

50 013 001. Rules and Regulations

F. USE OF CONTROLLED SUBSTANCES FOR CHRONIC (NON-TERMINAL) PAIN

1. DEFINITIONS:

For the purpose of Article F only, the following terms have the meanings indicated:

a. "Chronic Pain" is a pain state in which 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 none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain. Further, if a patient is receiving controlled substances for the treatment of pain for a prolonged period of time (more than six months), then they will be considered for the purposes of this regulation to have "de facto" chronic pain and subject to the same requirements of this regulation. "Terminal Disease Pain" should not be confused with "Chronic Pain." For the purpose of this Section, "Terminal Disease Pain" is pain arising from a medical condition for which there is no possible cure and the patient is expected to live no more than six (6) months.

b. "Acute Pain" is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma and acute illness. It is generally time limited and is responsive to therapies, including controlled substances as defined by the U.S. Drug Enforcement Administration. Title 21 CFR Part 1301 Food and Drugs.

c. "Addiction" is a neurobehaviorial syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

d. "Physical Dependence" is a physiological state of neuroadaptation to a substance which is characterized by the emergence of a withdrawal syndrome if the use of the substance is stopped or decreased abruptly, or if an antagonist is administered. Withdrawal may be relieved by re-administration of the substance. Physical dependence is a normal physiological consequence of extended opioid therapy for pain and should not be considered addiction.

e. "Substance Abuse" is the use of any substance(s) for non-therapeutic purposes; or use of medication for purposes other than those for which it is prescribed.

f. "Tolerance" is a physiological state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Tolerance occurs to different degrees for various drug effects, including sedation, analgesia and constipation. Analgesic tolerance is the need to increase the dose of opioid to achieve the same level of analgesia. Such tolerance may or may not be evident during treatment and does not equate with addiction.

2. Notwithstanding any other provisions of these rules and regulations, a physician may prescribe, administer, or dispense controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability to a person in the usual course of treatment of that person for a diagnosed condition causing chronic pain.

3. Notwithstanding any other provisions of these rules and regulations, as to the prescribing, administration, or dispensation of controlled substances in Schedules II, IIN, III, IIIN, IV and V, or other drugs having addiction-forming and addiction-sustaining liability, use of said medications in the treatment of chronic pain should be done with caution. A physician may administer, dispense or prescribe said medications for the purpose of relieving chronic pain, provided that the following conditions are met:

a. Before initiating treatment utilizing a Schedules II, IIN, III, IIIN, IV or V controlled substance, or any other drug having addiction-forming and addiction-sustaining liability, the physician shall conduct an appropriate risk/benefit analysis by reviewing his own records of prior treatment, or review the records of prior treatment which another treating physician has provided to the physician, that there is an indicated need for long term controlled substance therapy. Such a determination shall take into account the specifics of each patients diagnosis, past treatments and suitability for long term controlled substance use either alone or in combination with other indicated

modalities for the treatment of chronic pain. This shall be clearly entered into the patient medical record, and shall include consultation/referral reports to determine the underlying pathology or cause of the chronic pain.

b. Documentation in the patient record shall include a complete medical history and physical examination that indicates the presence of one or more recognized medical indications for the use of controlled substances.

c. Documentation of a written treatment plan which shall contain stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments. The plan should also contain an informed consent agreement for treatment that details relative risks and benefits of the treatment course. This should also include specific requirements of the patient, such as using one physician and pharmacy if possible, and urine/serum medication level monitoring when requested.

d. Periodic review and documentation of the treatment course is conducted at reasonable intervals (no more than every six months) with modification of therapy dependent on the physician's evaluation of progress toward the stated treatment objectives. This should include referrals and consultations as necessary to achieve those objectives.

4. No physician shall administer, dispense or prescribe a controlled substance or other drug having addiction-forming and addiction-sustaining liability that is nontherapeutic in nature or non-therapeutic in the manner the controlled substance or other drug is administered, dispensed or prescribed.

5. No physician shall administer, dispense or prescribe a controlled substance for treatment of chronic pain to any patient who has consumed or disposed of any controlled substance or other drug having addiction-forming and addiction-sustaining liability other than in strict compliance with the treating physician's directions. These circumstances include those patients obtaining controlled substances or other abusable drugs from more than one physician and those patients who have obtained or attempted to obtain new prescriptions for controlled substances or other abusable drugs before a prior prescription should have been consumed according to the treating physician's directions. This requirement will not be enforced in cases where a patient has legitimately temporarily escalated a dose of their pain medication due to an acute exacerbation of their condition but have maintained a therapeutic dose level, however it will be required of the treating physician to document in the patient record that such increase in dose level was due to a recognized indication and was within appropriate therapeutic dose ranges. Repetitive or continuing escalations should be a reason for concern and a re-evaluation of the present treatment plan shall be undertaken by the physician.

6. No physician shall prescribe any controlled substance or other drug having addiction-forming or addiction-sustaining liability to a patient who is a drug addict for the purpose of "detoxification treatment", or "maintenance treatment", and no physician shall administer or dispense any narcotic controlled substance for the purpose of "detoxification treatment" or "maintenance treatment" unless they are properly registered in accordance with Section 303(g) 21 U.S.C. 823(g). Nothing in this paragraph shall prohibit a physician from administering narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one (1) day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three (3) days. Nothing in this paragraph shall prohibit a physician from administering or dispensing narcotic controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.