Document: Proposed Rule, **Register Page Number:** 28 IR 3344
Source: August 1, 2005, Indiana Register, Volume 28, Number 11
Disclaimer: This document was created from the files used to produce the official CD-ROM Indiana Register.

TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Proposed Rule
LSA Document #05-91

DIGEST

Adds 844 IAC 5-5 to establish the guidelines for the use of controlled substances for the treatment of pain. Effective 30 days after filing with the secretary of state.

844 IAC 5-5

SECTION 1. 844 IAC 5-5 IS ADDED TO READ AS FOLLOWS:

Rule 5. Pain Management

844 IAC 5-5-1 Definitions
Authority: IC 25-22.5-2-7
Affected: IC 25-22.5

Sec. 1. The following definitions apply throughout this rule:
(1) "Acute pain" means the normal, predicted physiological response to a:
(A) noxious;
(B) chemical;
(C) thermal; or
(D) mechanical;
stimulus and typically is associated with invasive procedures, trauma, and disease. Acute pain is generally time-limited.
(2) "Addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, or physical consequences, the continued use of which results in a decreased quality of life. Physical dependence alone is not evidence of addiction.
(3) "Believes" or "has reason to believe" does not require absolute certainty or complete unquestioning acceptance, but only an opinion based on reasonable information that a patient is:
(A) suffering from addiction or drug abuse; or
(B) engaging in diversion of drugs.
(4) "Chronic pain" means a state:
(A) in which pain persists beyond the usual course of an acute disease or healing of an injury; or
(B) that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.
(5) "Dangerous drug" has the meaning set forth in 844 IAC 5-1-1(4).
(6) "Diversion" means the conveyance of a prescription drug to a person other than the person for whom the drug was prescribed or dispensed by a practitioner.
(7) "Drug abuse" means a maladaptive or inappropriate use or overuse of a medication.
(8) "Pain" means an unpleasant sensory and emotional experience:
(A) associated with actual or potential tissue damage; or
(B) described in terms of such damage.
(9) "Physical dependence" means a physiologic state of adaptation to a specific drug or medication characterized by the development of a withdrawal syndrome:
(A) following abrupt cessation of a drug; or
(B) on administration of an antagonist.
(10) "Practitioner" has the meaning set forth in 844 IAC 5-1-1(14).

(11) "Substance abuse" means the use of:

(A) any substance or substances for nontherapeutic purposes; or

(B) medication for purposes other than those for which it is prescribed.

(12) "Tolerance" means decreasing response to the same dosage of a prescription drug over time as a result of physiologic adaptation to that drug.

(Medical Licensing Board of Indiana; 844 IAC 5-5-1)

844 IAC 5-5-2 Guidelines for treatment

Authority: IC 25-22.5-2-7

Affected: IC 25-22.5

Sec. 2. When evaluating the treatment of pain, acute pain, or chronic pain, including the use of controlled substances, the practitioner shall comply with the accepted and prevailing standards of care, which shall include, but not be limited to, the following:

(1) A complete medical history and physical examination must be conducted and documented in the patient's medical record. The medical record shall document the following:

(A) The nature and intensity of the pain.

(B) Current and past treatments for pain.

(C) Underlying or coexisting diseases or conditions.

(D) The effect of the pain on physical and psychological function.

(E) History of substance abuse.

(F) The presence of one (1) or more recognized medical indications for the use of a controlled substance.

(2) An individualized written treatment plan shall be formulated and documented in the patient's medical record. The treatment plan shall:

(A) specify the medical justification of the treatment by utilizing prescription or dangerous drugs;

(B) indicate the intended role of the prescription or dangerous drug therapy within the overall plan;

(C) state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function;

(D) document the patient's response to treatment, and, as necessary, modify the treatment plan; and

(E) indicate if any further diagnostic evaluations or other treatments are planned.

After treatment begins, the practitioner shall adjust the drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(3) A practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The patient should receive prescriptions from one (1) physician and one (1) pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician may employ the use of a written agreement between the physician and patient outlining patient responsibilities, including the following:

(A) Urine/serum medication levels screening when requested.

(B) Number and frequency of all prescription refills.

(C) The reason for which the drug therapy may be discontinued, such as a violation of the agreement.

(4) At reasonable intervals based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy should depend on the physician's evaluation of progress toward stated treatment objectives, including the improvement in the patient's pain intensity or improved physical or psychosocial function, or both, such as the following:

(A) The ability to work.

(B) The need of health care resources.

(C) Activities of daily living.

(D) The quality of social life.

If treatment goals are not being achieved, despite medication adjustments, the practitioner shall reevaluate the appropriateness of continued treatment. The practitioner shall monitor patient compliance in medication usage and related treatment plans.

(5) The practitioner shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those pain patients:

(A) who are at risk for misusing their medications; and

(B) whose living arrangements pose a risk for medication misuse or diversion.

The management of pain of patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation, and consultation with or referral to an expert in the management of such patients.

(6) The practitioner shall keep accurate and complete records to include the following:

(A) Medical history and physical examination.

(B) Diagnostic, therapeutic, and laboratory results.

(C) Evaluations and consultations.

(D) Treatment objectives and discussion of risks and benefits.

(E) Treatments.

(F) Medications, including date, type, dosage, and quantity prescribed.

(G) Instructions and agreements.

(H) Periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

(7) To prescribe, dispense, or administer controlled substances, the practitioner shall comply with applicable federal and state regulations. Practitioners shall refer to the Physicians Manual of the U.S. Drug Enforcement Administration for specific rules governing controlled substances as well as applicable state regulations.

(Medical Licensing Board of Indiana; 844 IAC 5-5-2)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on August 26, 2005 at 11:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Conference Center Room A, Indianapolis, Indiana the Medical Licensing Board of Indiana will hold a public hearing on a proposed new rule to establish the guidelines for the use of controlled substances for the treatment of pain.

The Medical Licensing Board of Indiana has the authority to promulgate rules establishing the standards for the competent practice of medicine, osteopathic medicine, or any other form of practice regulated by a limited license or permit. This proposed rule establishes the guidelines for the use of controlled substances to treat pain and clarifies the practice of pain management. This proposed rule will have no costs to entities.

Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W072 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Frances L. Kelly
Executive Director
Indiana Professional Licensing Agency