

**TITLE 844 MEDICAL LICENSING BOARD OF INDIANA**

**Emergency Rule  
LSA Document #13-\_\_\_\_\_(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 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) 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 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 14 and 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 through 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.**

**TITLE 844 MEDICAL LICENSING BOARD OF INDIANA**

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Temporarily adds provisions regarding administrative authorizations to examine controlled substances prescribing records.

**SECTION 1. (a) This document establishes standards and procedures for the medical licensing board to authorize, where appropriate, the attorney general to examine a physician's records and controlled substances inventory and materials to investigate the physician's controlled substances prescribing practices and the physician's compliance with IC 25-22.5, IC 25-1-9, and 844 IAC in relation to controlled substances prescribing activities.**

**(b) Nothing in this document shall be interpreted or construed to abrogate, eliminate, reduce, restrict, or replace existing provisions authorizing the attorney general to issue subpoenas or civil investigative demands to investigate possible violations of IC 25-22.5, IC 25-1-9, and 844 IAC.**

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

**(b) All terms which are defined in IC 25-22.5 and IC 35-48 shall have the same meanings as they are so defined when used in this document.**

**(c) "Board" refers to the medical licensing board of Indiana established by IC 25-22.5-2-1.**

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

**(e) "Controlled substance registration" refers to registration required and permitted by IC 35-48-3.**

**(f) "OAG" refers to the office of attorney general.**

**(g) "Examination authorization" means an order issued by the board directing the OAG to examine records as specified in the order.**

**SECTION 3. (a) The OAG may file a verified petition with the board seeking an examination authorization.**

**(b) Subject to the provisions of this document, the board may issue an examination authorization if the board believes that the authorization is necessary for the OAG to conduct an investigation of a physician's controlled substance prescribing practices through review of relevant records.**

**(c) Examination authorizations may not be sought or issued for the purpose of unreasonably interfering with a physician's regular practice operations or for the purpose of imposing undue burden or expense on the physician.**

**SECTION 4. (a) The board may designate an individual member for purposes of reviewing a verified petition filed by the OAG and issuing an examination authorization.**

**(b) The board may designate an individual member for purposes of responding to a petition for modification, limitation, or discontinuance of an examination conducted pursuant to an examination authorization.**

**SECTION 5. (a) The board may issue an examination authorization permitting examination of records of a physician with a controlled substance registration or a physician engaging in activities for which a controlled substance registration is required.**

**(b) The OAG may petition the board for an examination authorization if the OAG has a good faith reason to believe that a physician may have violated or is likely to violate provisions of any statute or rule concerning the prescribing, dispensing, or administering of a controlled substance.**

**(c) A verified petition filed under this document shall include the following:**

- (1) facts establishing a good faith reason to believe that a violation of an applicable controlled substance prescribing, dispensing, or administrative statute or rule may have occurred or is likely to occur;**
- (2) an explanation of why the examination authorization is necessary to protect consumers or patients or to respond to a clear and immediate danger to public health and safety, including why issuance of a subpoena is not believed to be sufficient or appropriate under the circumstances;**
- (3) a description of the records or categories of records to be examined in enough specificity to allow the respondent physician to identify the documents at issue;**
- (4) a general description of the location or locations where the records are maintained or believed to be maintained; and**
- (5) a statement confirming that the request for access complies with 45 CFR § 164.512(f)(1)(ii)(C).**

**(d) After reviewing a verified petition filed under this rule, the board may issue an examination authorization. The examination authorization shall authorize the OAG to immediately inspect and copy records maintained by the physician concerning the prescribing, dispensing, or administering of a controlled substance.**

**(e) A physician that is the subject of an examination authorization issued by the board pursuant to this rule shall comply with the examination authorization and cooperate with the attorney general's reasonable efforts to carry out the examination authorization.**

**(f) In carrying out an examination authorization, the records authorized for examination by the board shall be produced to the OAG by the respondent physician in either printed format or in electronic format as agreed upon by the parties. If the parties cannot agree as to the format of production, the respondent physician shall produce the records in printed format.**

**(g) The OAG may not require production of records in electronic format under subsection (f) of this SECTION if they are not created or maintained in electronic format. If records are to be produced in electronic format, the OAG may specify that they shall be produced in either native format with all software necessary to read the electronic records, or in a complete, unencrypted manner that is easily readable without the use of proprietary software.**

**(h) Proof of license agreement preventing a respondent physician's compliance with subsection (f) of this SECTION is to be provided at the time the OAG executes an examination authorization; any such license agreement is subject for review as to authenticity by the OAG. If the agreement is found to be authentic and prevents a respondent physician's compliance with subsection (f) of this SECTION, the physician will not be considered noncompliant as to the electronic production of records but will however, be required to produce the records in printed format.**

**(i) Provisions regarding payment for copies in the Indiana Rules of Trial Procedure are applicable to copies made pursuant to an examination authorization; however, these provisions do not prohibit the board from ordering reimbursement of costs as provided under IC 25-1-9.**

**SECTION 6. (a) Every examination authorization issued under this document shall be in writing and include the following:**

- (1) requirements for the OAG to execute the authorization during the normal business hours of the physician's practice, unless a narrower timeframe is specified by the board;**
- (2) requirements for the OAG to execute the authorization within ten (10) business days of issuance, unless otherwise specified by the board;**
- (3) procedures that shall be followed by the OAG in conducting the examination to avoid unreasonable and unnecessary interference with the operation of the physician or the health care provider for which the physician works;**
- (4) notice to the physician of the physician's rights, including:**
  - (A) the right to be present and observe the examination and copying by the OAG, and the right to make an accounting of records examined and copied by the OAG;**
  - (B) the right to continue to conduct its health care practice without unreasonable and unnecessary interference by the OAG during the examination;**
  - (C) the right to consult with legal counsel in relation to rights specified in this rule and other applicable rights and remedies;**
  - (D) the right to petition the board for an order directing the OAG to modify, limit, or discontinue an examination conducted pursuant to this document if the physician believes that the examination is being carried out in a manner that is unreasonable or oppressive.**
- (5) notice to the physician that failure to cooperate with the examination authorization and that destruction, alteration, or removal of records that are the subject of the examination authorization may result in administrative sanctions by the board.**
- (6) requirements for the OAG to preserve the integrity of the physicians' original records.**

**(b) If the OAG has knowledge that the physician who is the subject of an examination authorization issued under this rule has retained an attorney to provide legal counsel in relation to pending consumer complaints that are being investigated, the OAG shall provide notice to the attorney upon execution of the examination authorization; however, the physician's representation by legal counsel shall not delay the physician's requirement to immediately comply with SECTION 5(e) of this document.**

**SECTION 7. (a) A physician may file a petition with the board requesting that the board:**

- (1) modify the terms or scope of the examination authorization that the board previously issued;**
- (2) limit the terms or scope of an examination authorization that the board previously issued; or**

(3) direct the OAG to discontinue an examination being conducted pursuant to an examination authorization that the board previously issued.

(b) In a petition filed under subsection (a) of this SECTION, a physician shall set forth reasons why the examination authorization should be modified, limited, or discontinued.

(c) Unless the board issues a temporary stay, the OAG's ability to continue conducting an examination pursuant to an examination authorization is not limited or affected during the pendency of the board's review of a petition by a physician under subsection (a) of this SECTION.

(d) The board may order the modification, limitation, or discontinuance of an examination authorization if the board finds that the physician has demonstrated any of the following:

- (1) the OAG has exceeded the scope or terms of the examination authorization;
- (2) the OAG has carried out the examination authorization in a manner that unreasonably interferes with the operation of the physician; or
- (3) that the examination is no longer necessary for the OAG to conduct an investigation of a physician's controlled substance prescribing practices.

(e) An order modifying, limiting, or discontinuing an examination authorization shall not be construed to require the OAG to return or disregard information and copies of records properly obtained pursuant to the examination authorization before its modification, limitation, or discontinuance. However, the OAG may not use records obtained by exceeding the scope of an examination authorization in a disciplinary proceeding involving the licensee. Records improperly obtained shall be returned to the physician or destroyed by the OAG based on agreement of the parties.

SECTION 8. (a) The board may consider failure to comply with an examination authorization issued under this rule as a violation of IC 25-1-9-4(a)(3) when a physician who is the subject of an examination authorization issued by the board pursuant to this rule:

- (1) fails to comply with the examination authorization; or
- (2) refuses to comply with the examination authorization.

(b) The board may take action under subsection (a) of this SECTION after a hearing if:

- (1) the OAG has brought a disciplinary action against the physician seeking sanctions under IC 25-1-9; or
- (2) the board has issued an order requiring the physician to show cause why the board should not impose disciplinary sanctions against the physician under IC 25-1-9.

SECTION 9. (a) An examination authorization issued by the board pursuant to this document shall not be considered to constitute "agency action" or "final agency action" as those terms are defined in IC 4-21.5-1-4 and IC 4-21.5-1-6 of the Administrative Orders and Procedures Act.

(b) The board has discretion to schedule a hearing to consider a petition for an examination authorization filed by the OAG. Nothing in this document shall be construed or interpreted to require a hearing or to provide a physician with hearing rights in relation to a petition filed by the OAG.

(c) The board has discretion to schedule a hearing to consider a petition filed by a physician under SECTION 7(a) of this document. Nothing in this document shall be construed or interpreted to



require a hearing or to provide a physician with hearing rights in relation to a petition filed by the physician.

(d) A petition for judicial review of an examination authorization under IC 4-21.5-5 may not be filed by a physician before:

- (1) all other available administrative remedies have been exhausted; and
- (2) the board takes action to impose disciplinary sanctions against the physician under IC 25-1-9.

SECTION 10. (a) Records relating to the following are subject to the confidentiality provisions, limitations, and exceptions in IC 25-1-7-10:

- (1) verified petitions requesting issuance of an examination authorization;
- (2) examination authorizations issued by the board;
- (3) petitions filed by physicians under SECTION 7(a) of this document; and
- (4) orders issued by the board modifying, limiting, or terminating examination authorizations under SECTION 7(e) of this document.

(b) Hearings held under SECTION 9 of this document are subject to IC 5-14-1.5, the open door law.