Indiana Professional Licensing Agency

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Michael R. Pence, Governor

Nicholas W. Rhoad, Executive Director

TO: Indiana Pharmacists and Pharmacies
FROM: Indiana Board of Pharmacy
RE: Corresponding Responsibility Guidance
DATE: March 10, 2014

Disclaimer: This document provides guidance to the regulated community and the general public on how the Indiana Board of Pharmacy ("Board") currently interprets the concept of "corresponding responsibility" for pharmacists as that term relates to the Indiana Medical Licensing Board's "pain management prescribing emergency rule," LSA #13-495(E). This document is advisory only and may be superseded at any time should conditions warrant. This guidance document does not substitute for statutory provisions or regulations, nor is it a regulation itself. Statutory provisions and regulations contain legally binding requirements. Where guidance herein conflicts with rules or laws, the rules or laws shall control. The guidance does not impose legally binding requirements on the Board or the regulated community, and might not apply to a particular situation based upon the circumstances. The Board retains the discretion to adopt approaches on a case-by-case basis that differ from this guidance where appropriate. Any decisions regarding a particular regulated individual or entity will be made on the basis of applicable statutes and regulations.

At the Board's February 10, 2014 meeting, the Board held a discussion with stakeholders regarding the Board's interpretation of the concept of "corresponding responsibility" as that term relates to the Indiana Medical Licensing Board's "pain management prescribing emergency rule," LSA #13-495(E). A copy of LSA #13-495(E) is attached to this guidance document for reference.

The Board does not interpret LSA #13-495(E) to place any new requirements on pharmacists to ensure a prescriber's compliance with the rule prior to dispensing. The Board does not expect pharmacists to take any specific action beyond exercising traditional professional judgment. Pharmacists should not fear disciplinary action from the Board for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice.

Section IX of the Drug Enforcement Administration's "Pharmacist Manual" states that "a pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription." The DEA "Pharmacist Manual" goes on to say that "the pharmacist who *deliberately ignores* a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances" (emphasis added).

Red flags that pharmacists should be aware of include: prescriptions for combinations of frequently abused controlled substances such as opiates, benzodiazepines, and muscle relaxants; prescriptions written from types of practitioners that normally do not prescribe controlled substances; patients or prescribers from outside of your local geographical region; similar quantities of similar drugs being prescribed by the same practitioner; and patients paying cash. This list is not comprehensive and a pharmacist who encounters a red flag should not automatically assign guilt to the patient or practitioner. However, a pharmacist that encounters a red flag should exercise his or her professional judgment and use critical thinking skills in making the determination as to whether or not the prescription should be filled.

The Board encourages pharmacists to utilize the State's prescription monitoring program, INSPECT. This tool provides useful information that may help a pharmacist determine whether or not a controlled substance prescription has been obtained for a legitimate medical purpose.

In conclusion, the Board does not expect pharmacists to practice medicine. The Medical Licensing Board's "pain management prescribing emergency rule" does not place any new requirements on pharmacists to ensure a prescriber's compliance with the rule prior to dispensing. Pharmacists should not fear discipline from this Board for filling controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice.

TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Emergency Rule
LSA Document #13-495(E)

DIGEST

Temporarily adds provisions under P.L.185-2013 (SEA 246) regarding physicians prescribing opioids for chronic pain. Effective December 15, 2013.

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 narcotics containing opium or one (1) or more of its natural or synthetic derivatives.

(f) "Outset of an opioid treatment plan" means that a patient has been prescribed opioids as described in SECTION 3(c) of this document, and, therefore, the provisions stated in SECTION 3(a) of this document 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.

SECTION 3. **(a) This SECTION and SECTIONS 4 through 11 of this document establish requirements concerning the use of opioids for chronic pain management for patients.**

(b) Notwithstanding subsection (a), this SECTION and SECTIONS 4 through 11 of this document 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; or
(2) a morphine equivalent dose of more than fifteen (15) milligrams per day;
for more than three (3) consecutive months.

(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), and 8(a) *[of this document]* **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 physicians conducts *[sic]* 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 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 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 or in addition to 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, 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 fourteen (14) and fifty-five (55) 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) 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.

(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 or taken.

(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 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.**

SECTION 8. **(a) At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall perform or order a 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 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 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) 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 document 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 document 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.

SECTION 11. **(a) Initial running of an INSPECT report as required under SECTION 7 of this document shall not be required for any patient who fell within the scope of SECTION 3(c) of this document before December 15, 2013. 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(c) of this document before January 1, 2015. 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 or annual conducting of a drug monitoring test.**

(b) Notwithstanding subsection (a) and SECTION 7 of this document, the first running of an annual INSPECT report under SECTION 7 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 sooner than required by this subsection.

(c) Notwithstanding SECTION 8(a) of this document, the first conducting of an annual drug monitoring test under SECTION 8(a) of this document shall not be required to be conducted before January 1, 2015. Nothing about this subsection shall be construed to prohibit a physician from conducting a test sooner than required by this subsection.

SECTION 12. SECTIONS 1 through 11 of this document take effect December 15, 2013.

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