribed opioids.

For more information about pain, patients' rights, communicating with the physician, and support:

American Alliance of Cancer Pain Initiatives
http://www.aacpi.org
American Cancer Society
http://www.cancer.org/docroot/home/index.asp
American Chronic Pain Association
http://www.theacpa.org
American Pain Foundation (homepage)
http://www.painfoundation.org
American Pain Foundation (brochure "Finding Help for your Pain")
http://www.painfoundation.org/downloads/FindingCare.pdf
Cancer Information Service
http://cis.nci.nih.gov
National Chronic Pain Outreach Association
http:/www.chronicpain.org
National Pain Foundation
http://www.painconnection.org

### 11. What kinds of problems might patients encounter when obtaining opioid prescriptions, in having them filled, or in taking the medications properly?

- Some physicians may be reluctant to prescribe pain medications due to uncertainty about the medical appropriateness, inadequate or inaccurate knowledge about pain management, limited information about opioid pharmacology, concern about the development of problematic drug-related behavior or addiction, and fear of scrutiny by regulatory and law enforcement agencies and the insurance industry. Physician communication with regulatory agencies, as well as information disseminated by organizations such as medical boards, can help to overcome these problems.
- Pharmacists sometimes react with suspicion to patients who are prescribed opioid drugs because of concern about drug abuse or lack of information about the proper role of opioid therapy in pain management. Some pharmacists even refuse to dispense controlled substances, and some do not understand what the law allows. Communication between the physician and pharmacist, as well as consultation with and information disseminated by pharmacy boards, can reduce these problems.
- Some pharmacies do not stock pain medications due to high cost, poor reimbursement, low prescription demand, and concerns about theft or robbery; clinicians may recommend certain pharmacies or may call ahead to be sure that the prescribed medication is in stock.
- Pharmacies sometimes provide drug information, including computer printouts, that provide an inaccurate perspective of the benefits and risks of opioid drugs, reinforcing patient concerns about the medicine.
- Family and friends, or health care providers who are not directly involved in the therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded fear of addiction; they may be exacerbated by widespread, sometimes inaccurate, media coverage about abuse of opioid pain medications.

***Relevant Resources:***


Joranson, D. E., and A. M. Gilson (2001). Pharmacists' knowledge of and attitudes toward opioid pain medications in relation to federal and state policies. *Journal of the American Pharmaceutical Association* 41 (2): 213–220. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/01japhak/index.htm)

Morrison, R. S., S. Wallenstein, D. K. Natale et al. (2000). "We don't carry that"—Failure of pharmacies in predominantly nonwhite neighborhoods to stock opioid analgesics. *New England Journal of Medicine* 342 (14): 1023–1026.


### 12. Can more than one opioid at a time be prescribed to a patient?

The physician may determine that it is beneficial for the patient to use more than one opioid at a time. In the treatment of cancer pain, the typical approach involves the prescription of a long-acting opioid to relieve baseline pain plus a short-acting opioid (known as the "rescue" dose) to be taken as needed for episodes of breakthrough pain. Many pain specialists now apply this approach to the management of chronic noncancer pain. The use of this rescue medication should be considered on a case-by-case basis. Some patients appear to be good candidates because their pain fluctuates, opioids help, and there is a reasonable expectation of responsible drug use; others may benefit more from administration of a single drug according to a fixed schedule. Other nonopioid controlled substances also may be coadministered during opioid therapy (see Question 9). A separate prescription form should be used for each opioid or other controlled substance prescribed.

### 13. What is "opioid rotation," and when is it appropriate?

Opioid rotation refers to a switch from one opioid to another. It is a common strategy to address the occurrence of intolerable side effects during opioid therapy. When a switch is made, the starting dose of the new drug is selected based on the information in an "equianalgesic dose table." Versions of this table are widely available, and the values it contains should be considered a broad guide to selecting the dose. In most cases, the dose of the new opioid is reduced from the calculated equianalgesic dose because cross-tolerance between opioids is incomplete and there is substantial variation in the dose-response across individuals. This reduction reduces the risk of side effects from a calculated dose that may be, in effect, too high for the patient. The extent of the dose reduction varies with the specific drug and the clinical situation of the patient. The usual 30-50% reduction in the calculated equinalgesic dose is increased (usually to 75-90%) when the switch is to methadone, and is decreased (sometimes to no reduction at all) when the switch is to transdermal fentanyl; the reduction is increased if the patient has significant opioid side effects or is medically frail, and it is decreased if the patient has a high level of pain. After treatment with the new drug is initiated, the dose usually must be adjusted, often repeatedly, to optimize the balance between pain relief and side effects.

***Relevant Resources:***


Anderson, R., et al. (2001). Accuracy in equianalgesic dosing. Conversion dilemmas. *Journal of Pain and Symptom Management* 21 (5): 672–687.

Arnold, R., and D. E. Weissman (2003). Calculating opioid dose conversions #36. *Journal of Palliative Medicine* 6 (4): 619–620.

Pereira, J., et al. (2001). Equianalgesic dose ratios for opioids. A critical review and proposals for long-term dosing. *Journal of Pain and Symptom Management* 22 (2): 672–687.

Southern California Cancer Pain Initiative. *Pocket Card*. (Available at http://sccpi.coh.org)

### 14. What do the terms "tapering" and "drug holiday" mean?

Tapering (or "weaning") is when the physician discontinues a pain patient's opioid therapy by progressively reducing the dose to prevent withdrawal symptoms. If opioid therapy must be stopped, the dose should be tapered rather than being discontinued abruptly. The observation that opioid therapy can be discontinued without uncomfortable abstinence by carefully tapering the dose supports the view that opioid therapy can be initiated as a trial. If the patient benefits, treatment can be continued; if the patient does not benefit, or benefits for a time but then develops problems, the treatment can be stopped without risk of the significant physiologic perturbations associated with withdrawal.

Tapering of a patient being treated for pain is legally distinct from "detoxification" of a patient being treated for addiction. Physicians who are directing the taper of a therapy do not need a separate DEA registration as do those who are directing detoxification programs under Title 21 of the U.S. Code of Federal Regulations §1306.07. There are no federal or state regulations governing the tapering from opioids of a patient being treated for pain.

A "drug holiday" usually means the cessation of opioid therapy for reasons other than inadequate pain relief, unacceptable adverse effects, or decreased quality of life. There is no medical justification for an enforced drug holiday of an opioid in the management of ongoing pain.

### 15. Is a written agreement between the clinician and the patient required before instituting treatment with an opioid?

Although not required by federal regulations, written agreements regarding opioid treatments can be an important part of treatment for some patients and may be required or considered the standard of practice in some states. Pain specialists have differing opinions about the contents and use of agreements, but some believe they should be used whenever long-term opioid therapy is instituted. Some clinicians use agreements as routine office policy for every patient receiving chronic opioid therapy. Written agreements should advance a positive therapeutic relationship, reflect a willingness to have an open dialogue about the responsibilities and risks associated with opioid therapy, and contain clear and accurate information and instructions for the patient. Such agreements—a copy of which is kept by both physician and patient—may be useful to:

- Describe the treatment goals and plan.
- Clarify the responsibilities and expectations of both physician and patient.
- Serve as a reference point if there is any disagreement about expectations and responsibilities.
- Serve as written informed consent regarding the possible side effects and risks of opioid medications.
- Establish parameters for opioid use and consequences for misuse.
- Aid in the diagnosis of problematic drug-related behavior, should it occur.

Examples of such agreements can be found at:

- American Academy of Pain Management http://www.aapainmanage.org/literature/Articles/OpioidAgreements.pdf
- American Academy of Pain Medicine http://www.painmed.org/productpub/statements

***Relevant Resources:***

Gitlin, M. C. (1999). Contracts for opioid administration in the management of chronic pain: a reappraisal. *Journal of Pain and Symptom Management* 18: 6–8.

### 16. What should be documented when prescribing opioids?

Requirements for documentation when prescribing opioids for the treatment of pain vary from state to state, but there are several features that endorsed commonly:

- The medical record should have evidence that the treatment is taking place within the standards of medical practice.
  - For an initial evaluation, this includes a history and physical examination, a pain assessment, and a treatment plan.
  - For follow-up visits, this includes an appropriate interim history and focused examination when indicated, pain reassessment, and reevaluation of the treatment plan.
- The medical record should reveal evidence that the physician has evaluated the nature of the pain complaint, earlier treatments, impact of the pain, important comorbidities, and alcohol and drug history.
- The medical record should show that a range of outcomes have been repeatedly assessed during the course of opioid therapy, including:
  - pain intensity;
  - physical and psychosocial functioning;
  - side effects of therapy; and
  - drug use behaviors (that is, whether any problematic behaviors occur).

The Federation of State Medical Boards of the United States (FSMB) "Model Policy for the Use of Controlled Substances for the Treatment of Pain" provides more detailed direction on documentation at http://www.fsmb.org. State requirements can be obtained from your state medical board (directory provided at http://www.fsmb.org) and from state pain policies for each state and can be found at http://www.medsch.wisc.edu/painpolicy/matrix.htm.

# SECTION V
# RISKS IN THE MEDICAL USE OF OPIOID ANALGESICS

### 17. What is the extent of prescription opioid abuse?

It is difficult to measure with precision trends in the abuse of prescription controlled substances, including the opioid analgesics. Several information systems exist and are described in the references below. Some useful perspective can be obtained from one nationally representative information system, the Drug Abuse Warning Network (DAWN), although periodic changes in data collection methodology make its interpretation difficult over time. According to The DAWN Report (January 2003), published by the Substance Abuse and Mental Health Services Administration:

> Concern about the abuse of prescription painkillers has risen dramatically in the U.S. Of particular concern is the abuse of pain medications containing opiates (also known as narcotic analgesics), marketed under such brand names as Vicodin®, Oxycontin®, Percocet®, Demerol®, and Darvon®. According to the Drug Abuse Warning Network (DAWN), the incidence of emergency department (ED) visits related to narcotic analgesic abuse has been increasing in the U.S. since the mid-1990's, and more than doubled between 1994 and 2001.

The DAWN system collects data from EDs about the number of times drugs are mentioned[1] in drug overdoses. In 2002, the total number of DAWN ED mentions was 1,209,938. These included:

- 17% alcohol-in-combination with other drugs (24% increase from 1995);
- 16% cocaine (47% increase from 1995);
- 10% marijuana (164% increase from 1995);
- 10% all narcotic analgesics combined (163% increase from 1995); and
- 8% heroin (34% increase from 1995).

Of the opioid analgesic category:

- Codeine: 4,961 mentions; a decrease of 43% from 1995
- Fentanyl: 1,506 mentions; an increase of 6745% over 1995
- Hydrocodone: 25,197 mentions; an increase of 160% over 1995
- Hydromorphone data not available
- Meperidine: 722 mentions; a decrease of 31% from 1995
- Methadone: 11,709 mentions; an increase of 176% over 1995
- Morphine: 2,775 mentions; an increase of 116% over 1995
- Oxycodone: 22,397 mentions; an increase of 560% over 1995
- Propoxyphene: 4,676 mentions; a decrease of 25% from 1995

Given the well accepted limitations of DAWN data, this report should not be considered a detailed or comprehensive accounting of the epidemiology of drug abuse. Nonetheless, the DAWN system has been used for many years as an indicator of drug abuse patterns. From this indicator and other data, there is a high likelihood that prescription drug abuse has increased substantially during the past decade.

[1] A drug mention refers to the number of times a drug is mentioned as being involved in a drug-related emergency room visit.

***Relevant Resources:***


Brookoff, D. (1993). Abuse potential of various opioid medications. *Journal of General Internal Medicine* 8: 688–690.

Gilson, A. M., K. M. Ryan, D. E. Joranson, and J. L. Dahl (in press). A reassessment of trends in the medical use and abuse of opioid analgesics. *Journal of Pain and Symptom Management*.

Ling, W, D. R. Wesson, and D. E. Smith (2003). Abuse of prescription opioids. In A. W. Graham, T. K. Schultz, M. F. Mayo-Smith, R. K. Ries, and B. B. Wilford (eds.), *Principles of Addiction Medicine* (3rd ed). Chevy Chase, MD: American Society of Addiction Medicine, Inc., pp. 1483–1492.

Zacny, J., G. Bigelow, P. Compton et al. (2003). College on Problems of Drug Dependence taskforce on prescription opioid non-medical use and abuse: Position statement. *Drug and Alcohol Dependence* 69: 215–232.


### 18. What are the common ways opioids are diverted to illicit uses?

"Diversion" refers to the unlawful transfer of prescription drugs from legitimate to illicit channels of distribution, often resulting in episodes of abuse. Opioids are diverted in many ways, all of which are illegal. At the top of the distribution chain, there are thefts from drug manufacturers and wholesalers. The most common type of diversion at this level is from in-transit losses. Depending on the size of the "heist," this source could account periodically for a large number of opioids reaching the illicit market.

At the retail level, there are thefts from pharmacies, also a potentially large source of diversion. The most common pharmacy theft is the "night break-in." There are also numerous reports of armed robbery of pharmacies. The individuals who commit these crimes can be dangerous and may be motivated by their own addiction or to sell the drugs on the illicit market. Diversion from pharmacies also includes employee pilferage and customer theft. There is also "Internet" diversion, where drugs are illegally purchased online from foreign and domestic websites.

Some physicians knowingly and intentionally prescribe opioid medications for profit or other personal gain and others may become involved in "prescription fraud," which occurs whenever prescriptions for controlled substances are obtained under false pretenses, including when prescriptions are forged or altered to authorize additional quantities or refills, or when prescriptions are called in to pharmacies by individuals posing as patients or claiming to represent a physician. Patients sometimes sell their prescription forms or medications to others, and nonpatients may steal a patient's prescriptions or medications. Some physicians unwittingly contribute to diversion by careless prescribing or failure to maintain control over their prescription pads. To reduce these occurrences, practitioners should write prescriptions in a way that precludes alteration, keep prescription forms in a secure location, and contact local law enforcement if prescription forms are ever stolen.

Drug abusers may visit multiple physicians and present themselves convincingly so that physicians who are unfamiliar with drug abuse may inadvertently contribute to drug diversion. This method of diversion is called "doctor shopping." Skilled "professional patients" seek out physicians and use them, willingly or unwillingly, as suppliers of drugs that are then diverted to the illicit market. Any physician can be duped, and physicians are encouraged to familiarize themselves with how to spot a drug abuser (see answer to Question 19) or go to DEA website for "Don't be scammed by a drug abuser," http://www.deadiversion.usdoj.gov/pubs/brochures/index.html), while at the same time ensuring that their pain patients receive the pain relief they need.

There are few data about the extent to which these various sources contribute to overall diversion and abuse. The source of diversion for which there is the most consistent and reliable data comes from DEA registrants, including pharmacies, who are required to report all significant losses and thefts to the DEA. (An example of pharmacy theft data can be found on the DEA website, http://www.deadiversion.usdoj.gov/drugs_concern/oxycodone/oxycodone.htm).

***Relevant Resources:***


Gilson, A. M., K. M. Ryan, D. E. Joranson, and J. L. Dahl (in press). A reassessment of trends in the medical use and abuse of opioid analgesics. *Journal of Pain and Symptom Management*.

### 19. How can clinicians assess for risks of abuse, addiction, and diversion and manage their patients accordingly?

Some patients engage in aberrant drug-related behavior during treatment with an opioid or another controlled substance prescription drug. In some cases, this abuse is relatively minor and transitory, but in others, it is serious and persistent. Clinicians should recognize that these behaviors may have any number of causes, including addiction. It is recommended that clinicians adopt a "universal precautions" approach to the use of potentially abusable drugs, including opioids, as discussed below. This approach monitors behaviors over time and structures prescribing consistent with the degree of risk of abuse, addiction, and diversion. By establishing treatment expectations for each patient, and structuring therapy appropriately, physicians can identify those patients who are at risk for abuse, addiction, or diversion; help those who may need controls to manage the therapy responsibly; and provide the monitoring that is needed for safe and effective prescribing.

Clinicians should consider the following approaches in developing a “universal precautions” approach:

1. In assessing patients for opioid therapy, take a detailed history and perform an appropriate physical examination (see Question 4). The medical history should include a history of controlled prescribed drug use and alcohol, cannabis and nicotine use. Screen for addictive behaviors of other family members. Take into consideration any social, psychological, or work-related factors that may indicate a potential for abuse, addiction, or diversion. Identify concurrent psychiatric illness, especially where poor impulse control is a feature.

2. Establish diagnoses for the pain problem and for relevant comorbidities, and record these in the chart. Base the diagnosis on appropriate evaluations and review of patient records, if available. A patient’s unwillingness to allow contact with previous providers should be evaluated and documented.

3. Consider multiple approaches to the treatment of chronic pain. Nonpharmacological and nonopioid analgesic approaches may be preferred. Some states have special requirements for treatments that should be tried before opioids.

4. Consider opioid therapy for all patients with chronic moderate to severe pain, but evaluate the answers to the following questions first and make case-by-case decisions about the appropriateness of an opioid trial (see Question 6):

   - *What is conventional medical practice in the treatment of this type of pain?*
   - *Are there other treatments that are effective and feasible and have a risk-to-benefit profile as good as, or better than, the opioids?*
   - *Is the patient particularly vulnerable to opioid side effects?*
   - *Is the patient likely to take medications responsibly or, if problems seem likely, could a plan for structuring the therapy and monitoring it be successful?*

5. Recognize that opioid therapy is as much a "therapeutic trial" as any other treatment. If the benefits are not clear, or the risks of adverse effects are not easily managed, the therapy can be modified or stopped.

6. One practitioner should have primary responsibility for management of chronic pain in patients with a known or suspected history of abuse, addiction, or diversion.

7. When a patient has a known history of abuse, addiction, or diversion, it is particularly important that the clinician be clear from the beginning about expectations in the treatment plan. The treatment plan may include a written agreement with the patient describing the requirements (see Question 15 regarding agreements), such as limited quantities of medication, routine urine screens, consultation with a specialist, and the consequences of not adhering to the agreement.

If the clinician decides to initiate opioid therapy, it is appropriate to begin by titrating the amount of opioid to ensure that maximum therapeutic effect can be reached. Continuation of therapy is justified if the benefit is demonstrably greater than the adverse outcomes; this should be clearly documented. Once adequate pain relief has been achieved, a successfully treated patient is one who remains responsible over time, follows the agreement for use of the opioids and exhibits neither drug abuse behaviors nor indications of addiction, and experiences enhanced comfort and an improved quality of life. At the other extreme, patients who manifest the disease of addiction exhibit a range of maladaptive behaviors and experience a decreased quality of life. They do not follow the agreement for use of opioids, do not conform to the agreed-upon dosing schedule; and may lose prescriptions, repeatedly seek early refills, or obtain additional supply from other sources. They continue or escalate medication use despite adverse consequences; appear unaware of, or in denial about, abuse of the medication; and may always have a "story." In some cases, such a patient will "doctor shop" or alter prescriptions to increase his or her supply of the medication. (See answers to Question 22 and Question 23 for more information).

A "universal precautions" approach to the prescribing of controlled prescription drugs does not mean that all patients who have the capacity to engage in abuse or diversion will be identified, or prevented from these behaviors over time. Nonetheless, the approach emphasizes the value of ongoing assessment and close monitoring, which are essential aspects to the appropriate, safe and effective use of these over time.

***Relevant Resources:***


Compton, P., J. Darakjian, and K. Miotto(1998). Screening for addiction in patients with chronic pain and "problematic" substance use: Evaluation of a pilot assessment tool. *Journal of Pain and Symptom Management* 16 (6): 355–363.

Covington, E. (2001). *Lawful Opioid Prescribing and Prevention of Diversion*. Dannemiller Education Foundation CD ROM, October.

Drug Enforcement Administration. (1999) "Recognizing the Drug Abuser." (Available at http://www.deadiversion.usdoj.gov/pubs/brochures/drugabuser.htm)

Gourlay, D., and H.A. Heit: Universal Precautions in Pain Medicine: A rational approach to the treatment of chronic non-cancer pain. Submitted for publication.

Savage, S. R. (2002). Assessment for addiction in pain-treatment settings. *Clinical Journal of Pain* 18: S28–S38.

Savage, S. R. (2003). Principles of pain management in the addicted patient. In A. W. Graham, T. K. Schultz, M. F. Mayo Smith et al. (eds.), *Principles of Addiction Medicine* (3rd ed.). Chevy Chase, MD: American Society of Addiction Medicine, Inc., pp. 1405–1419.

Schnoll, S. H., and J. Finch (1994). Medical education for pain and addiction: Making progress toward answering a need. *Journal of Law, Medicine & Ethics* 22: 252–256.


### 20. What behaviors are potential indicators of problems for patients on long-term opioid therapy?

Patients who received opioids or other controlled prescription drugs for legitimate medical purposes may engage in problematic drug-related behaviors. The range of behaviors is broad and their meaning may be difficult to clarify. Some behaviors that are clear-cut indicators of abuse or addiction when they occur in those with no legitimate medical problem become more challenging to interpret when there are unrelieved symptoms that are the target of therapy. In all cases, problematic drug-related behaviors must be carefully assessed, even as efforts are undertaken to eliminate or limit them. The differential diagnosis of problematic behavior includes addiction and diversion, but also pseudoaddiction (see Appendix A), confusion related to organic brain disease, and numerous psychiatric disorders associated with impulsive or self-destructive drug use.

Some of the problematic drug-related behaviors that occur in populations with chronic pain should be noted, and managed, by clinicians, but are generally recognized as relatively less egregious, and therefore, probably less likely to be predictive of addiction. These include:

- complaints about need for more medication;
- drug hoarding;
- requesting specific pain medications (others "don’t work");
- openly acquiring similar medications from other providers;
- occasional unsanctioned dose escalation; and
- nonadherence to other recommendations for pain therapy.

These behaviors are not acceptable and could lead to any of a number of responses on the part of the clinician, including the decision to taper and discontinue treatment. Clinicians also should be aware that some of these types of behaviors, such as the effort to acquire medications from other providers, may be violating the laws of some states. It is important to recognize, however, that these behaviors cannot be perceived to be an immediate reflection of addiction. Rather, the assessment may reveal other potential explanations, including the possible effects of unrelieved pain.

The following behaviors are more egregious, and as such, are more probable indicators of abuse, addiction, or diversion (see DEA website, http://www.deadiversion.usdoj.gov/pubs/brochures/index.html):

- Deterioration in functioning at work, in the family, or socially
- Illegal activities, such as selling medications, forging prescriptions, stealing drugs from other patients, buying prescription drugs from nonmedical sources
- Injection or snorting of medication
- Multiple episodes of "lost" or "stolen" prescriptions
- Resistance to changes in therapy, regardless of adverse effects
- Refusal to comply with random urine drug screens or referral to specialist
- Concurrent abuse of alcohol or illicit drugs
- Use of multiple physicians and pharmacies

These behaviors also cannot be assumed to be diagnostic of addiction, but they do indicate a relatively greater degree of pathology and presumably signal a higher likelihood of this disorder. Even if the criteria for addiction are not met, the severity of these problems emphasizes the need for a competent assessment and appropriate management, possibly including referral to a specialist in addiction medicine.

Several recent surveys suggest that the occurrence of problematic drug-related behaviors of one sort or another is very common in populations treated with long-term opioid therapy. As a result, monitoring for problematic behaviors must be considered to be an essential aspect of the long-term management of opioid therapy. These behaviors should not be taken to mean that a patient does not have pain, or that opioid therapy is contraindicated. Rather, they indicate the need for assessment, informed diagnosis and appropriate management. Management may or may not include continuation of therapy, depending on the circumstances (see Question 21). If the decision is made to terminate the physician-patient relationship, there must always be a good faith effort to avoid patient abandonment by providing referrals.

Pharmacists, whose principal professional obligation is to provide medications to the patient, and to counsel the patient on safe and effective use of the medications, must evaluate whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the course of professional practice. The main indicator that pharmacists should watch for is whether the prescription appears to be forged or altered. Pharmacists also should check patient profiles for seemingly duplicative or excessive controlled substance use and communicate with the prescribers in such cases. In addition, DEA says that the following signs should also be considered:

- Unsettling patient presentation
- A pattern of early requests for prescription refills (that is, more than a few days before the patient should be running out)
- Unreasonable quantities
- Time of prescription presentation, that is, weekends or after hours
- Patient unknown to pharmacist
- Prescriber unknown to pharmacist

These "red flags" do not mean that drug abuse or diversion is occurring. Patients are the focus of the practice of pharmacy, so professional judgment must serve the patient's needs first and foremost. Stereotypes of what an abuser "looks like" can harm legitimate patients because people who abuse prescription medicine can exhibit some of the same behaviors as patients who have unrelieved pain (see Appendix A for definition of pseudoaddiction).

Physicians and pharmacists should expect some degree of interaction with law enforcement authorities if their patients are involved in illegal activities, especially when patients sell the drugs that have been prescribed for them or when there is a need to substantiate prescription forgeries.

***Relevant Resources:***


Brushwood, D. B. (2003). Drug control policy out of balance. *Pain & The Law*. (Available at http://www.painandthelaw.org/mayday/brushwood_090403.php)

Compton, P., J. Darakjian, and K. Miotto (1998). Screening for addiction in patients with chronic pain and "problematic" substance use: evaluation of a pilot assessment tool. *Journal of Pain and Symptom Management* 16 (6): 355–363.

Drug Enforcement Administration. (2003). *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act of 1970* (8th ed.). Washington, DC: U.S. Department of Justice. (Available at http://www.deadiversion.usdoj.gov/pubs/manuals/index.html)

Passik, S. D., K. L. Kirsh, M. V. McDonald et al. (2000). A pilot survey of aberrant drug-taking attitudes and behaviors in samples of cancer and AIDS patients. *Journal of Pain and Symptom Management* 19 (4): 274–286.

Portenoy, R. K. (1996). Opioid therapy for chronic nonmalignant pain: Clinicians' perspective. *Journal of Law Medicine & Ethics* 24 (4): 296–309. (Available at http://www.painandthelaw.org/aslme_content/24-4c/portenoy.pdf)




***21. If a patient receiving opioid therapy engages in an episode of drug abuse, is the physician required by law to discontinue therapy or to report the patient to law enforcement authorities?***

Federal drug laws do not require physicians to report to law enforcement authorities patients who have engaged in drug abuse. The controlling federal legal standard is that the physician must issue prescriptions for controlled substances only for legitimate medical purposes and in the usual course of professional practice. However, some state policies state that a physician should not prescribe, administer, or dispense opioid analgesics to a person the physician knows or should know is using controlled substances for nontherapeutic purposes. State laws and regulations should be consulted on whether a report of patient drug abuse is necessary or use of opioids must cease under such circumstances.

In states with no specific legal requirements on this subject, if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is recommended (see the answer to Question 23).

Incontrovertible evidence of criminal activity, such as diversion, is grounds for termination of the doctor-patient relationship.

***22. Is it legal and acceptable medical practice to prescribe long-term opioid therapy for pain to a patient with a history of drug abuse or addiction, including heroin addiction?***

It is within the scope of current federal law to prescribe opioids for pain to patients with a history of substance abuse or addiction. However, some state policies may be more restrictive than federal law (see the answer to Question 21 as well as http://www.medsch.wisc.edu/painpolicy/2003_balance).

In general, pain patients fall into three groups. The first includes patients whose pain is not complicated by current addiction or a history of substance abuse. This group includes the majority of patients.

The second group comprises those patients who have histories of substance abuse or addiction but are in established recoveries. Some of these patients are receiving substitution therapy (methadone or buprenorphine), and some are in drug-free recovery. It is prudent to consult with a specialist in addiction medicine when considering long-term opioid therapy for patients who fall into this group. Therapy for patients in this group typically includes more controls than does therapy for those with no such history.

The third group, which includes those who are actively abusing substances, poses the greatest challenge. These patients require care of an advanced nature, which may not available in the primary care setting (see Question 23 for guidance about treating pain in patients who are currently abusing drugs, and Question 26 regarding the need to distinguish between the use of methadone for analgesia or substitution treatment). Referral of such patients to an addiction medicine specialist is appropriate (see state lists of addiction medicine specialists at www.asam.org).

***Relevant Resources:***


Compton, P., J. Darakjian, and K. Miotto (1998). Screening for addiction in patients with chronic pain and "problematic" substance use: evaluation of a pilot assessment tool. *Journal of Pain and Symptom Management* 16 (6): 355–363.

Dunbar, S. A., and N. P. Katz (2001) Chronic opioid therapy for nonmalignant pain in patients with a history of substance abuse: report of 20 cases. *Journal of Pain and Symptom Management* 11 (3): 163–171.

Gilson, A. M., and D. E. Joranson (2002) U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain* 18 (4 suppl): S91–S98. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/02cjpn/index.htm)

### 23. What strategies can be used to treat pain successfully in patients who are actively abusing drugs?

Federal law and regulations do not prohibit the use of opioids to treat pain if a patient is abusing controlled substances. However, state policies vary with respect to this therapy. Some states' policies discourage, if not prohibit, physicians from prescribing opioid analgesics to patients whom they know or should know are using controlled substances for nontherapeutic purposes (see answer to Question 21).

Using opioids to treat pain in such patients is very challenging. Physicians who proceed with this treatment should consider the following suggestions:

- Refer the patient to an addiction medicine specialist for concurrent treatment.
- Work closely with the addiction medicine specialist to coordinate the patient's care.
- Use a written agreement to outline treatment plan, including expectations and consequences.
- Structure the treatment in a manner that maintains the safety of the patient, and increases both the patient's ability to maintain control and the clinician's ability to identify medication misuse. Depending on the specifics of the case, this structure may include the prescribing of small quantities, frequent visits, the use a single drug (typically a long-acting opioid), pill counts, the use of a single pharmacy, defined contacts with historians other than the patient (e.g., family members or employers), required attendance at a drug-treatment program, and regular screening of urine toxicology (to provide evidence of therapeutic adherence and non-use of other drugs). The structure of the treatment plan should be tailored to reflect the clinician's assessment of the severity of drug abuse risk. Clear and regular communication between the clinician and the patient is an extremely valuable part of the treatment plan.

Continued drug abuse despite repeated interventions may, in some cases, indicate the need to discontinue prescribing of potentially abusable drugs, and in other cases, provide the impetus for termination of the physician-patient relationship. The clinician should be prepared to respond in these ways, and should understand both the options for nondrug therapies and the approach to termination without abandonment.

***Relevant Resources:***


Dunbar, S. A., and N. P. Katz (2001). Chronic opioid therapy for nonmalignant pain in patients with a history of substance abuse: report of 20 cases. *Journal of Pain and Symptom Management* 11 (3): 163–171.

Gilson, A. M., and D. E. Joranson (2002). U.S. policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clinical Journal of Pain* 18 (4 suppl): S91–S98. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/02cjpn/index.htm)

Gourlay, D., H.A. Heit, and Y. Caplan (2002). Urine drug testing in primary care, dispelling the myths & designing strategies. *California Academy of Family Physicians (CAFP).* PharmaCom Group, Inc. Stamford, CT. (Available at http://www.familydocs.org/UDT.pdf)

Heit, H.A., and D. Gourlay (2004). Urine drug testing in pain medicine. *Journal of Pain and Symptom Management* 27 (3): 260-67.

Savage, S. R. (2002). Assessment for addiction in pain-treatment settings. Clinical Journal of Pain 18: S28–S38.

Savage, S. R. (2003). Principles of pain management in the addicted patient. In A. W. Graham, T. K. Schultz, M. F. Mayo-Smith et al. (eds.), *Principles of Addiction Medicine* (3rd ed.). Chevy Chase, MD: American Society of Addiction Medicine, Inc., pp. 1405–1419.

Wesson, D., W. Ling, and D. E. Smith (1993). Prescription of opioids for treatment of pain in patients with addictive disease. *Journal of Pain and Symptom Management* 8: 289–296.




# SECTION VI
# OTHER LEGAL AND REGULATORY CONSIDERATIONS

### 24. What requirements must physicians and pharmacists meet to comply with federal and state laws regulating opioids?

For a physician to apply for a federal controlled substances registration to administer, prescribe, and/or dispense controlled substances, the physician must be licensed to practice medicine. In addition, some states require a state controlled substance registration.

If a physician loses or has restrictions placed upon his or her state-granted authority to use controlled substances, or is convicted of a drug-related felony or has lost his or her authority to participate in federal health care programs, there may be a legal impact on the physician's DEA registration status.

Physicians are legally authorized to administer, dispense, and/or prescribe controlled substances only for legitimate medical purposes, and the prescription must be issued in the usual course of a professional practice in the context of a doctor/patient relationship.

DEA regulations (http://www.access.gpo.gov/nara/cfr) affecting prescriptions include the following:

- Schedule II prescriptions must be signed by the physician or nurse practitioner unless there is an emergency.
- In the case of a bona fide emergency, the physician may telephone a pharmacy and authorize a prescription; however, a signed prescription must be forwarded to the pharmacy within seven days to account for the emergency prescription.
- Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates.
- Prescriptions written for controlled substances in schedules III, IV, and V may be refilled up to five times within six months. They may be telephoned or transmitted via facsimile to the pharmacy. Office staff may communicate the information to the pharmacy when acting as an agent of the registered physician.
- The amount of a controlled substance prescription is not limited by federal regulations to a maximum quantity or a specific period, although some states do have such limitations.
- Federal regulations do not require physicians to maintain prescribing records for controlled substances, although many states do.

Federal regulations are being developed that will provide a legal basis for the secure transmission of prescription information electronically, including via the Internet, between physicians and pharmacies. Practitioners should also be aware that an individual state's requirements for controlled substance prescriptions might be more restrictive than federal provisions.

Dispensing physicians are also subject to the following DEA regulations:

- Physicians who purchase controlled substances or who receive controlled substances as complimentary samples must maintain records to account for the receipt and use of the controlled substances.
- Physicians must physically inventory the drugs once every two years and have a copy of the inventory available for inspection by DEA diversion investigators.
- An official DEA order form must be used to obtain or transfer Schedule II drugs. The records of receipt and distribution (dispensing) must clearly identify the source of the drugs and the recipient (patient).

These are the basic requirements. Physicians should consult with DEA field offices if they have questions about the separate registration needed for the use of opioids to treat opioid-dependent patients, or if they have multiple offices or special situations that require clarification. A list of the DEA's field offices with staff contacts can be found at the DEA diversion website, http://www.deadiversion.usdoj.gov.

***Relevant Resources:***


Good, P. M. (2003). *DEA Policy Concerning the Legality of a Practitioner Issuing Several Schedule II Prescriptions on the Same Date for the Same Medication for a Stable Patient*. Letter from Chief of the Liaison and Policy Section, DEA Office of Diversion Control, to Dr. Howard Heit, January 31. (Available at http://www.asam.org/pain/federal_regulations_for_prescrib.htm)

Joranson, D. E. (1993). Guiding principles of international and federal laws pertaining to medical use and diversion of controlled substances. In J. R. Cooper, D. J. Czechowicz, S. P. Molinari, and R. C. Petersen (eds.). *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care: Monograph 131*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute on Drug Abuse, pp. 18–34. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/93nida.htm)

*Public Policy Statement on the Rights and Responsibilities of Healthcare Professionals in the use of Opioids for the Treatment of Pain* (2004) Adopted by the American Society of Addiction Medicine's Public Policy Committee, the American Academy of Pain Medicine, and the American Pain Society. (http://asam.org/) Power Point slides of Federal Regulations of Prescribing a Controlled Substance.

Pharmacists filling a prescription for controlled substances have a corresponding responsibility under the law to ensure that the prescription was written by a properly authorized prescriber and that it was written for a valid medical purpose. Pharmacists must be familiar with both state and federal requirements and are encouraged to document their efforts to ensure they have fulfilled their responsibilities under the law. They are also encouraged to develop a working relationship with their state pharmacy board (contact information can be found at http://www.nabp.net/) and DEA representatives to achieve open channels for communication. Finally, pharmacists are encouraged to read the DEA's Pharmacist Manual for guidance about the Controlled Substances Act and its implementing regulations, at http://www.deadiversion.usdoj.gov/pubs/manuals/index.html.

### 25. What regulations do physicians need to know and observe when prescribing opioid analgesics for pain?

*State level:* The privilege of prescribing drugs, including controlled substances, is based on having a license to practice medicine or osteopathy issued by a licensing and disciplinary board in each of the states where a practitioner wishes to practice. Some states also require an additional registration for prescribing controlled substances (information about how to contact state controlled substances authorities can be obtained at http://www.nascsa.org/HOME.htm). State statutes and regulations list prohibited controlled substances activities. Most states also have issued a regulation, guideline, or policy statement that provides guidance and, in some cases, a standard of care, for prescribing opioid analgesics for pain (http://www.medsch.wisc.edu/painpolicy/matrix.htm).

*Federal level:* Once a practitioner has satisfied state requirements of licensure and registration, the DEA issues a federal controlled substances registration, enabling the prescribing of controlled substances for legitimate medical purposes. The specific requirements for prescribing controlled substances are listed in Title 21, Parts 1300–1999 of the Code of Federal Regulations (http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1) and are summarized in a presentation format (http://www.asam.org/pain/federal_regulations_for_prescrib.htm). Further information about controlled substances and prescribing requirements can be obtained at http://www.deadiversion.usdoj.gov.

Prescribing opioids (referred to as narcotic drugs in federal regulations) for pain, including "intractable" pain, is lawful when there is a physician-patient relationship established by an examination, a treatment plan, and medical records.

### 26. Can methadone be used for pain control, and, if so, is a clinician required to have a special license to prescribe it?

Methadone is approved by the Food and Drug Administration as safe and effective for medical use as an analgesic. Although its low cost and effectiveness in some settings is driving increasing use, it is important to emphasize that its unique pharmacology is associated with a relatively higher risk of unintentional toxicity. This relates to a long and variable half-life and the potential for a greater-than-expected potency when a switch is made from an alternative opioid. The safe use of methadone requires knowledge of these characteristics and an ability to monitor therapy closely after it is initiated or changed.

State and federal regulations do not restrict the use of methadone to treat pain. It is recommended that the physician note in the chart that the methadone is for analgesia only. Any physician who has a DEA registration for controlled substances that includes Schedule II can prescribe methadone, just as any other Schedule II opioid medication, for pain. An additional separate DEA registration is needed only when dispensing methadone for outpatient maintenance or detoxification, not when prescribing it for pain, and the supply and records must be separate from its use for analgesia.

***Relevant Resources:***


Anderson, R., et al. (2001). Accuracy in equianalgesic dosing. Conversion dilemmas. *Journal of Pain and Symptom Management* 21 (5): 672–687.

Dole, V. P. (1988). Implications of methadone maintenance for theories of narcotic addiction. *Journal of the American Medical Association* 260: 3025–3029.

Garrido, M. J., and I. F. Troconiz (1999). Methadone: A review of its pharmacokinetic/ pharmacodynamic properties. *Journal of Pharmacological and Toxicological Methods* 42 (2): 61–66.

Gazelle, G., and P. G. Fine (2003). Methadone for the treatment of pain #75. *Journal of Palliative Medicine* 6 (4): 620–621.

Pereira, J., et al. (2001). Equianalgesic dose rations for opioids. A critical review and proposals for long-term dosing. *Journal of Pain and Symptom Management* 22 (2): 672–687.


### 27. Under what circumstances will the federal Drug Enforcement Administration (DEA) investigate and prosecute a doctor or pharmacist or refer cases to other agencies?

According to the DEA, the vast majority of DEA-registered practitioners are honest, ethical people who strive to satisfy their legal and regulatory responsibilities. The targets of DEA complaint investigations are the small number of practitioners who operate with criminal intent. For a physician to be convicted of illegal sale, the authorities must show that the physician knowingly and intentionally prescribed or dispensed controlled substances outside the scope of legitimate practice.

The DEA focuses its limited manpower and resources on the most flagrant violators. To understand the DEA's intent and practices, it is important to keep in mind that:

- State and local agencies, including licensing boards, police departments, Medicaid fraud units, etc., also conduct investigations related to controlled substance diversion, fraud, or improper medical practice.
- The DEA investigates only a small number of physicians[2] (for example, during fiscal year 2003, the DEA initiated a total of 732 investigations concerning doctors, 584 of which resulted in some form of sanction. In short, approximately 0.075% of all physicians registered with the DEA were the subject of some type of DEA investigation during the year.)
- A significant number of theses investigations were initiated because the physician in question was no longer licensed to practice medicine and was therefore no longer entitled to DEA registration. In 424 such cases, the physicians elected to surrender their DEA registrations. This represents 72.7% of the 584 "sanctions" imposed by the DEA.
- In 34 cases, physician's DEA registration was revoked.
- During fiscal year 2003, the DEA arrested 50 physicians whose activities were deemed to be knowingly and intentionally beyond the scope of medical practice, that is, criminal. This represents 0.005% of physician registrants.
- Most frequently, the DEA responds to complaints, allegations of diversion, or some other impropriety. Depending on the content, most of these are referred to state medical boards or local police.
- Joint investigations may occur when local police and state or federal agencies seek out the DEA for its expertise.
- The DEA does use administrative sanctions (for example, Letters of Admonition, Memoranda of Understanding) rather than criminal investigations when the complaint or allegation relates to such activities as faulty record keeping. In fact, of the 584 actions mentioned above taken during fiscal year 2003, 67 were of this nature.

Following receipt of information concerning a physician or pharmacist, an investigator would make inquiries to ascertain the validity of the allegation. Practitioners should be aware that a preliminary inquiry does not necessarily mean that wrongdoing has occurred. The nature of the inquiry varies based on the type of information received. For example, if the allegation pertains to a doctor prescribing controlled substances without conducting medical examinations, the investigator would be required to obtain information about the doctor's prescribing habits. In the absence of a prescription-monitoring program, investigators would be required to visit pharmacies to review prescription files. If the complaint pertained to a pharmacist, a review of the pharmacy's prescriptions and possibly an audit would be conducted.

An investigation that uncovers inappropriate activity may be resolved through a variety of administrative, civil, or criminal actions. Factors that are considered when law enforcement personnel are determining what action to take include the opinion of medical experts, the egregiousness of the violations, and whether the practitioner is thought to have engaged in the violation knowingly or intentionally. The legal system does not allow practitioners to consciously disregard indications that illegal drug-related activities might be occurring.

A DEA criminal investigation may involve a search warrant, but only if the DEA has sufficient evidence to convince a federal judge or magistrate that it is warranted. Although a search is not a charge and may not result in an arrest, it is a very serious matter, and normal police protocol involves control of the premises and safety of the participants.

Cases generally would be referred to other agencies if a practitioner's activities are found to be outside the course of professional practice, but not significant enough to warrant federal prosecution.

[2] The term physician includes dentists, osteopaths, podiatrists, veterinarians, medical doctors and a small number of mid-level practitioners. In May of 2004, there were 972,008 practitioners registered with the DEA. Medical doctors account for 71 percent of the total physicians registered with the DEA. Osteopaths account for another 4.6 percent. Dentists account for 13.3 percent. Veterinarians account for 5.1 percent.

### 28. *Should efforts to address diversion avoid interfering with medical practice and patient care?*

To avoid interfering with legitimate medical practice and patient care, there needs to be a balanced approach between physicians and regulators. The principle of balance, which should be fundamental to national and state drug control policy, asserts that efforts to prevent abuse of opioid analgesics, while necessary, should not interfere with medical practice and patient care. Health professionals should avoid contributing to diversion, and law enforcement and regulatory authorities should avoid interfering in pain management.

A 2003 comprehensive evaluation of all relevant federal and state policies according to the principle of balance can be found at http://www.medsch.wisc.edu/painpolicy/2003_balance.

Key law enforcement and regulatory organizations endorse the principle of balance. For example:

- In 1998, the Federation of State Medical Boards of the U.S. issued model guidelines that state regulatory boards can use to encourage better pain management, address physicians' concerns about regulatory scrutiny, and maintain compliance with existing legal requirements for prescribing (http://www.fsmb.org). These guidelines have been endorsed by the National Association of Boards of Pharmacy, the National Association of State Controlled Substances Authorities, and the U.S. Drug Enforcement Administration. The guidelines have since been revised as a model policy in 2004.
- In 2001, the DEA and many leading health care groups issued a joint statement, titled "Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act." It has been endorsed by 43 organizations and can be accessed at http://www.lastacts.org/briefingoct01/endorse.html.
- In its 2003 report, "Improving End-of-Life Care: The Role of Attorneys General," the National Association of Attorneys General stated its support for the concept of balance, recognizing the need for a positive regulatory environment for pain management and emphasizing that law enforcement efforts should not affect provision of patient care.

For law enforcement to stop diversion, it is necessary to accurately identify the sources of diversion. The sources are individuals who unlawfully divert prescription controlled substances to other than legitimate medical purposes. When an individual is suspected of robbing a pharmacy, there is little chance that apprehension and prosecution will interfere with medical practice and patient care; indeed, solving such crimes protects good medical care. When the suspect is a physician, pharmacist, or patient, the need for law enforcers to distinguish the medical use of opioid analgesics to manage pain from unlawful activities is critically important. This FAQ presents information that can be valuable to enforcement personnel in such situations. In some cases, consultation with a pain medicine specialist may be useful to law enforcement and regulatory officials (see answer to Question 29).

***Relevant Resources:***


Drug Enforcement Administration, Last Acts, Pain & Policy Studies Group et al. (2001). *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*. Washington, DC: Last Acts. (Available at http://www.medsch.wisc.edu/painpolicy/dea01.htm)

Federation of State Medical Boards of the United States Inc. (1998). *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. Euless, TX: Federation of State Medical Boards of the United States Inc. (Available at http://www.fsmb.org)

Federation of State Medical Boards of the United States Inc. (2004). *Model Policy for the Use of Controlled Substances for the Treatment of Pain*. Dallas, TX: Federation of State Medical Boards of the United States Inc. (Available at http://www.fsmb.org)

Joranson, D. E. (1993). Guiding principles of international and federal laws pertaining to medical use and diversion of controlled substances. In J. R. Cooper, D. J. Czechowicz, S. P. Molinari, and R. C. Petersen (eds.), *Impact of Prescription Drug Diversion Control Systems on Medical Practice and Patient Care: Monograph 131*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute on Drug Abuse, pp. 18—34. (Available at http://www.medsch.wisc.edu/painpolicy/publicat/93nida.htm)

National Association of Attorneys General. (2003). *Improving End-of-Life Care: The Role of Attorneys General*. Washington, DC: National Association of Attorneys General.

Pain & Policy Studies Group. (2003). *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation* (2nd ed.). Madison, WI: University of Wisconsin Comprehensive Cancer Center. (Available at http://www.medsch.wisc.edu/painpolicy/2003_balance)


### 29. *When should a law enforcement officer turn to a pain specialist for advice?*

The timing of a consultation with a pain specialist varies, according to the information needed by an investigator. The identified specialist should have current knowledge about pain management, including the use of opioids. In consulting with a pain specialist, an investigator may seek confirmation that prescriptions are being issued for legitimate medical purposes and that the care being provided is within the bounds of professional practice. There is great potential for misunderstanding at the interface of pain treatment, addiction, and the therapeutic use of controlled substances. Consequently, investigators are encouraged to consult a pain specialist or addiction medicine specialist whenever there are questions about using controlled substances to treat pain. The following questions are examples:

- How can you tell this patient has a chronic pain problem?
- Is there justification for the drugs that have been prescribed?
- Are the prescribed amounts appropriate?
- If a patient is displaying drug-seeking behaviors, is this a sign of undertreated pain, addiction, or involvement in diversion?

***Relevant Resources:***


Andrew, L. B. (2003). The ethical medical expert witness. *Federation Bulletin, Journal of Medical Licensure & Discipline* 89 (3): 125—131.


### 30. *Do the number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, or the duration of therapy with these drugs by themselves indicate abuse or diversion?*

The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves, indicate a problem, and they should not be used as the sole basis for an investigation by regulators or law enforcement. However, these factors, combined with others, may indicate that prescriptions are being issued or dispensed for other than legitimate medical purposes or not in the course of professional practice.

Characteristics of a practitioner or pharmacy that warrant further inquiry that could lead to an investigation include:

- A large proportion of prescriptions being paid for in cash.
- Large distances between the doctor, patients, and pharmacy, particularly if a sizable proportion of a doctor's prescriptions are being filled at a pharmacy not conveniently located to either the doctor or the patients.
- Drugs and doses being prescribed are not individualized.
- One physician writing multiple prescriptions for numerous patients that are filled consecutively in one pharmacy, indicating that either one person is presenting multiple prescriptions, or several people are filling similar prescriptions at the same time.
- A high frequency of prescriptions to replace lost prescriptions or medications.
- Frequent premature renewal or refilling of prescriptions.
- Frequent prescribing of unusual combinations of drugs, such as stimulants and depressants.

# APPENDIX A

***Abuse:*** A term used in the psychiatric ("Substance Abuse") nomenclature to describe a maladaptive pattern of substance use, not related to a therapeutic purpose, resulting in recurrent and significant adverse consequences. Repeated nontherapeutic use of a substance causes harm that can manifest in physical or social impairment but does not meet the criteria of compulsive use despite harm. In common parlance, "abuse" may also refer to the use of a substance, including a controlled prescription drug, that is outside of social norms (including the norm of adherence to prescribed drug treatments).

***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. Addiction is considered distinct from, though sometimes interrelated with, tolerance and physical dependence. Neither physical dependence nor tolerance to prescribed drugs is sufficient evidence of addiction. Unlike tolerance or physical dependence, addiction is not a predictable effect of drug exposure but represents an idiosyncratic adverse reaction in biologically and psychosocially vulnerable individuals, for which drug exposure is only one of the etiologic factors. Simple exposure to opioids does not produce addiction.

***Narcotic:*** A legal term that refers to all those substances covered by the Single Convention on Narcotic Drugs, 1961, and the 1972 Protocol amending that Convention, including opiates, opioids as well as cocaine and marijuana.

***Opiate:*** A substance that is produced from the poppy plant, such as codeine and morphine.

***Opioid:*** A scientific term that refers to both natural and synthetic drugs whose effects are mediated by specific receptors in the central and peripheral nervous systems, including codeine, morphine, oxycodone, and fentanyl.

***Physical Dependence:*** A state of adaptation that is manifested by a specific withdrawal syndrome that can be produced by abrupt cessation of dosing, rapid dose reduction, and/or administration of an antagonist. Most patients on long-term opioid therapy develop physical dependence, which is not predictive of addiction.

***Pseudoaddiction:*** A term used to describe an iatrogenic phenomenon in which a patient with undertreated pain is perceived by health care professionals to exhibit behaviors similar to those seen in addiction but is not true addiction. Patients may become focused on obtaining medications, may "clock watch," and may otherwise seem inappropriately "drug seeking." The term has been used to describe even such behaviors as illicit drug use and deception, if they appear to be primarily driven by the patient's efforts to obtain relief. It is believed that pseudoaddiction can be distinguished from true addiction because the behaviors resolve and do not recur when pain is effectively treated. Clinicians should be aware that abuse or addiction, and pseudoaddiction can co-exist, and a pattern of maladaptive drug-related behaviors could signal the presence of addiction, undertreated pain, or both.

***Tolerance:*** Tolerance is a state of adaptation in which exposure to a drug induces changes that result in a diminution of one or more of the drug's effects over time. Tolerance often occurs in the absence of addiction, as when drugs are used therapeutically over a period of time, and usually requires increased doses of the drug to produce the pharmacologic effects initially resulting from smaller doses.

* The definitions of addiction, physical dependence, and tolerance are from American Academy of Pain Medicine, American Pain Society, and American Society of Addiction Medicine (2001). Definitions relate to the use of opioids for the treatment of pain.

***Relevant Resources:***


American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine (2001). *Definitions Related to the Use of Opioids for the Treatment of Pain*. Glenview, IL: AAPM, APS, ASAM. (Available at http://www.ampainsoc.org/advocacy/opioids2.htm)

Savage, S. R., D. E. Joranson, E. C. Covington et al. (2003). Definitions related to the medical use of opioids: Evolution towards universal agreement. *Journal of Pain and Symptom Management* 26 (1): 655–667. (Available at http://www.medsch.wisc.edu/painpolicy/biblio.htm)

Weissman, D. E., and J. D. Haddox (1989). Opioid pseudo-addiction—an iatrogenic syndrome. Pain 36: 363–366.

Heit, H.A., (2003) Addiction, Physical Dependence, and Tolerance: Precise Definitions to Help Clinicians Evaluate and Treat the Patient with Chronic Pain. Journal of Pain and Palliative Care Pharmacotherapy.