

## CHAPTER 10

# RISK MANAGEMENT IN LONG-TERM OPIOID THERAPY

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Clinicians who prescribe opioid analgesics for the treatment of chronic pain have an obligation to implement therapy according to accepted principles of prescribing and to minimize the risk of misuse, abuse, addiction, and diversion through individualized application of risk assessment and management strategies. The necessity of a basic skill set in addiction medicine to prescribe opioid therapy safely has been highlighted in recent years by a documented increase in prescription drug abuse, the devastating consequences of endemic abuse of specific drugs (eg, oxycodone abuse in varied regions of the United States), and the strong call for “balance” by both pain specialists and those in the regulatory and law enforcement communities. Clinicians must understand the regulations and laws that govern the use of controlled prescription drugs and must be able to structure a prescription regimen that is consistent with the perceived risk of abuse or addiction and includes the monitoring necessary to identify problems if they occur.

### **Laws and regulations governing prescription drugs**

Uncertainty regarding regulatory issues and a fear of potential disciplinary action may give physicians pause when considering whether to prescribe long-term opioid therapy. Surveys have shown that physicians have a very real fear of disciplinary action for prescribing controlled substances, particularly if the patient has nonmalignant pain or a history of drug abuse. Even in patients with cancer pain or HIV-related pain, for which there is wide acceptance of opioid therapy, concerns about regulatory scrutiny are believed to be a significant cause of undertreatment.

The framework of laws and regulations governing the use of opioids and other controlled substances has 3 tiers: (1) international laws and treaties, (2) federal laws and regulations, and (3) state laws and regulations. National governments are obligated to ensure the availability of opioid medications for legitimate medical and scientific purposes. International treaties have been designed to achieve a balance between ensuring the availability of controlled substances for medical purposes and preventing illegal diversion.

The International Narcotics Control Board was established in 1968 as an independent and quasi-judicial body empowered to

implement the United Nations drug conventions. It attempts to ensure that adequate supplies are available for medical and scientific uses and that leakages from licit sources to illicit traffic do not occur. To accomplish this, the board administers an estimates system for opioids and monitors international trade in drugs. It also monitors government control over chemicals used in the illicit manufacture of drugs, and assists governments in preventing diversion of these chemicals into illicit traffic. Finally, the board also attempts to identify where weaknesses in the national and international control systems exist.

At the federal level, the FDA and the Drug Enforcement Agency (DEA) work together to regulate drugs and thereby prevent drug diversion and abuse. Before a pain medication can become available to patients, the FDA must assess its efficacy and safety, including its potential for abuse. If a product does not receive marketing approval (or an exemption) from the agency, it cannot be legally produced or prescribed.

The Controlled Substances Act empowers the DEA to classify drugs into different schedules based on the risk of abuse and diversion, medical use, and safety. Controlled substance schedules range from I to V. Schedule I drugs (eg, heroin, LSD, marijuana) have a high potential for abuse, a lack of accepted safety, and no current federally accepted medical use. Schedule II drugs (eg, morphine, fentanyl, hydromorphone, levorphanol, methadone, oxycodone, oxymorphone, methylphenidate, dextroamphetamine, dronabinol) have a high potential for abuse, produce severe psychologic or physical dependence liability, and have current accepted medical uses. Drugs classified into schedules III through V (eg, hydrocodone, codeine, diazepam) represent substances considered to have progressively less abuse potential and relatively reduced psychologic or physical dependence.

The DEA enforces the Controlled Substances Act and the laws regulating the manufacture, distribution, dispensing, and record-keeping requirements for controlled substances. It also sets production quotas for controlled drugs, which are intended to accommodate all legitimate medical and scientific uses of scheduled drugs.

Each state works with the federal government to oversee the movement of controlled prescription drugs and minimize abuse and diversion. Each also has sole responsibility for maintaining standards of healthcare practice through licensure of professionals. Law enforcement involvement occurs at the local and the state level through numerous agencies. Medical practice and licensure is governed through state medical boards, whose members are appointed by the governor.

Historically, the policies, laws, and regulations that govern the use of controlled prescription drugs in most states have been skewed toward enforcement and not patient care. The principle of balance found in international and federal law has not been central to the oversight efforts of the states. During the past 5 years, however, many states have attempted to redress the major concerns and explicitly recognize the need to protect clinical practice while reducing opioid abuse and diversion. In the area of medical practice, for example, the Federation of State Medical Boards, a national organization, has drafted model regulations for the medical use of controlled substances (“Model Guidelines for the Use of Controlled Substances for the Treatment of Pain”), which have now been adopted, at least in part, by almost half of the states.

Progress has been made in establishing a dialogue with members of the federal and state regulatory and law enforcement communities about the evolving role of opioid analgesics in pain management. However, physician concerns about investigation, and potential sanction, are not unfounded. The number and complexity of the agencies that can initiate an investigation after a complaint, the variation in laws and regulations from jurisdiction to jurisdiction, the lack of certainty that local investigators follow the intentions of senior management in any agency, and the potential to be duped by those who would divert drugs into the illicit market combine to create an irreducible level of prescriber risk associated with prescribing controlled drugs. Anecdotal reports of physicians who have been investigated (a costly and highly stressful process, even if the outcome is favorable), disciplined by their licensing boards, or prosecuted for alleged criminal activities further lead to a high level of concern and may produce a chilling effect that contributes to the undertreatment of pain.

To minimize risk, prescribers must follow laws and regulations when prescribing, prescribe in accordance with accepted medical practice, and document appropriately. A clinician who recognizes the necessity of risk assessment and management is best able to maintain the controls necessary to prescribe in a manner consistent with federal and state requirements.

### **Structuring therapy to reduce risk**

Just as opioid treatment must be individualized from the perspective of medication selection and dosing, treatment strategies must be individually fashioned to minimize the likelihood of misuse, abuse, addiction, and diversion and must create an appropriate level of monitoring for these potential adverse

outcomes. Although the science of prediction is still limited, the clinician must rely on the assessment to ascertain whether the patient should be categorized as having a relatively low risk of abuse or a high risk of abuse. Proactive strategies should be adopted at the start of therapy on the basis of perceived level of this risk (table 28).

During the course of treatment, all patients should be monitored for development of aberrant drug-related behaviors (see chapter 8, page 80). If problematic behavior is identified, reassessment usually is needed to clarify the meaning of the behavior and to generate one or more potential diagnoses (eg, addiction, pseudoaddiction, another psychiatric disorder associated with impulsive drug taking, family disturbances, criminal activity). Often, the meaning of the behavior is not clear when the behavior first occurs. If involvement with the patient continues, the diagnosis may become evident over time as the patient deals with new contingencies.

On the basis of the severity of the problematic behavior, patient history, and the findings of the reassessment, the clinician must decide about continuation of treatment and referral. Pain treatment may be continued with opioids (using a different structure for prescribing) or continued without opioids, or the patient may be discharged from the practice. The decision to again continue treatment with the opioid is based on the severity of the problematic behavior and the reassessment. Treatment should not be continued unless (1) favorable outcomes (ie, pain relief and maintained function) are manifest, (2) there is a high likelihood that control over the therapy can be reacquired, and (3) restructuring allows better monitoring of drug-related behavior. Discharge from the practice may be warranted if the possibility of therapeutic progress has been severely undermined by mistrust or the assessment reveals that the patient lacks interest in treatments other than the opioid agent.

When aberrant drug-related behavior occurs, the clinician must also decide about the need for referral. If a diagnosis of addiction is tenable, referral to a specialist in addiction medicine or an addiction program should be strongly considered. Addiction is a disease like any other, and it is no more appropriate to neglect referral for this disorder once it is suspected than it is to neglect referral for any other complex, potentially life-threatening disease. The clinician also might consider referral to a pain specialist or to a mental healthcare provider (other than an addiction specialist), depending on the needs identified.

If the decision is made to continue prescribing the opioid, strategies should be implemented to reduce the risk of further

**Table 28. Proactive and reactive strategies to minimize risk of abuse and enhance monitoring****Proactive strategies**

- Written agreement after detailed consent discussion
- Prescribe long-acting drug without “rescue” dose
- Frequent visits and small quantities prescribed
- Urine drug screen at baseline and expressed intention to request occasional screens in the future
- Requirement that only one pharmacy be used (with permission to contact)
- Instruction to bring pill bottle to appointment (for count)
- Instruction that there will be no early refills and no replacement of lost prescription without a police report documenting loss
- Requirement for nonopioid therapies, including psychotherapy
- Requirement for all prior records and permission to contact all other health-care providers prior to prescribing
- Required referral to addiction medicine specialist for all at-risk patients
- Requirement that others (eg, spouse) be allowed to give feedback to the physician
- In states with electronic prescription reporting/tracking, intention to query the database initially and on a regular basis

**Reactive strategies**

- Written agreement that addresses specific behaviors and outlines consequences going forward
- Discontinue rescue dose
- Frequent visits and small quantities prescribed
- Urine drug screen at baseline and expressed intention to request screens in the future
- Requirement that only one pharmacy be used (with permission to contact)
- Instruction to bring pill bottle to appointment (for count)
- Instruction that there will be no early refills and no replacement of lost prescription without a police report documenting loss
- Requirement for nonopioid therapies, including psychotherapy
- Requirement that all other healthcare providers be contacted
- Required referral to addiction medicine specialist, with follow-up treatment for aberrant behaviors
- Requirement that others (eg, spouse) be allowed to give feedback to the physician
- In states with electronic prescription reporting, intention to query the database on a regular basis going forward

problems and to monitor therapy. For patients who are vulnerable to abuse or addiction, a more rigid structure for therapy, such as frequent visits, small quantities prescribed, and use of urine drug screens (see table 28), may be helpful in maintaining control. This structure also provides the clinician with the reassurance necessary to continue to act in the patient's best interest. Patients who are taught that a new structure for prescribing is not punitive but instead is fundamentally therapeutic are more likely to accept the new restrictions without difficulty. Indeed, patients may express gratitude that the clinician is willing to continue a helpful therapy and assist them in maintaining control.

If therapy must be restructured, it is important that documentation be comprehensive and complete. The medical record should reflect the thoughtful reassessment, and the written plan should be explicit. It may be useful to provide the patient with a letter that clarifies the next steps, his or her obligations, and the consequences should problems recur.

### **The role of opioid agreements or contracts**

A formal written agreement between the patient and the physician at the start of opioid therapy also is becoming a common tool for defining expectations and documenting informed consent. These agreements are often called contracts, although they have no force of law.

Pain specialists differ in their views of this approach. On the positive side, these agreements outline the clinician's policy for providing controlled prescription drugs and describe the consequences of problematic drug-related behavior. They can reinforce that opioid medications must be used responsibly and also assure patients that medication will be prescribed as long as there is adherence to the plan of care. They can be used as educational tools.

On the negative side, these agreements can contribute to the stigmatization of opioid therapy and possibly reduce the likelihood of success. If they are framed in a manner that the patient perceives as threatening, they may contribute to assessment difficulties as the patient withholds or skews information in an effort to meet expectations. If the agreements make demands (such as no driving) that are inconsistent with the literature and would compromise function if accepted, they could undermine the goals of therapy or encourage the patient to lie. If they give a clinician a false sense of security and thereby reduce the vigilance, monitoring, and use of appropriate proactive and reactive strategies that are essential to risk management, they could paradoxically increase risk. Finally, if the agreements implicitly hold a clinician

to a certain level of clinical performance, they could ultimately be used adversely in a medicolegal dispute. Given these potential negatives—and the lack of consensus about the role of this approach—each clinician must decide whether the use of an agreement is appropriate and likely to be beneficial.

**Table 29. Statement groups found most often in opioid contracts**

<b>Statement category</b>	<b>Contracts (%)</b>
1. Avoid improper use of controlled substances (includes overdosing, seeking medication elsewhere, selling medication, stopping medication abruptly)	95
2. Terms of disciplinary termination (medication abuse, missed appointments, contract violation, inappropriate behavior)	92
3. Limitations for replacing medication or changing prescriptions	85
4. Inform physician of relevant information (ie, side effects, other medications, changes in condition)	74
5. Submit to random drug screens	69
6. Terms regarding appointments (missing appointment follow-up, appearing without appointment)	62
7. Include additional healthcare providers involved in care (eg, primary care physician, physical therapist, psychologist)	59
8. Limits on drug refills (phone allowances, only in person, call in advance, normal office hours)	56
9. Education about side effects (including withdrawal)	56
10. Terms of nondisciplinary termination (eg, no improvement, pregnancy, tolerance, toxicity)	51
11. Education on addiction risks and behavior	49
12. Education on opioids and chronic pain	49
13. Healthcare providers informed of prescription (eg, primary care physician, pharmacist)	46
14. Pharmacy issues included (use of only one pharmacy, use of in-state pharmacy)	44
15. Goals (outline goals)	38
16. Additional risks discussed (eg, other drug use, misuse, pregnancy)	38
17. Necessity of contract discussed (reasons why necessary, including federal guidelines and abuse)	36
18. Legal considerations discussed	33
19. Single prescriber for all opioid prescriptions	33
20. Dosing limitation (how much, interval between prescriptions, "rescue" dosing, as-needed use, dose escalation)	31

*Adapted, with permission, from Fishman SM, Bandman T, Edwards A, et al. The opioid contract in the management of chronic pain. J Pain Symptom Manage 1999;18:27-37.*

SAMPLE FOR ADAPTATION AND REPRODUCTION ON PHYSICIAN LETTERHEAD. PLEASE CONSULT WITH YOUR ATTORNEY.

## Long-term controlled substances therapy for chronic pain

### SAMPLE AGREEMENT

*A consent form from the American Academy of Pain Medicine (AAPM)*

The purpose of this agreement is to protect your access to controlled substances and to protect our ability to prescribe for you.

The long-term use of such substances as opioids (narcotic analgesics), benzodiazepine tranquilizers, and barbiturate sedatives is controversial because of uncertainty regarding the extent to which they provide long-term benefit. There is also the risk of an addictive disorder developing or of relapse occurring in a person with a prior addiction. The extent of this risk is not certain.

Because these drugs have potential for abuse or diversion, strict accountability is necessary when use is prolonged. For this reason the following policies are agreed to by you, the patient, as consideration for, and a condition of, the willingness of the physician whose signature appears below to consider the initial and/or continued prescription of controlled substances to treat your chronic pain.

1. All controlled substances must come from the physician whose signature appears below or, during his or her absence, by the covering physician, unless specific authorization is obtained for an exception. (Multiple sources can lead to untoward drug interactions or poor coordination of treatment.)
2. All controlled substances must be obtained at the same pharmacy, where possible. Should the need arise to change pharmacies, our office must be informed.

The pharmacy that you have selected is: \_\_\_\_\_ Phone: \_\_\_\_\_

3. You are expected to inform our office of any new medications or medical conditions and of any adverse effects you experience from any of the medications that you take.
4. The prescribing physician has permission to discuss all diagnostic and treatment details with dispensing pharmacists or other professionals who provide your healthcare, for purposes of maintaining accountability.
5. You may not share, sell, or otherwise permit others to have access to these medications.
6. These drugs should not be stopped abruptly, as an abstinence syndrome will likely develop.
7. Unannounced urine or serum toxicology screens may be requested, and your cooperation is required. Presence of unauthorized substances may prompt referral for assessment for addictive disorder.
8. Prescriptions and bottles of these medications may be sought by other individuals with chemical dependency and should be closely safeguarded. It is expected that you will take the highest possible degree of care with your medication and prescription. They should not be left where others might see or otherwise have access to them.
9. Original containers of medications should be brought in to each office visit.
10. Since the drugs may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, you must keep them out of reach of such people.
11. Medications may not be replaced if they are lost, get wet, are destroyed, left on an airplane, etc. If your medication has been stolen and you complete a police report regarding the theft, an exception may be made.
12. Early refills will generally not be given.
13. Prescriptions may be issued early if the physician or patient will be out of town when a refill is due. These prescriptions will contain instructions to the pharmacist that they not be filled prior to the appropriate date.
14. If the responsible legal authorities have questions concerning your treatment, as might occur, for example, if you were obtaining medications at several pharmacies, all confidentiality is waived and these authorities may be given full access to our records of controlled substances administration.
15. It is understood that failure to adhere to these policies may result in cessation of therapy with controlled substance prescribing by this physician or referral for further specialty assessment.

**Figure 1. Sample opioid agreement by the American Academy of Pain Medicine.**

16. Renewals are contingent on keeping scheduled appointments. Please do not phone for prescriptions after hours or on weekends.
17. It should be understood that any medical treatment is initially a trial and that continued prescription is contingent on evidence of benefit.
18. The risks and potential benefits of these therapies are explained elsewhere (and you acknowledge that you have received such explanation).
19. You affirm that you have full right and power to sign and be bound by this agreement and that you have read, understand, and accept all of its terms.

\_\_\_\_\_  
Physician signature

\_\_\_\_\_  
Patient signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient name (printed)

Approved by the AAPM Executive Committee on April 2, 2001.

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Use of opioid agreements may be informed by a recent survey that identified the most common elements used by 39 university-affiliated pain management centers (table 29). This work highlighted the necessity for careful consideration of prohibitions endorsed. For example, rather than prohibiting patients from driving while taking long-term opioid therapy, it may be prudent to prohibit driving during periods of initial opioid dosing or after dose escalations. Likewise, rather than prohibiting pregnancy during treatment, the agreement may outline the prescriber's concerns about pregnancy and require notification should pregnancy occur or be anticipated, so that counseling and appropriate perinatal referral can be provided. In an effort to further clarify the type of language that may be most appropriate for these agreements, the American Academy of Pain Medicine developed a model approach (figure 1).

**Suggested readings**

Fishman SM, Kreis PG. The opioid contract. *Clin J Pain* 2002;18:S70-5

Gilson AM, Joranson DE. US policies relevant to the prescribing of opioid analgesics for the treatment of pain in patients with addictive disease. *Clin J Pain* 2002;18:S91-8

Joranson DE, Gilson AM, Dahl JL, et al. Pain management, controlled substances, and state medical board policy: a decade of change. *J Pain Symptom Manage* 2002;23:138-47

Joranson DE, Carrow GM, Ryan KM, et al. Pain management and prescription monitoring. *J Pain Symptom Manage* 2002;23(3):231-8

Savage SR. Long-term opioid therapy: assessment of consequences and risk. *J Pain Symptom Manage* 1996;11:274-86