**TITLE 844 MEDICAL LICENSING BOARD OF INDIANA**

**Proposed Rule**
LSA Document #15-415

DIGEST

Amends 844 IAC 5-6-2, 844 IAC 5-6-3, 844 IAC 5-6-5, and 844 IAC 5-6-8 to establish standards and protocols for the prescribing of controlled substances, including the use of abuse deterrent formulations. Effective 30 days after filing with the Publisher.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

**844 IAC 5-6-2; 844 IAC 5-6-3; 844 IAC 5-6-5; 844 IAC 5-6-8**

SECTION 1. 844 IAC 5-6-2 IS AMENDED TO READ AS FOLLOWS:

**844 IAC 5-6-2 Definitions**

**Authority: IC 25-22.5-2-7; IC 25-22.5-13-2**
**Affected: IC 25-1-9; IC 25-22.5; IC 35-48-1-9**

Sec. 2. (a) The definitions in this section apply throughout this rule.

**(b) "Abuse deterrent formulation" means an opioid formulation that has properties shown to meaningfully deter the intentional, nontherapeutic use, even once, to achieve a desirable psychological or physiological effect, even if such formulation does not fully prevent such intentional, nontherapeutic uses.**

~~(b)~~ **(c)** "Chronic pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

~~(c)~~ **(d)** "Controlled substances" has the meaning set forth in IC 35-48-1-9.

~~(d)~~ **(e)** "Morphine equivalent dose" means a conversion of various opioids to a standardized dose of morphine by the use of accepted conversion tables.

~~(e)~~ **(f)** "Opioid" means any of various narcotics containing opium or one (1) or more of its natural or synthetic derivatives. However, if such a narcotic is not a controlled substance, it shall not be an opioid for the purposes of this rule.

~~(f)~~ **(g)** "Outset of an opioid treatment plan" means that a patient has been prescribed opioids as described in section 3(c) of this rule, and, therefore, the provisions stated in section 3(a) of this rule become applicable to that patient.

~~(g)~~ **(h)** "Terminal" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty:
(1) there can be no recovery; and
(2) progression to death can be anticipated as an eventual consequence of that condition.

*(Medical Licensing Board of Indiana; 844 IAC 5-6-2; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.])*

SECTION 2. 844 IAC 5-6-3 IS AMENDED TO READ AS FOLLOWS:

**844 IAC 5-6-3 Triggers for imposition of requirements; exemptions**

**Authority: IC 25-22.5-2-7; IC 25-22.5-13-2**
**Affected: IC 16-21; IC 16-25; IC 16-28; IC 25-1-9; IC 25-22.5**

Sec. 3. (a) This section and sections 4 through 10 of this rule establish requirements concerning the use of opioids for chronic pain management for patients.

(b) Notwithstanding subsection (a), this section and sections 4 through 10 of this rule shall not apply to the use of opioids for chronic pain management for the following:

(1) Patients with a terminal condition.
(2) Residents of a health facility licensed under IC 16-28.
(3) Patients enrolled in a hospice program licensed under IC 16-25.
(4) Patients enrolled in an inpatient or outpatient palliative care program of a hospital licensed under IC 16-21 or a hospice licensed under IC 16-25.

However, a period of time that a patient who was, but is no longer, a resident or patient as described in subdivisions (2) through (4) shall be included in the calculations under subsection (c).

(c) The requirements in the sections identified in subsection (a) only apply if a patient has been prescribed:

(1) more than sixty (60) opioid-containing pills a month for more than three (3) consecutive months;
(2) a morphine equivalent dose of more than fifteen (15) milligrams per day for more than three (3) consecutive months;
(3) a transdermal opioid patch for more than three (3) consecutive months;
(4) at any time it is classified as a controlled substance under Indiana law, tramadol, but only if the patient's tramadol dose reaches a morphine equivalent dose of more than sixty (60) milligrams per day for more than three (3) consecutive months; or
(5) ~~a hydrocodone-only~~ **an** extended release **opioid** medication that is not in an abuse deterrent form **for which an FDA-approved abuse deterrent form is available.**

~~Subsections (c)(1) and (c)(2)~~ **Subdivisions (1) and (2)** do not apply to the controlled substances addressed by ~~subsections (c)(3) through (c)(5).~~ **subdivisions (3) through (5).**

(d) Because the requirements in the sections identified in subsection (a) do not apply until the time stated in subsection (c), the initial evaluation of the patient for the purposes of sections 4, ~~7(a),~~ **7,** and 8(a) of this rule shall not be required to take place until that time.

(e) Notwithstanding subsection (d), the physician may undertake those actions earlier than required if the physician deems it medically appropriate and, if those actions meet the requirements, a further initial evaluation is not required. If the physician conducts actions earlier than required under this subsection, any subsequent requirements are determined by when the initial evaluation would have been required and not at the earlier date it actually was conducted.

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SECTION 3. 844 IAC 5-6-5 IS AMENDED TO READ AS FOLLOWS:

**844 IAC 5-6-5 Physician discussion with patient; treatment agreement**

**Authority: IC 25-22.5-2-7; IC 25-22.5-13-2**
**Affected: IC 25-1-9; IC 25-22.5**

Sec. 5. The physician shall discuss with the patient the potential risks and benefits of opioid treatment for chronic pain, as well as expectations related to prescription requests and proper medication use. In doing so, the physician shall **do the following:**

(1) Where alternative modalities to opioids for managing pain exist for a patient, discuss them with the patient.
(2) Provide a simple and clear explanation to help patients understand the key elements of their treatment ~~plan.~~ **plans.**
(3) Counsel women between fourteen (14) and fifty-five (55) years of age with child bearing potential about the risks to the fetus when the mother has been taking opioids while pregnant. Such described risks shall include fetal opioid dependency and neonatal abstinence syndrome (NAS).

(4) Discuss with the patient risks of dependency and addiction.
(5) Discuss with the patient safe storage practices for prescribed opioids.
(6) Provide a written warning to the patient disclosing the risks associated with taking extended release medications that are not in an abuse deterrent form, if the physician prescribes for the patient a hydrocodone-only extended release medication that is not in an abuse deterrent form.
**(7) Discuss with the patient the risks and benefits of using an abuse deterrent formulation, as opposed to a non-abuse deterrent formulation, if such a formulation exists for the opioid product the physician is prescribing to the patient. Nothing in this subdivision shall be construed to require a physician to prescribe an opioid in an abuse deterrent formulation.**
~~(7)~~ **(8)** Together with the patient, review and sign a "Treatment Agreement", which shall include at least the following:
(A) The goals of the treatment.
(B) The patient's consent to drug monitoring testing in circumstances where the physician determines that drug monitoring testing is medically necessary.
(C) The physician's prescribing policies, which must include at least a:
(i) requirement that the patient take the medication as prescribed; and
(ii) prohibition of sharing medication with other individuals.
(D) A requirement that the patient inform the physician:
(i) about any other controlled substances prescribed or taken by the patient; and
(ii) if the patient drinks alcohol while taking opioids.
(E) The granting of permission to the physician to conduct random pill counts.
(F) Reasons the opioid therapy may be changed or discontinued by the physician.
A copy of the treatment agreement shall be retained in the patient's chart.

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SECTION 4. 844 IAC 5-6-8 IS AMENDED TO READ AS FOLLOWS:

**844 IAC 5-6-8 Drug monitoring testing**

**Authority: IC 25-22.5-2-7; IC 25-22.5-13-2**
**Affected: IC 25-1-9; IC 25-22.5**

Sec. 8. (a) ~~After December 31, 2014,~~ At any time the physician determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test using a method selective enough to differentiate individual drugs within a drug class, on the patient.

(b) In determining whether a drug monitoring test under subsection (a) is medically necessary, the physician shall consider, subject to the provisions of subsection (c), each of the following factors where applicable and reasonably feasible:
(1) Whether there is reason to believe a patient is not taking the prescribed opioids or is diverting the opioids.
(2) Whether there has been no appreciable impact on the patient's chronic pain despite being prescribed opioids for a period of time that would generally have an impact.
(3) Whether there is reason to believe the patient is taking or using controlled substances other than opioids or other drugs or medications including illicit street drugs that might produce significant polypharmacological effects or have other detrimental interaction effects.
(4) Whether there is reason to believe the patient is taking or using opioids in addition to the opioids being prescribed by the physician and any other treating physicians.
(5) Attempts by the patient to obtain early refills of opioid containing prescriptions.
(6) The number of instances in which the patient alleges that ~~their~~ **the patient's** opioid containing prescription has been lost or stolen.
(7) When the patient's INSPECT report provides irregular or inconsistent information.
(8) When a previous drug monitoring test conducted on the patient raised concerns about the patient's usage of opioids.
(9) Necessity of verifying that the patient no longer has substances in the patient's system that are not appropriate under the patient's treatment plan.
(10) When the patient engages in apparent aberrant behaviors or shows apparent intoxication.

(11) When the patient's opioid usage shows an unauthorized dose escalation.
(12) When the patient is reluctant to change medications or is demanding certain medications.
(13) When the patient refuses to participate in or cooperate with a full diagnostic workup or examination.
(14) Whether a patient has a history of substance abuse.
(15) When the patient has a health status change (for example, pregnancy).
(16) Co-morbid psychiatric diagnoses.
(17) Other evidence of chronic opioid use, controlled substance abuse or misuse, illegal drug use or addiction, or medication noncompliance.
(18) Any other factor the physician believes is relevant to making an informed professional judgment about the medical necessity of a prescription.

(c) It shall not be considered a violation of this section for a physician to fail to conduct a review of all eighteen (18) factors listed in subsection (b) if the physician reasonably determines following a review of less than all of the factors listed in ~~subection~~ **subsection** (b) that a drug monitoring test is medically necessary.

(d) Nothing about subsection (b) shall be construed to prohibit the physician from performing or ordering a drug monitoring test at any other time the physician considers appropriate.

(e) If a test performed under subsection (a), or conducted under subsection (d), reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required. Documentation of the revised treatment plan and discussion with the patient must be recorded in the patient's chart.

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Notice of Public Hearing

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