

Prescribing Issue

Opioid Agreements & Contracts

Opioid Agreements/Contracts: The American Academy of Pain Management's Take on the Subject

The American Academy of Pain Management's Board of Directors unanimously endorsed the Conjoint Statement of the American Pain Society and the American Academy of Pain Medicine concerning the use of long-term opioid therapy for patients suffering with chronic pain in September 1998. Rather than create another position statement, the Academy's Directors elected to support the 1997 Conjoint Statement of the other pain organizations. The Academy does not recommend opioid medications alone or in combination with other therapies for all patients under all circumstances, but advise practitioners with prescribing privileges to consider all potential therapies when working with patients suffering from painful disorders. Patients should have individualized plans for care that comprehensively address their physical, psychological, social and spiritual needs. To do less is to offer only fragmented care with little likelihood of addressing all of their treatment needs.

Practitioners must fully realize what an agreement/contract signifies when negotiating treatment options with patients for any medical services including, but not limited to, the prescribing of controlled substances. Agreements/contracts between practitioners and patients minimally define behavior between both parties of the agreement/contract. There are no "bullet-proof" agreements/contracts that are binding for all patients, under all circumstances, for all states and legal jurisdictions. Practitioners using agreements/contracts with their patients taking controlled substance medications should obtain legal advice specific for the jurisdiction where they practice before using these documents.

Minimally, agreements/contracts should define all aspects of care, not just the use of the controlled substances. Patients receiving opioid therapies must have clearly articulated treatment goals (pain will be reduced or performance of activities of daily living will be enhanced), defined measures for outcome (pain level will be "x"/10 or number of blocks walked each day will be "y", etc.), identified/defined "other services and treatments" beyond only controlled substances (PT, OT, home stretching program, use of biofeedback, hours of TENS wear per day, etc.), and clear rules with consequences for contractual violation (lost prescriptions, need for a police report if medications is stolen, requirements for urine drug testing, etc.). Since agreements/contracts tie all parties, these documents should be as comprehensively written as possible.



A recent article in *Anesthesiology News* (Volume 28, Number 6, June 2002) reviewed “Opioid Contracts for Chronic Pain Therapy: The Pros and Cons” and quoted Dr. Scott Fishman’s review of opioid contracts from 38 major academic pain centers. Dr. Fishman found that these facilities minimally used 12 general categories, 43 statement groups and 125 individual statements. The general statements included: terms of treatment, prohibited behaviors, points of termination, patient responsibilities, issues about education, addiction treatments, emergency issues, goals, prescription limitations, legal considerations, discouraged behavior and responsibilities of staff. Contracts ran from one to ten pages in length. The full article appeared in *J Pain Symptom Management* 1999;18:6-8.

The Use of Opioids for the Treatment of Chronic Pain:

A consensus statement from American Academy of Pain Medicine and American Pain Society

I. The management of pain is becoming a higher priority in the United States. In the last several years, health-policymakers, health professionals, regulators, and the public have become increasingly interested in the provision of better pain therapies. This is evidenced, in part, by the U.S. Department of Health and Human Services' dissemination of Clinical Practice Guidelines for the management of acute pain and cancer pain.

These publications, which have been endorsed by AAPM and APS, state that opioids, sometimes called "narcotic analgesics," are an essential part of a pain management plan. There is currently no nationally accepted consensus for the treatment of chronic pain not due to cancer, yet the economic and social costs of chronic pain are substantial, with estimates ranging in the tens of billions of dollars annually.

II. Current conditions dictate the need for a joint consensus statement of two major national pain organizations. AAPM and APS believe that the United States is in a critical phase of state-level policy development with respect to the use of opioids in pain treatment. In this regard, there has been recent activity in state legislatures (i.e., intractable pain treatment acts and the establishment of pain commissions) and at the regulatory level (statements of policy from state boards of medical examiners). In response to inquiries from concerned boards, AAPM and APS wish to encourage a dialogue with regulators about the appropriate relation between law and the practice of pain medicine. The purpose of laws that govern controlled substances and professional conduct is to protect the public. Our objective is for state policies to recognize but not interfere with the medical use of opioids for pain relief, while continuing to address the issue of prescribing that may contribute to drug abuse and diversion.

It is imperative that this statement not be misconstrued as advocating the imprudent use of opioids. Rather, if a practitioner decides to treat chronic pain with opioids, this document should serve as a guide for both the practitioner and regulators with regard to the judicious use of these drugs in the course of medical practice.

III. Pain is often managed inadequately, despite the ready availability of safe and effective treatments. Many strategies and options exist to treat chronic noncancer pain. Since chronic pain is not a single entity but may have myriad causes and perpetuating factors, these strategies and options vary from behavioral methods and rehabilitation approaches to the use of a number of different medications, including opioids.



Pain is one of the most common reasons people consult a physician, yet it frequently is inadequately treated, leading to enormous social cost in the form of lost productivity, needless suffering, and excessive healthcare expenditures.

Impediments to the use of opioids include concerns about addiction, respiratory depression and other side effects, tolerance, diversion, and fear of regulatory action.

IV. Current information and experience suggest that many commonly held assumptions need modification.

Addiction: Misunderstanding of addiction and mislabeling of patients as addicts result in unnecessary withholding of opioid medications. Addiction is a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, the continued use of which results in a decreased quality of life. Studies indicate that the de novo development of addiction when opioids are used for the relief of pain is low. Furthermore, experience has shown that known addicts can benefit from the carefully supervised, judicious use of opioids for the treatment of pain due to cancer, surgery, or recurrent painful illnesses such as sickle cell disease.

Respiratory depression and other side effects: Fear of inducing respiratory depression is often cited as a factor that limits the use of opioids in pain management. It is now accepted by practitioners of the specialty of pain medicine that respiratory depression induced by opioids tends to be a short-lived phenomenon, generally occurs only in the opioid-naïve patient, and is antagonized by pain. Therefore, withholding the appropriate use of opioids from a patient who is experiencing pain on the basis of respiratory concerns is unwarranted. Other side effects, such as constipation, can usually be managed by attention to diet, along with the regular use of stool softeners and laxatives. Sedation and nausea, possible early side effects, usually dissipate with continued use.

Tolerance: It was previously thought that the development of analgesic tolerance limited the ability to use opioids efficaciously on a long-term basis for pain management. Tolerance, or decreasing pain relief with the same dosage over time, has not proven to be a prevalent limitation to long-term opioid use. Experience with treating cancer pain has shown that what initially appears to be tolerance is usually progression of the disease. Furthermore, for most opioids, there does not appear to be an arbitrary upper dosage limit, as was previously thought.

Diversion: Diversion of controlled substances should be a concern of every health professional, but efforts to stop diversion should not interfere with prescribing opioids for pain management. Attention to patterns of prescription requests and the prescribing of opioids as part of an ongoing relationship between a patient and a healthcare provider can decrease the risk of diversion.

V. Policy is evolving. State law and policy about opioid use are currently undergoing revision. The trend is to adopt laws or guidelines that specifically recognize the use of opioids to treat intractable pain. These statements serve as indicators of increased public awareness of the sequelae of undertreated pain and help clarify that the use of opioids for the relief of chronic pain is a legitimate medical practice.



VI. Accepted principles of practice for the use of opioids should be promulgated. Due to concerns about regulatory scrutiny, physicians need guidance as to what principles should generally be followed when prescribing opioids for chronic or recurrent pain states. Regulators have also expressed a need for guidelines to help them to distinguish legitimate medical practice from questionable practice and to allow them to appropriately concentrate investigative, educational, and disciplinary efforts, while not interfering with legitimate medical care.

VII. Principles of good medical practice should guide the prescribing of opioids. AAPM and APS believe that guidelines for prescribing opioids should be an extension of the basic principles of good professional practice.

Evaluation of the patient: Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.

Treatment plan: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of noninvasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. If a trial of opioids is selected, the physician should ensure that the patient or the patient's guardian is informed of the risks and benefits of opioid use and the conditions under which opioids will be prescribed. Some practitioners find a written agreement specifying these conditions to be useful.

An opioid trial should not be done in the absence of a complete assessment of the pain complaint.

Consultation as needed: Consultation with a specialist in pain medicine or with a psychologist may be warranted, depending on the expertise of the practitioner and the complexity of the presenting problem. The management of pain in patients with a history of addiction or a comorbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids.

Periodic review of treatment efficacy: Review of treatment efficacy should occur periodically to assess the functional status of the patient, continued analgesia, opioid side effects, quality of life, and indications of medication misuse. Periodic reexamination is warranted to assess the nature of the pain complaint and to ensure that opioid therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life as a result of opioid use.

Documentation: Documentation is essential for supporting the evaluation, the reason for opioid prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient.



VIII. The Mission Statements of AAPM and APS are consistent with this collaborative effort. The American Academy of Pain Medicine is the AMA-recognized specialty society of physicians who practice pain medicine. The American Pain Society is the national chapter of the International Association for the Study of Pain and is composed of physicians, nurses, psychologists, scientists, and members of other disciplines who have an interest in the study and treatment of pain.

The mission of the American Academy of Pain Medicine is to enhance pain medicine practice in this country by promoting a socioeconomic and political climate conducive to the effective and efficient practice of pain medicine and by ensuring quality medical care by physicians specializing in pain medicine, for patients in need of such services.

The mission of the American Pain Society is to serve people in pain by advancing research, education, treatment, and professional practice. The undertreatment of pain in today's society is not justified. This joint consensus statement has been produced pursuant to the missions of both organizations, to help foster a practice environment in which opioids may be used appropriately to reduce needless suffering from pain.

The statement was prepared by the following committee members: J. David Haddox, DDS MD (Chair); David Joranson, MSSW (Vice Chairman); Robert T. Angarola, Esq.; Albert Brady, MD; Daniel B. Carr, MD; E. Richard Blonsky, MD; Kim Burchiel, MD; Melvin Gitlin, MD; Matthew Midcap, MD; Richard Payne, MD; Dana Simon, MD; Sridhar Vasudevan, MD; Peter Wilson, MBBS, PhD. Consultant: Russell K. Portnenoy, MD.

Approved by the AAPM Board of Directors on June 29, 1996
Approved by the APS Executive Committee on August 20, 1996



An Example of the implementation of the AAPM/APS statement by AZ:

Arizona's Medical Board Guidelines for Patient Care when prescribing controlled substances for chronic pain

A) Pain Assessment

Pain assessment should occur during initial evaluation, after each new report of pain, at appropriate intervals after each pharmacological intervention, and at regular intervals during treatment. Unless a patient is terminally ill and death is imminent (in which case the diagnosis is usually evident and diagnostic evaluations may be of little value and discomfoting to the patient), the evaluation should include:

1. Medical history, including the presence of a recognized medical indication for the use of a controlled substances, the intensity and character of pain, and questions regarding substance abuse;
2. Psycho-social assessment, which may include but is not limited to:
 - a. The patient's understanding of the medical diagnosis, expectations about pain relief and pain management methods, concerns regarding the use of controlled substances, and coping mechanisms for pain;
 - b. Changes in mood which have occurred secondary to pain (i.e., anxiety, depression); and
 - c. The meaning of pain to the patient and his/her family.
3. Physical examination, including a neurologic evaluation and examination of the site of pain.

B) Treatment Plan

A treatment plan should be developed for the management of chronic pain and state objectives by which therapeutic success can be evaluated, including:

1. Pain relief;
2. Improved physical functioning;
3. Proposed diagnostic evaluations (i.e., blood tests, radiologic, psychological and social studies such as CAT and bone scans, MRI and neurophysiologic examinations such as electromyography); and
4. Analysis of inclusion and exclusion criteria for opioid management: Inclusion criteria include: a clear diagnosis has been made, consistent with symptoms; the exploration of all reasonable alternative therapies have been explored; the patient is reliable and communicates well; and there has been informed consent or a treatment agreement signed. Potential exclusion criteria include a history of chemical dependency, major psychiatric disorder, chaotic social situation, or a planned pregnancy.



C) Informed Consent

The physician should advise the patient, guardian, or designated surrogate of the risks and benefits of the use of controlled substances. The patient should be counseled on the importance of regular visits, the impact of recreational drug use, the number of physicians and pharmacies used for prescriptions, taking medications as prescribed, etc.

D) Ongoing Assessment

The assessment and treatment of chronic pain mandates continuing evaluation, and if necessary, modification and/or discontinuation of opioid therapy. If clinical improvement does not occur, the physician should consider the appropriateness of continued opioid therapy, and consider a trial of alternative pharmacologic and nonpharmacologic modalities.

E) Consultation

The physician should refer patients as necessary for additional evaluation to achieve treatment objectives. Physicians should recognize patients requiring individual attention, in particular, patients whose living situations pose a risk for misuse or diversion of controlled substances. In addition, the prescription of controlled substances to patients with a history of substance abuse requires extra care, monitoring, and documentation, and may also require consultation with an addiction medicine specialist. The physician may also consider the use of physician-patient agreements or contracts that specify the rules for medication use and the consequences of misuse or abuse.

F) Documentation

The physician must maintain adequate, accurate and timely records regarding items A-E from above. "Adequate Records," pursuant to A.R.S. §32-1401(2), "means legible records containing, at a minimum, sufficient information to identify the patient, support the diagnosis, justify the treatment, adequately document the results, indicate advice and cautionary warnings provided to the patient, and provide sufficient information for another practitioner to assume continuity of the patient's care at any point in the treatment." Specific to chronic pain patients, the documentation should include:

1. The medical history and physical examination;
2. Related evaluations and consultations, treatment plan and objectives;
3. Evidence of discussion regarding informed consent;
4. Prescribed medications and treatments;
5. Periodic reviews of treatments and patient response; and
6. Any physician-patient agreements or contracts.



AZ Compliance with Laws and Regulations

To prescribe controlled substances, physicians must comply with all applicable laws, including the following:

1. Possess a valid current license to practice medicine in the State of Arizona;
2. Possess a valid and current controlled substances Drug Enforcement Administration registration for the schedules being prescribed.



SAMPLE MODEL PAIN MANAGEMENT AGREEMENT

The purpose of this Agreement is to prevent misunderstandings about certain medicines you will be taking for pain management. This is to help both you and your doctor to comply with the law regarding controlled pharmaceuticals.

I understand that this Agreement is essential to the trust and confidence necessary in a doctor/patient relationship and that my doctor undertakes to treat me based on this Agreement.

I understand that if I break this Agreement, my doctor will stop prescribing these pain-control medicines.

In this case, my doctor will taper off the medicine over a period of several days, as necessary, to avoid withdrawal symptoms. Also, a drug-dependence treatment program may be recommended.

I will communicate fully with my doctor about the character and intensity of my pain, the effect of the pain on my daily life, and how well the medicine is helping to relieve the pain.

I will not use any illegal controlled substances, including marijuana, cocaine, etc.

I will not share, sell or trade my medication with anyone.

I will not attempt to obtain any controlled medicines, including opioid pain medicines, controlled stimulants, or antianxiety medicines from any other doctor.

I will safeguard my pain medicine from loss or theft. Lost or stolen medicines will not be replaced.

I agree that refills of my prescriptions for pain medicine will be made only at the time of an office visit or during regular office hours. No refills will be available during evenings or on weekends.

I agree to use _____ Pharmacy,
located at _____,
telephone number _____, for filling prescriptions for all
of my pain medicine.

I authorize the doctor and my pharmacy to cooperate fully with any city, state or federal law enforcement agency, including this state's Board of Pharmacy, in the investigation of any possible misuse, sale, or other diversion of my pain medicine. I authorize my doctor to provide a copy of this Agreement to my pharmacy. I agree to waive any applicable privilege or right of privacy or confidentiality with respect to these authorizations.

I agree that I will submit to a blood or urine test if requested by my doctor to determine my compliance with my program of pain control medicine.



I agree that I will use my medicine at a rate no greater than the prescribed rate and that use of my medicine at a greater rate will result in my being without medication for a period of time.

I will bring all unused pain medicine to every office visit.

I agree to follow these guidelines that have been fully explained to me. All of my questions and concerns regarding treatment have been adequately answered. A copy of this document has been given to me.

This Agreement is entered into on this _____ day of

_____, _____.

Patient signature: _____

Physician signature: _____

Witnessed by: _____

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Please note that this document is provided as a resource for AAPM members and other practitioners requesting information about opioid prescribing in the USA. It has not been prepared by, recommended by or endorsed by the American Academy of Pain Management. This document is not intended to be a definitive legal opinion and no guarantees, warranties or other assurances are implied. Practitioners must always prescribe controlled substance prescriptions within the usual course of their practices, and must follow all applicable federal and state laws.



Prescribing Opioids Wisely

Strategies for helping your patients and avoiding problems with regulators

By B. Eliot Cole, MD

- **Perform thorough physical exams and obtain complete histories of your patients to determine what causes the pain. Screen your patients for substance abuse.**
- **Chart everything. Every entry should be so detailed that it could stand alone if separated from the rest of the chart. Explain how you intend to follow them over time, what alternatives have been considered, and why you believe opioid analgesics will be helpful.**
- **Obtain informed consent so that there is no doubt about the treatment proposed. Your patients must agree that only you will prescribe controlled substances for their pain and that they will not go to the emergency room for pain medication without your permission.**
- **Get your patients to agree to use only one pharmacy and explain to the pharmacist why you intend to prescribe long-term opioids. Does the pharmacist have any concerns about your patients receiving opioids? Make certain that the pharmacy stocks the medications you expect to prescribe.**
- **Get a second opinion from a pain management specialist, a specialist in the organ system that is the source of pain, or a specialist in the overall disease process. Share the responsibility for prescribing opioid analgesics with another physician.**
- **Prescribe long-acting opioid analgesics to be taken on a regular schedule to achieve stable levels. Avoid “as needed” medications and use immediate-release medications only to cover periods of breakthrough pain.**
- **See your patients regularly. Document why your patients continue to need opioid medications. Avoid telephone prescriptions and do not give open-ended prescriptions with refills.**
- **Determine the minimum dose patients need to maintain daily activities by occasionally decreasing daily dosage by 25% to 35%. Discuss this strategy with your patient before decreasing the dose.**
- **Rule out drug diversion by documenting that you are able to recover the prescribed medication with a urine drug screen. Urine screens also show that you are alert to the patient’s potential use of illicit substances.**
- **Continue to receive opioid analgesic education by attending meetings and conferences such as the Annual Clinical Meeting of the American Academy of Pain Management.**

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