A Protocol-Contract for Opioid Use in Patients with Chronic Pain Not Due to Malignancy

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The legal, psychosocial, and medical factors that we believe have contributed to the success of our protocol-contract in prescribing opioids to patients with chronic pain not due to malignancy are outlined. These factors may be applicable to the treatment of a variety of chronic nonmalignant pain syndromes such as postherpetic neuralgia or human immunodeficiency virus/acquired immunodeficiency syndrome. The intended target audience of this paper is the physician (primary care, chronic pain specialist) who is involved in prescribing opioids for the treatment of chronic, nonmalignant pain. © 1998 by Elsevier Science Inc.

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Introduction

Chronic nonmalignant disease states can cause extreme pain. In many instances, clinicians treating reflex sympathetic dystrophy (RSD) use opioid analgesics to help their patients deal with this pain. However, the prescribing of such analgesics can result in intense scrutiny by regulatory agencies, including the licensing board of the physician involved in the treatment of such patients. Medically, the treatment of patients with opioid analgesics may result in the development of side effects, addiction, and on discontinuation, physical withdrawal symptoms. In addition, patients with chronic pain commonly develop significant psychiatric problems, which may result in a misapprehension of the clinician’s intentions in prescribing opioid analgesics and the filing of a complaint with a regulatory agency. Physicians specializing in chronic pain management are accustomed to patients accusing other physicians of getting them “hooked” on opioids.

In a previous report,* we evaluated the effectiveness of a protocol-contract in

prescribing opioids to 20 consecutive patients with advanced RSD. The protocol-contract defined the appropriate expectations and hazards of chronic oral opioid use (e.g., side effects, physical withdrawal, and addiction). For example, RSD is not well understood, even by many medical practitioners. In some cases, the diagnosis and treatment of RSD depends entirely on the symptoms reported by the patient, without objective findings or test results to verify the diagnosis. Many experts believe that if RSD is diagnosed early and treated, it is curable. If undiagnosed and allowed to progress, RSD can lead to permanent deformities and immobility of limbs, and can spread to large segments of the body. As a result of this paucity of objective findings, physicians prescribing opioid analgesics to patients with RSD may come under intense scrutiny by other providers and regulatory agencies.

In this article, we present an overview of the regulatory provisions common in the United States, and we provide clinicians who prescribe chronic opioid analgesics with risk management guidelines so that they may minimize the possibility of an interaction with the regulatory agency, including disciplinary action. The risk management techniques described also can assist in the defense of a civil medical malpractice case. In most jurisdictions, a regulatory agency need not establish all of the elements of a civil medical malpractice claim to prosecute a physician. Traditionally, a physician may only be sued for medical malpractice if the patient can establish the four elements of the cause of action for negligence. These elements include duty, breach of duty, injury, and causation. In most jurisdictions, a disciplinary action can be undertaken without establishing that the patient has been injured or that any injury suffered by the patient was caused by an act or omission of the physician. The regulatory agency merely has to establish duty and breach of duty. All physicians who undertake the care of patients have a duty to treat those patients with that level of care, skill, and competency that is recognized by a reasonably prudent physician under similar conditions and circumstances. If the physician has failed to meet that duty, a breach has occurred. Therefore, a physician can be prosecuted in most jurisdictions by the regulatory agency, without a patient ever having been harmed.

**Legal Factors**

Regulatory provisions for the prescription and use of opioid analgesics vary widely within the United States. All states have some provision that allows investigation and disciplinary action against physicians who have deviated from acceptable standards of care or have committed medical malpractice. In addition, many states have specific disciplinary sections that may relate to the prescribing of controlled substances, including opioid analgesics. These provisions may include specific sections that allow a physician to be disciplined for prescribing inappropriately or in excessive quantities; provisions also may allow discipline for failure to maintain medical records that justify the course of treatment of the patient. In addition, many states have provisions that incorporate federal or state controlled substance acts by reference.

Florida has a rather sophisticated disciplinary mechanism, which includes numerous available causes of action, or charges, which can be used to initiate a disciplinary action against the license of a physician. The regulatory scheme in Florida is presented as an example to describe the types of provisions that may be used by regulatory agencies in various states.

**State of Florida Regulation**

The practice of medicine in Florida is governed by Chapter 458, Florida Statutes, Medical Practice Act. The grounds for disciplinary action when the treatment involves alleged excessive prescribing of opioids are enumerated in Section §458.331(1), Florida Statutes. They include:

1. failing to perform any statutory or legal obligation placed upon a licensed physician
2. failing to keep written medical records justifying the course of treatment of the patient, including, but not limited to, patient histories, examination results, test results, records of drugs prescribed, dispensed, or administered, and reports of consultations and hospitalizations
3. prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician’s professional practice. For purposes of this paragraph, it shall be legally presumed that the prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive inappropriate quantities, is not in the best interest of the patient and is not in the course of the physician’s professional practice, without regard to his intent (emphasis supplied).
4. gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment that is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances

In Florida, the provisions of paragraph §458.331(1)(g), Florida Statutes, are commonly used by the regulatory agency to incorporate by reference provisions of the Florida and federal controlled substance acts that may apply to the prescribing issue. Specifically, Section §893.05, Florida Statutes, provides, in pertinent part that “A practitioner, in good faith and in the course of his professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance.”

In most instances, when a physician is investigated by the regulatory agency in Florida, the investigation will evaluate all of the potential charges referenced above. The investigation is commonly focused on whether the quantities of drugs are indeed excessive, and it also includes inquiries as to whether the standard of care for a similar physician has been violated, and whether the medical
records justify the course of treatment of the patient. Therefore, even if it is eventually determined that the patient was in extreme pain, and the treatment rendered was appropriate, the physician may be subject to disciplinary action for failing to keep appropriate records.

Many regulatory investigations involve long-term prescribing of opioid analgesics to patients with nonterminal illnesses. Thus, physicians involved in the treatment of chronic pain are susceptible to investigation and potential prosecution. The best defense to such inquiries is careful documentation during the treatment of the patient. Given the time required to carry out such extensive documentation in a busy medical practice, the value of a preprinted protocol-contract cannot be overstated.

Investigations of physicians typically include interviews and the obtaining of the medical records of the treatment of the patient, not only from the subject’s physician but also from other treating physicians. It is essential that physicians who prescribe large quantities of opioid analgesics keep meticulous medical records to justify the patient’s course of treatment. These records should clearly specify the medications prescribed. Medical records should be routinely reviewed to identify those patients who are potentially overusing medications, so that appropriate steps can be taken to control this behavior, including the referral of such patients to appropriately qualified physicians for treatment. The regulatory agency may assert that a physician should attempt a trial of other pain management modalities such as a transcutaneous electrical nerve stimulation (TENS) unit, biofeedback techniques, and psychiatric or psychological consultations. If alternative modalities of pain management are used, records should be kept, including an evaluation of the efficacy of the same. If alternative pain management modalities are not used, a notation should be made specifying the reason that the modality was not employed or was discontinued.

Because regulatory cases, as well as cases involving allegations of civil medical malpractice, may be based primarily on the evaluation of the health care practitioner’s medical records, meticulous record keeping can minimize the exposure of physicians involved in the prescribing of opioid analgesics. A review of the elements of good medical records can be helpful.

The diagnosis should be clearly noted. There should be a record of the patient’s history, physical findings, and relevant test results sufficient to justify the diagnosis. Records of drugs prescribed to the patient should be kept in a meticulous fashion. Such records should include the drug prescribed, dosage unit, quantity, and number of refills authorized.

If drugs are administered or dispensed by the physician or the physician’s staff, documentation should be kept on the patient’s chart. This documentation should include the drug, dosage unit, and quantity of medication administered or dispensed. The Drug Enforcement Administration (DEA) requires that records of all controlled substances administered or dispensed through a physician’s office be maintained in a readily retrievable manner for inspection. Many states, including Florida, also require that separate records of the administration or dispensing of controlled substances by physicians be maintained in a readily retrievable manner for inspection. Some states do not consider information in a patient’s medical record to be “readily retrievable” because of confidentiality provisions applicable to medical records. Therefore, these regulations may require the maintenance of a log or perpetual inventory of controlled substances dispensed or administered by the physician or the physician’s staff.

The use of appropriate consultations also can minimize the possibility of a disciplinary action, as well as a potential civil action. If the patient is referred to an independent physician for consultation, a record should be kept in the patient’s chart of the ordering of such a consultation, and the result thereof, even if a consultation report is provided. The recording of the order for a consultation, and the results of same, within the patient’s chart enables a reviewer to follow the flow of the physician’s treatment plan much more effectively, and it may minimize the risk of a regulatory action against the physician. Providing the patient with a copy of the consult request and documenting this action in the medical record can facilitate the process and provide additional legal protection. Practitioners face another challenge in modern medical practice as it relates to obtaining desired tests and consultations. Managed care plans may be reluctant to authorize indicated tests and consultations. When a patient’s managed care plan declines to authorize an indicated test or consultation, the physician should become the patient’s advocate with the insurance company and attempt to provide information sufficient to convince the company of the need for additional service. If the service will not be authorized, the physician must document the justification for the recommended service in the chart and advise the patient as to why the service has been recommended. The patient may have legal remedies available. Similarly, if the patient is hospitalized for treatment, a note should be made in the patient’s chart relating the hospitalization, including the date, purpose, summary of the evaluations or procedures done, and the results of same. This note will also allow a reviewer to follow the development of the patient’s treatment plan, and usually will result in a request of hospital records by the reviewer so as to fully evaluate the care provided in a fair manner.

Physicians should avoid authorizing large quantities of medication, or multiple refills, when the efficacy of the medication has not been established in the patient or if a change in medication is anticipated. Some patients will continue to have previously authorized prescriptions filled even after the physician has changed the patient’s medication. The physician may then use multiple medications without the physician’s knowledge. If a physician suspects a patient is continuing to use medications that have been discontinued, the physician should appropriately instruct the patient as to the risks inherent in such activity, attempt to cancel any previously authorized refills of discontinued medications, and appropriately document these efforts. Physicians have been subject to regulatory actions that concern prescriptions to patients who have suffered overdoses as a result of the concomitant use of drugs, some of
which had previously been discontinued by the physician. The regulatory agency may assert that the physician should not have authorized multiple refills of the medications, or should have taken affirmative steps to assure the refills were canceled when the patient’s medication was changed. One way to minimize this problem is to alert the patient of this potential hazard in the protocol-contract.

Physicians also should be aware of the requirements of informed consent in the jurisdictions in which they practice. In most jurisdictions, informed consent must be obtained from the patient when a “procedure” is performed. Informed consent generally requires that the physician discuss with the patient the intended procedure, so that the patient has a general understanding of it. In addition, the physician should advise the patient of the medically acceptable alternative procedures or treatments and the substantial risks and hazards inherent in the proposed treatment or procedures. Jurisdictions vary as to whether the consent must be evidenced in writing. Although the prescribing of analgesics is not generally considered a “procedure,” it is appropriate for a notation to be made in the chart documenting the discussion with the patient, regardless of whether a separate consent document is executed. Therefore, it is prudent for physicians to document the discussions they have with patients concerning the use of opioid analgesics and the risks inherent in the use of these substances.

The protocol-contract is a convenient and efficient method to document informed consent. The contract serves to further the goals of an informed consent discussion, and it can be effective in responding to formal or official investigations. The protocol-contract also can assist the physician in gaining the cooperation of difficult patients in adhering to proposed treatment plans. It can also be disseminated to other physicians participating in the care of the patient to assure proper coordination of efforts.

**Sources of Information**

Regulatory agencies have many sources of information that are used to develop cases against physicians. In most jurisdictions, the access of agencies to otherwise confidential patient information is increasing. Many states receive reports of peer review actions taken against physicians by hospitals or managed care organizations. In addition, colleagues and pharmacists may report suspicions of excessive prescribing to regulatory agencies. In many jurisdictions, the regulatory agency has the authority to conduct surveys of prescription information at pharmacies. Because almost all pharmacies are now computerized, it is very easy for the regulatory investigator to access compilations of the drugs prescribed to individual patients. In addition, computer records expedite the surveying of pharmacy records to identify physicians who are “heavy prescribers.” Most jurisdictions also give the regulatory agency the authority to inspect the records of physicians who dispense or administer medications in their offices. The agency also may have access to records from wholesale drug distributors and may survey these records to locate physicians who order large quantities of opioid analgesics. Finally, in many jurisdictions, reports of civil, medical malpractice claims are sent to the regulatory agency and may serve as the genesis of an investigation.

**New Legislation on Chronic Pain**

One positive development has been the enactment of legislation, in several states, that provides physicians with some protection from prosecution when prescribing controlled substances to patients who suffer from a diagnosed condition causing “intractable pain.” In 1990, California enacted the Intractable Pain Treatment Act, which is found in Section §2241.5 of the California Business & Professions Code. This statute provides, in pertinent part, that:

- a. Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician’s and surgeon’s treatment of that person for a diagnosed condition causing intractable pain.
- b. “Intractable pain,” as used in this section, means a pain state in which (1) the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or (2) none has been found after reasonable efforts by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.
- c. No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

This statutory provision does require that the prescription or administration of the controlled substance be for a therapeutic purpose, and that complete and accurate records of the purchase and disposition of controlled substances be maintained by the physician.

Florida has enacted a similar provision, Section §458.326, Florida Statutes, which provides, in pertinent part, that:

1. For the purpose of this section, the term “intractable pain” means pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.
2. Intractable pain must be diagnosed by a physician licensed under this chapter and qualified by experience to render such diagnosis.
3. Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II–V, as provided for in §893.03, to a person for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably
prudent physician under similar conditions and circumstances.

These provisions, as well as similar provisions in other states, provide the physician some protection when treating patients suffering from chronic pain. However, as can be seen by the language of the statutory provisions, a physician still must be able to establish that the treatment was within the acceptable standard of care. Again, medical records specifying the reasons for the selection of certain treatment modalities and consultation with another provider (where appropriate) are essential to establish that the standard of care has been met.

Psychosocial Factors

In behavioral psychotherapy, a widely accepted method of improving adherence to treatment regimens is contingency contracting. A contingency contract is a detailed, personalized written document signed by both patient and doctor. It spells out expected behaviors, as well as rewards and/or consequences contingent on the behavior(s). The contribution of contingency contracting to improved adherence in nondrug abusing chronic pain populations has not been subjected to controlled studies. Such contracting has become an accepted technique for clinical management in methadone programs.2 Dolan et al.3 have even demonstrated some success using the technique with subjects previously considered to be treatment failures in a methadone program.

Even in patients with chronic pain who are not known or suspected to be substance abusers, nonadherence to medication regimens can be a significant problem. Research on adherence indicates that patients do not adhere to their physician’s recommendations roughly 50% of the time.4 The distraction of chronic pain and the impaired concentration often accompanying anxiety in chronic pain patients can negatively affect the patient’s comprehension of verbally explained treatment regimens. Furthermore, these same cognitive variables can significantly interfere with retention of verbal instructions even when initially understood. A detailed written contract, copies of which are signed and retained by the physician, the patient, and the psychologist or psychiatrist who will monitor the patient during the treatment regimen, provides a standard reference to which all can refer in the case of forgetfulness, confusion, or misunderstanding. Such a contract also significantly limits the amount of manipulation that can be used by patients to alter or escape the terms of the initial agreement. The solemnity with which it is signed by all parties is a clear indicator that adherence is regarded as highly important by the treating physicians and sends a message to the patient that nonadherence will not be taken lightly. Regular pill counts and examination of the patient’s pain journals by health care personnel reinforce this message on a repeated basis. Under such documented strict control, the patient is less inclined to file a frivolous complaint against the physician.

As noted, the superiority of written contracts with pain patients undergoing a narcotic regimen has not been tested in controlled studies. The practical advantages of such contracts are clear. Given the importance of informed patient consent, and the critical importance of careful adherence to an opioid regimen, failure of the treating physician to use written contracts should be considered imprudent at best.

Medical Factors

Efficacy

The majority of physicians in the United States maintain at least some patients with noncancer pain who take long-term opioid therapy.5 There are three well-controlled trials demonstrating clinical efficacy of opioids in the treatment of nonmalignant pain.6,7 Published surveys and open-label clinical trials support the safety and effectiveness of opioid analogues in carefully selected patients with chronic nonmalignant pain,8–19 including pain of neuropathic origin.8,11,15,19–22 Although the role of opioids in cancer pain is now well established, there is still considerable resistance to their use in chronic nonmalignant pain, due to a perceived lack of efficacy, concerns about analgesic tolerance, side effects, addiction, and adverse regulatory sanctions.24–26 In view of this continuing debate and the need to provide informed consent, it is appropriate to bring this controversy to the attention of the patient in the protocol-contract.

Tolerance

Experience with administration of opioids to patients with cancer pain and data obtained from surveying patients with nonmalignant pain8,19 suggest that patients develop a degree of tolerance to a number of common side effects of opioid analogues with continued administration. Tolerance to the central nervous system (CNS) side effects of opioids, especially sedation and respiratory depression, is common.19 Tolerance to the gastrointestinal effects (i.e., constipation) seldom occurs and is by far the most common complication of treatment.19 Nonetheless, many patients admitted to pain management programs complain that opioids have proved ineffective in relieving their pain and frequently complain of unwanted effects such as sedation, reduced concentration, and constipation.27 The protocol-contract addresses these potential complications in two ways:

1. The patient is not allowed to exceed a maximum dosage of opioid during a 24-hour period. If the patient does not achieve a significant relief of pain at the maximum dose, the trial is considered a failure and the patient is weaned from the opioid. The setting of a maximum dose is based on recommendations found in the Physicians’ Desk Reference. A recent study suggests


that patients receiving long-term opioid for nonmalignant pain can develop pain management skills to limit their intake when a limited dose is set as a goal.27

2. With the protocol-contract the patient agrees to attempt to wean himself or herself from the opioid at least once every 6 months in order to evaluate its effectiveness. A recent study suggests that patients can learn to wean themselves from opioids without the need to be institutionalized or the need to use a “blinded” cocktail.27

Physical Withdrawal:

The protocol-contract advises the patient of the early signs and symptoms of narcotic withdrawal and advises her/him that withdrawal symptoms are unlikely to worsen after 72 hours.

Addiction:

The term “addiction” is often misunderstood and must be distinguished from tolerance and physical dependence. Addiction is a drug-related phenomena characterized by (a) loss of control over drug use, (b) compulsive drug use, and (c) continued use despite harm.28 Although the diagnosis of an addiction disorder may be relatively straightforward in patients who engage in highly aberrant behaviors (such as prescription forgery or injecting an oral formulation), less egregious behaviors are more common and challenging to assess. The complexity of this assessment is reflected in the term pseudoaddiction, which has been used to describe aberrant drug-related behaviors in patients who are reacting to the experience of uncontrolled pain.29

Addiction to opioid, when prescribed for therapeutic objectives such as acute postoperative pain or malignant pain, is rare.30 This fact has led to the Food and Drug Administration (FDA) approved statement on the fentanyl (Duragesic) package insert: “Iatrogenic addiction following opioid administration is relatively rare.”31

However, mental evaluations are extremely important for patient safety and should be a mandatory part of every examination of patients on opioids. In other words, evaluation of treatment effectiveness with full and systematic documentation by clinicians must include not only analgesic efficacy, but cognitive efficiency as well (e.g., attention, concentration, orientation, calculation ability, working memory, reaction time), for this is the ultimate determinant of quality of life. The protocol-contract addresses the initial psychosocial evaluation and follow-up monitoring based on the risk of addiction for a particular opioid. The DEA rates the relative risk of drug abuse according to a “Schedule.” Accordingly, we have developed two protocol-contracts based on the Schedule assigned to the opioid by the DEA. In general, we feel it is important that the physician prescribing a Schedule II opioid (e.g., morphine and morphine-like drugs) work in close collaboration with a psychologist or psychiatrist in the patient’s care. Such a collaborative relationship might not only improve patient care, but make it less likely for the patient to target the prescriber who makes a decision the patient does not like and will afford the prescriber of the opioid greater legal protection as well (see Appendix). Schedule III and IV opioids have been viewed by the DEA as potentially less addictive and have been grouped together in a single protocol-contract. The protocol-contract may require repeated revisions as knowledge and experience accumulate. Most of all, long-term follow-up and well controlled clinical trials of opioid use for chronic noncancer pain in a number of countries and cultures are urgently needed.

Summary

According to a private sector panel convened by the U.S. Department of Health and Human Services, “the ethical obligation to manage pain and relieve the patient’s suffering is at the core of a health professional’s commitment.”32 Although some states have passed legislation to provide some protection for physicians who compassionately prescribe opioids for intractable pain, prescription of opioid analgesics for chronic pain can nevertheless leave the physician vulnerable to intense scrutiny by regulatory agencies. Indeed, as suggested by others, “any patient considered for opioid treatment should be assessed thoroughly within the setting of a multidisciplinary clinic and that all reasonable alternative treatment modalities should be tried first.”33 Reasons for this action include: (a) problematic side-effects with opioid analgesics; (b) patients can develop secondary psychiatric problems that could result in noncompliance and/or inappropriate blame of the physician and subsequent filing of a complaint; and, (c) many practitioners still have a very poor understanding of chronic pain and openly may disagree with another physician’s opioid prescription, leading the patient to file a complaint.

Indeed, the role of opioids in the treatment of chronic pain continues to be debated. Some assistance to help guide the practitioner have been offered in a consensus statement published recently by a collaborative effort of the American Pain Society and the American Academy of Pain Medicine.34 Most recently, the Medical Society of Virginia’s special Pain Management Subcommittee has provided its practitioners with guidelines for logical and safe medical practice when prescribing opioids to the chronic pain patient.35

In addition to sound clinical judgment and knowledge of federal and state regulations, thorough recordkeeping is crucial to minimize the prescribing physician’s risk of exposure to disciplinary action. A written protocol-contract, signed by the prescribing physician, the patient, and other health-care providers involved in the patient’s treatment, is recommended to facilitate documentation of both the opioid treatment plan and informed consent. This contract details the risks of opioid usage, the specific parameters of use allowed, and the patient’s substantial responsibilities (including the responsibility to pursue other less invasive psychosocial modalities of pain management).
References


Appendix I

University of South Florida Pain Management Clinic

PATIENT’S NAME: ____________________________

Opioid Treatment Protocol—Schedule II Pain Medications

The use of opioids (also called narcotics) to treat patients dying from cancer is well-established. However, the use of opioids to treat patients without cancer who are suffering with chronic pain is controversial. The opioid you will be taking is called _____________. This opioid is designated as a Schedule II control substance by the U.S. Drug Enforcement Agency (which means the drug has the highest potential for abuse, addiction and illegal diversion).

The purpose of this contract is to summarize an agreement among all parties involved in the care of the above named patient. The ultimate responsibility for management in the patient’s chronic pain is placed upon the patient. Our responsibility is to help the patient to become as effective a manager of the pain experience as possible. The patient agrees to decrease reliance on opioid use as much as possible and focus more on issues of minimizing...
The goal in prescribing pain medications is to reduce suffering, changing attitudes and lifestyle, reducing disability, and accepting responsibility for one’s own health destiny.

The patient will agree to the following (as indicated by the signature to this contract):

1. The patient will visit and be re-evaluated by the prescribing physician and the patient’s psychologist (or psychiatrist) at least once every month during the initial trial period, unless notified by the physicians involved. After the initial trial period, the patient will be re-evaluated at least once every 3 months. All re-evaluations will be scheduled appointments, not walk-in appointments.

2. There will be no change in the patient’s prescriptions by telephone. The patient must appear in person and will not be allowed to change the dosing without prior authorization. One physician will assume responsibility for all pain medications, and no other physician(s) will prescribe them.

3. The patient will keep a daily record of all opioid tablets taken. The patient will record the reason for taking each opioid tablet. This information will be provided to the prescribing physician and psychologist (or psychiatrist) in a summarized form by the patient at each office visit. In addition, at each visit, the patient will provide a list of all opioids in his or her possession to ensure that all opioids are accounted for.

4. The patient has agreed not to take the opioid tablets unless the pain limits the patient’s functions significantly or if the pain is severe. It is not appropriate for the patient to attempt total relief of the pain with opioid. To do so places the patient at increased risk of respiratory depression, sedation, nausea, constipation, and tolerance. A 50% reduction in pain is a realistic goal.

5. The patient must report significant side effects due to opioid; for example, oversedation, nausea, vomiting, constipation, confusion, euphoria (high feelings), and dysphoria (down feelings). There are other side effects which are very rare. These side effects, which may be related to opioid use, include nausea, vomiting, dizziness, sweating, respiratory depression, gastrointestinal upset, involuntary movements, jerks or tremors, headaches, weakness, tremors, seizures, bad dreams, muscle rigidity, transient hallucinations and disorientation, visual disturbances, insomnia, dry mouth, diarrhea, stomach cramps, taste alterations, flushing of face, chills, increased or decreased heart rate, increased or decreased blood pressure, difficulty with urination, itching, skin rashes, and swelling of skin.

6. The goal in prescribing pain medications is to reduce the need for them in a reasonable amount of time. For example, the underlying pain may decrease over time, and the patient should attempt to learn safer ways to manage his or her pain (e.g., relaxation techniques, self-hypnosis, biofeedback, etc). Approximately every 6 months the need for this medication will be re-evaluated, and the patient agrees to attempt to reduce or discontinue the pain medication altogether.

7. The patient understands that:
   a. Patients who take opioids can potentially develop psychological and/or physical dependence and/or tolerance.
   b. Opioids may impair mental and/or physical ability required for the performance of potentially hazardous tasks (e.g., driving, operating a machine).
   c. Opioids should not be taken with alcohol or other CNS (central nervous system) depressants (sleep aids, tranquilizers) because additive effects, including CNS depression, may occur. The physician prescribing the opioid should be consulted if other medications are currently being used or are prescribed for future use. Failure to report the use of any pain medications other than those prescribed by this physician shall be a breach of contract by the patient and constitutes sufficient cause for termination of this contract.
   d. The patient understands that sometimes abrupt cessation or a sudden reduction in dose of opioid after prolonged use may result in withdrawal symptoms (initial symptoms including sweating, gooseflesh, tearing of eyes, runny nose, yawniess, restess sleep, and enlarged pupils). After 24 to 72 hours, the symptoms may include irritability, anxiety, weakness, twitching and spasm of muscle, diarrhea, kicking movements, severe backache, stomach (abdominal) and leg pains and cramps, hot and cold flashes, insomnia, nausea, loss of appetite, vomiting, increased body temperature, increased breathing rate, blood pressure, heart rate, and sneezing. Excessive loss of fluid from increased sweating, diarrhea, and vomiting may lead to severe dehydration. Death may occur. Without treatment of withdrawal from opioid, most symptoms disappear in 5 to 14 days; some symptoms (insomnia, irritability, and muscle aches) may last 2 to 6 months. Withdrawal symptoms can be minimized by slow withdrawal of opioid (e.g., the dose of opioid may be reduced by half on a weekly basis to minimize withdrawal symptoms). After 72 hours of withdrawal, it is unlikely that withdrawal symptoms will worsen.
   e. Tablets must be taken whole, and are not to be broken, chewed, or crushed. Otherwise, the opioid could be rapidly absorbed causing toxicity.
   f. If the patient fails to comply with the requirements of this treatment protocol, the physician prescribing the opioid may discontinue the opioid at an appropriate rate (detoxification from opioid) and discontinue the doctor-patient relationship with the patient. Similarly, any unethical behavior by the patient will be grounds to discontinue the care of the patient (e.g., diversion or selling opioids to others or taking opioids for emotional reasons). The patient understands that he or she already has a chronic pain problem, and that we do not want to add a drug problem. The patient understands that successful treatment of the chronic pain will require more than pain medications; it will require learning new pain management strategies, increasing activity, and becoming as
healthy as possible. One of the treatment goals for many patients is the eventual discontinuation of all opioids and other pain medications where advisable.

If the patient becomes stabilized on an effective dose of opioids, a primary care physician may assume responsibility for the patient’s care, including the writing of prescriptions for opioids. The patient will follow the requirements dictated by the new physician who is prescribing the opioids.

The patient agrees to the use of periodic drug screens to assure appropriate use of medications.

Treatment Protocol:

1. The patient will undergo a therapeutic trial with opioids to determine if they are a candidate for continued use.

2. The dose will be prescribed at __________, every__________hour(s). Approximately __________ tablets will be prescribed on a monthly basis. The patient agrees not to exceed __________ tablet(s) in a 24-hour period.

3. Prescription of opioid will be renewed only on a monthly basis.

4. Confusion caused by the opioid, which cannot be controlled by adjustment of dosage, will be a basis for discontinuing its use and considering an alternative treatment.

5. Sedation without confusion may be treated by decreasing the dose of opioid.

6. It may be necessary to treat nausea and vomiting with Reglan 10 mg q6h or Compazine 10 mg q6h by oral or rectal routes.

7. The patient may be treated for constipation by adjustment of diet or with:
   a. Colace 200 mg b.i.d.
   b. Concurrent administration of Senokot two tablets b.i.d. This may be increased to four tablets b.i.d. In addition, the patient may take Dulcolax suppositories 1 PRN q daily.

8. The patient will actively pursue and document other non-medication methods of managing pain. These other methods may include relaxation training, self-hypnosis, biofeedback, meditation, pool exercises, and/or any other modalities that may be helpful in reducing pain, increasing pain tolerance, or increasing levels of life-enhancing activities.

Date:__________

I, (the patient), have read, understood, and agree to abide by the contents of this document.

Prescribing Physician ____________________________  Psychologist (or psychiatrist) ____________________________