TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Final Rule
LSA Document #14-289(F)

DIGEST

Adds 844 IAC 5-6 to establish requirements for the prescribing of opioid controlled substances for pain management. Effective November 1, 2014. *NOTE: 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 October 7, 2014.*

844 IAC 5-6

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

Rule 6. Opioid Prescribing Requirements

844 IAC 5-6-1 Scope

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

Sec. 1. This rule establishes standards and protocols for physicians in the prescribing of opioid controlled substances for pain management treatment.

(Medical Licensing Board of Indiana; 844 IAC 5-6-1; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

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) "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 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) "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) "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 [NOTE: 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.])

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 extended release medication that is not in an abuse deterrent form.
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) *[sic]***, 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.

(Medical Licensing Board of Indiana; 844 IAC 5-6-3; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

844 IAC 5-6-4 Evaluation and risk stratification by physician

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

Sec. 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 an appropriately focused history and physical exam and obtain or order appropriate tests, as indicated.

(2) Making a diligent effort to obtain and review records from previous health care providers to supplement the physician's 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 nonopioid options instead of or in addition to prescribing opioids.

(Medical Licensing Board of Indiana; 844 IAC 5-6-4; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

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:
(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.
(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) 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.

(Medical Licensing Board of Indiana; 844 IAC 5-6-5; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

844 IAC 5-6-6 Patient visits to physician

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

Sec. 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.

(Medical Licensing Board of Indiana; 844 IAC 5-6-6; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

844 IAC 5-6-7 INSPECT report

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 25-1-9; IC 25-22.5; IC 35-48-7-11.1

Sec. 7. At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids 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.

(Medical Licensing Board of Indiana; 844 IAC 5-6-7; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

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 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 *[sic]* **(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.

(Medical Licensing Board of Indiana; 844 IAC 5-6-8; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

844 IAC 5-6-9 Morphine equivalent doses above 60; revising of assessments and treatment plans

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

Sec. 9. When a patient's opioid dose reaches a morphine equivalent dose of more than sixty (60) 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 sixty (60) milligrams per day, the physician must develop a revised assessment and treatment plan for ongoing treatment. The revised assessment and treatment 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.

(Medical Licensing Board of Indiana; 844 IAC 5-6-9; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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.])

844 IAC 5-6-10 Physician assistants and advanced practice nurses

Authority: IC 25-22.5-2-7; IC 25-22.5-13-2
Affected: IC 25-1-9; IC 25-22.5; IC 25-23-1; IC 25-27.5-5; IC 25-27.5-6

Sec. 10. (a) IC 25-27.5-5 addresses the scope of practice of physician assistants in their dependent practice under supervising physicians including limiting the duties and responsibilities of physician assistants to those that are delegated by the supervising physician and that are within the supervising physician's scope of practice. IC 25-27.5-6 addresses supervisory responsibilities of the supervising physician, or when applicable, a physician designee. The prescribing of opioids for chronic pain management as regulated by this rule falls within the requirements on supervising physicians, or when applicable, on physician designees, under IC 25-27.5-5 and IC 25-27.5-6 including appropriate delegating

of duties and responsibilities to physician assistants and appropriate supervision of physician assistants.

(b) IC 25-23-1-19.4 through IC 25-23-1-19.8 and 848 IAC 5 address the practice of advanced practice nurses with prescriptive authority in collaboration with a physician. The prescribing of opioids for chronic pain management as regulated by this rule falls within the requirements on collaborating physicians regarding the prescriptive authority for advanced practice nurses under IC 25-23-1-19.4 though IC 25-23-1-19.8 and 848 IAC 5.

(Medical Licensing Board of Indiana; 844 IAC 5-6-10; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [NOTE: 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. SECTION 1 of this document takes effect November 1, 2014. *NOTE: 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 October 7, 2014.*

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