TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Emergency Rule
LSA Document #13-XXX(E)
DIGEST

Temporarily adds provisions regarding . . .

SECTION 1. **This document establishes standards and protocols for physicians in the prescribing of controlled substances for pain management treatment. It is adopted under the authority of IC 25-22.5-13-2.**

SECTION 2. **(a) The definitions in this SECTION apply throughout this document.**

(b) "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) "Controlled substances" has the meaning set forth in IC 35-48-1-9.

(d) "Morphine Equivalent Dose" means a conversion of various opioids to a standardized dose of morphine by the use of accepted conversion tables.

(e) "Opioid" means any of various sedative narcotics containing opium or one or more of its natural or synthetic derivatives.

(f) "Terminal" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty:

(A) there can be no recovery; and

(B) death will occur from the condition within a short period without the provision of life prolonging procedures.

SECTION 3. **(a) This SECTION and SECTIONS 4 through 9 of this document establish requirements concerning the use of opioids for chronic pain management for patients who are not terminal.**

(b) 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; or

(2) a morphine equivalent dose of more than fifteen (15) milligrams per day;

for more than three (3) consecutive months.

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

(d) Notwithstanding subsection (c), the physician may undertake those actions earlier than required if the physician so chooses and if those actions meet the requirements a further initial evaluation is not required. If the physicians 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.

SECTION 4. (a) **The physician shall do the physician's own evaluation and risk stratification of the patient by doing the following in the initial evaluation of the patient:**

(1) Performing a detailed history and physical exam and obtain appropriate tests, as indicated.

(2) Making a diligent effort to obtain and review records from previous health care providers to supplement the physicians understanding of the patient's chronic pain problem, including past treatments, and documenting this effort.

(3) Asking the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns.

(4) Assessing both the patient's mental health status and risk for substance abuse using available validated screening tools.

(5) After completing the initial evaluation, establishing a working diagnosis and tailoring a treatment plan to meaningful and functional goals with the patient reviewing them from time to time.

(b) Where medically appropriate, the physician shall utilize non-opioid options instead of prescribing opioids.

SECTION 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:**

(1) Where alternative modalities to opioids for managing pain exist for a patient who is not terminal, discuss them with the patient.

(2) Provide a simple and clear explanation to help patients understand the key elements of their treatment plan.

(3) Counsel women between the ages of 14 and 55 about the risk of fetal opioid dependency and neonatal abstinence syndrome with opioid use during pregnancy.

(4) 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 toxicology screening.

(C) The physician's prescribing policies which must include at least:

(i) a requirement that the patient take the medication as prescribed; and

(ii) a prohibition of sharing medication with other individuals.

(D) A requirement that the patient inform the physician about any other controlled substances prescribed.

(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.

SECTION 6. **(a) Physicians shall not prescribe opioids for patients without periodic scheduled visits. Visits for patients with a stable medication regimen and treatment plan shall occur face to face at least once every four (4) months. More frequent visits may be appropriate for patients working with the physician to achieve optimal management. For patients requiring changes to the medication and treatment plan, if changes are prescribed by the physician, the visits required by this subsection shall be scheduled at least once every two (2) months until the medication and treatment has been stabilized.**

(b) During the visits required by subsection (a) the physician shall evaluate patient progress and compliance with the patient's treatment plan regularly and set clear expectations along the way (such as, attending physical therapy, counseling or other treatment options).

SECTION 7. **At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing controlled substances for a patient shall run an INSPECT report on that patient under IC**

35-48-7-11.1(d)(4) and document in the patient's chart whether the INSPECT report is consistent with the physician's knowledge of the patient's controlled substance use history.

SECTION 8. (a) **At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing controlled substances for a patient shall perform a urine or saliva drug monitoring test, which must include a confirmatory test, on the patient.**

(b) If the test required under subsection (a) 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 plan and discussion with the patient must be recorded in the patient's chart.

SECTION 9. **When a patient's opioid dose reaches a morphine equivalent dose of more than fifty (50) milligrams per day, a face-to-face review of the treatment plan and patient evaluation must be scheduled, including consideration of referral to a specialist. If the physician elects to continue providing opioid therapy at a morphine equivalent dose of more than fifty (50) milligrams per day, the physician must develop a revised assessment and plan for ongoing treatment. The revised assessment and plan must be documented in the patient's chart, including an assessment of increased risk for adverse outcomes, including death, if the physician elects to provide ongoing opioid treatment.**

SECTION 10. **(a) SECTIONS 1 through 9 of this document take effect December 15, 2013.**

(b) Initial running of an INSPECT report as required under SECTION 7 of this document and initial conducting of a drug monitoring test as required under SECTION 8(a) of this document shall not be required for any patient who fell within the scope of SECTION 3(b) of this document before December 15, 2013. However, all other requirements of this document apply to these patients; that is, every requirement except for the initial running of the INSPECT report and the initial conducting of a drug monitoring test.

(c) Notwithstanding subsection (a) and SECTIONS 7 and 8(a) of this document, the first running of an annual INSPECT report under SECTION 7 of this document and the first conducting of an annual drug monitoring test under SECTION 8(a) of this document shall not be required to be conducted before November 1, 2014. Nothing about this subsection shall be construed to prohibit a physician from running a report or conducting a test sooner than required by this subsection.