TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Final Rule
LSA Document #15-420(F)

DIGEST

Adds 844 IAC 2.2-3 to establish requirements for the prescribing of opioid controlled substances for pain management by physician assistants. Effective 30 days after filing with the Publisher.

844 IAC 2.2-3

SECTION 1. 844 IAC 2.2-3 IS ADDED TO READ AS FOLLOWS:

Rule 3. Opioid Prescribing Requirements

844 IAC 2.2-3-1 Scope

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5

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

(Medical Licensing Board of Indiana; 844 IAC 2.2-3-1; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-2 Definitions

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5; 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.

(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.

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

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

(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.

(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.

(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 2.2-3-2; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-3 Triggers for imposition of requirements; exemptions

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 16-21; IC 16-25; IC 16-28; IC 25-1-9; IC 25-27.5

Sec. 3. (a) This section and sections 4 through 9 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 9 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) 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) an extended release opioid medication that is not in an abuse deterrent form for which an FDA-approved abuse deterrent form is available.
Subdivisions (1) and (2) do not apply to the controlled substances addressed by 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, and 8(a) of this rule shall not be required to take place until that time.

(e) Notwithstanding subsection (d), the physician assistant may undertake those actions earlier than required if the physician assistant deems it medically appropriate and, if those actions meet the requirements, a further initial evaluation is not required. If the physician assistant 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 2.2-3-3; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-4 Evaluation and risk stratification by physician assistant

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5

Sec. 4. (a) The physician assistant shall do the physician assistant'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 assistant'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 assistant shall utilize nonopioid options instead of or in addition to prescribing opioids.

(Medical Licensing Board of Indiana; 844 IAC 2.2-3-4; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-5 Physician assistant discussion with patient; treatment agreement

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5

Sec. 5. The physician assistant 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 assistant 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 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 assistant 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 assistant is prescribing to the patient. Nothing in this subdivision shall be construed to require a physician assistant to prescribe an opioid in an abuse deterrent formulation.
(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 assistant determines that drug monitoring testing is medically necessary.
(C) The physician assistant'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 assistant:
(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 assistant to conduct random pill counts.
(F) Reasons the opioid therapy may be changed or discontinued by the physician assistant.
A copy of the treatment agreement shall be retained in the patient's chart.

(Medical Licensing Board of Indiana; 844 IAC 2.2-3-5; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-6 Patient visits to physician assistant

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5

Sec. 6. (a) Physician assistants 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 assistant to achieve optimal management. For patients requiring changes to the medication and treatment plan, if changes are prescribed by the physician assistant, 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 assistant 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 2.2-3-6; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-7 INSPECT report

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5; IC 35-48-7-11.1

Sec. 7. At the outset of an opioid treatment plan, and at least annually thereafter, a physician assistant 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 assistant's knowledge of the patient's controlled substance use history.

(Medical Licensing Board of Indiana; 844 IAC 2.2-3-7; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-8 Drug monitoring testing

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5

Sec. 8. (a) At any time the physician assistant determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, a physician assistant 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 assistant 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 assistant and any other treating practitioner.
(5) Attempts by the patient to obtain early refills of opioid containing prescriptions.
(6) The number of instances in which the patient alleges that 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 assistant 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 assistant to fail to conduct a review of all eighteen (18) factors listed in subsection (b) if the physician assistant reasonably determines following a review of less than all of the factors listed in subsection (b) that a drug monitoring test is medically necessary.

(d) Nothing about subsection (b) shall be construed to prohibit the physician assistant from performing or ordering a drug monitoring test at any other time the physician assistant 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 2.2-3-8; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-9 Morphine equivalent doses above 60; revising of assessments and treatment plans

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-27.5

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 assistant elects to continue providing opioid therapy at a morphine equivalent dose of more than sixty (60) milligrams per day, the physician assistant 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 assistant elects to provide ongoing opioid treatment.

(Medical Licensing Board of Indiana; 844 IAC 2.2-3-9; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

844 IAC 2.2-3-10 Scope of practice in prescribing opioids

Authority: IC 25-22.5-2-7; IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-22.5; IC 25-27.5

Sec. 10. 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.

(Medical Licensing Board of Indiana; 844 IAC 2.2-3-10; filed Sep 2, 2016, 1:04 p.m.: 20160928-IR-844150420FRA)

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