KRIEG DEVAULT

Insights

Indiana Boards to Adopt Rules to Align the Practice of Prescribing Controlled Substances to Patients with Chronic Pain

July 4, 2016

By: Brandon W. Shirley

The Indiana General Assembly passed legislation during the 2015 General Session directing certain boards to establish protocols and standards for prescribing controlled substances for pain management treatment that "complement" existing rules for physicians.[1] Those boards include: the Board of Podiatric Medicine (podiatrists); the Indiana Medical Licensing Board (physician assistants); the Indiana State Board of Dentistry (dentists); and the Indiana State Board of Nursing (advanced practice nurses with prescription authority).[2] Indiana law also required the medical licensing board to establish, by rule, protocols for "opioid abuse deterrent formulations."[3] The law directed each board to adopt the rules prior to March 1, 2016, although the rules are still in the early stages of being drafted and will not be finalized until later this year. If adopted without modification, the rules will essentially impose the same exceptions and requirements for physicians on all regulated non-physicians.

LSA #15-415 Physicians

LSA #15-415 proposes to require physicians prescribing controlled substances at certain levels for chronic pain to "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 is prescribing to the patient."[4] In essence, "abuse deterrent formulations" are opioids that are chemically altered in order to discourage, but not prevent, patients who may abuse such drugs. The proposal does not require a physician to prescribe an abuse deterrent formulation.

The proposed rule does not change existing provisions except that now physicians treating 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 16-28; and (4) patients enrolled in an outpatient or inpatient palliative care program of a hospital licensed under IC 16-21 or a hospice licensed under IC 16-25.[5] As such, the proposed rule only impacts those physicians who are not excepted by the existing rule and who prescribe controlled substances above a certain level ("triggering provision"). A regulated physician may be subject to disciplinary actions under existing rules for failing to follow this new requirement.[6]

Next action: The Indiana Medical Licensing Board intends to hold a public hearing to accept public comment on the proposed rule on **June 23, 2016, at 2:00 p.m.** at the Indiana Government Center South Building, 402 West Washington Street, Room W064, Indianapolis, Indiana. The board anticipates a rule effective date of October 1, 2016.[7]

LSA #15-420 (physician assistants); 15-380 (advanced practice nurses with prescriptive authority); 15-416 (podiatrists)

Three other proposed rules impose the same physician requirements and exceptions, including the triggering provision, on physician assistants, advanced practice nurses with prescriptive authority, and podiatrists (collectively, “non-physicians”). These new rules also include the proposed changes found in the physician rule (LSA #15-415) regarding opioid deterrent formulations. Thus, if adopted without any change, all non-physicians prescribing controlled substances for chronic pain treatment to patients at certain levels will be subject to the same standards and treatment protocols that presently apply to physicians.

The propose rules expressly exempt non-physicians who do not prescribe opioids for chronic pain management to: (1) patients with a terminal condition; (2) residents of a health facility[8] licensed by the Indiana State Department of Health (ISDH); (3) patients enrolled in a hospice program licensed by the ISDH; or (4) patients enrolled in an inpatient or outpatient palliative care program of a hospital licensed by the ISDH (collectively, “covered non-physicians”). Additionally, the covered non-physician must comply with the requirements only when he or she prescribes: (a) more than 60 opioid containing pills in a month for more than three consecutive months; (b) a morphine equivalent dose of more than 15 milligrams per day for more than 3 consecutive months; (c) a transdermal opioid patch for more than 3 consecutive months; (d) tramadol, but only if the patient’s tramadol dose reaches a morphine equivalent dose of more than 60 milligrams per day for more than 3 consecutive months; or (e) an extended release opioid medication that is not in an abuse deterrent form for which an abuse deterrent form is available.

Under the proposed rule, covered non-physicians whose prescribing practices meet the triggering provision must:

- Conduct a comprehensive assessment of the patient and the patient’s medical history, assess the patient’s risk for substance abuse, and develop a treatment plan with meaningful goals. The covered non-physician shall, when medically appropriate, utilize non-opioid options as alternatives to opiates.
- Educate patients about the risks and benefits of opioid treatment including alternatives for pain management. The rules accomplish this objective by requiring that the covered non-physician discuss certain matters and closely monitor the patient’s use of prescription opiates.
- Conduct mandatory face-to-face visits at varying intervals with patients in order to continue the medication regimen.
- Check and update INSPECT.
- Perform or order a drug monitoring test when the covered non-physician determines that it is medically necessary in consideration of various facts and circumstances including the patient’s use or misuse of controlled substances. The covered non-physician must review the treatment plan if a drug test reveals inconsistent medication use.
- Immediately schedule a face-to-face interview with and evaluate the patient to cover the treatment plan if a patient's opioid dose reaches a morphine equivalent dose of more than 60 milligrams per day.

Next action: LSA 15-420. The Indiana Medical Licensing Board will hold a public hearing to accept public comment on the proposed rule on **June 23, 2016, at 2:00 p.m**. at the Indiana Government Center South, 402 West Washington Street, Room W064, Indianapolis, Indiana.[9]

Next action: LSA 15-380. The Indiana State Board of Nursing will hold a public hearing to accept public comment on the proposed rule on **June 16, 2016, at 2:00 p.m**., local time, in the Auditorium of the Indiana Government Center South, 402 West Washington Street, Indianapolis, Indiana.[10]

Next action: LSA 15-416. The Board of Podiatric Medicine held a public hearing on May 13, 2016. The board has adopted the rule and sent it to the Attorney General’s office for approval and expects it to be effective on

August 22, 2016,[11] though such date could occur sooner.

LSA #15-378 Dentists

LSA 15-378 also imposes the same requirements on dentists using controlled substances to treat chronic pain, but due to the nature of that practice, the rule does so more succinctly. For instance, the proposed rule codifies the same exemptions and prescribing limits that trigger the rule's requirements for physicians.[12] However, the proposed rule states that dentists do not generally prescribe opiates at the levels that would trigger the rule's requirements.[13] Accordingly, a dentist who prescribes opiates at such levels shall become subject to the physician prescribing requirements under 844 IAC 5-6.[14]

Next action: LSA 15-378. The Indiana State Board of Dentistry held a public hearing on June 10, 2016, at 9:15 a.m., at the Indiana Government Center South, 402 West Washington Street, Room W064, Indianapolis, Indiana.[15] This board amended the rule to require the dentist to refer the patient to a physician if treatment falls outside the dentist's scope of practice.

We plan on attending the upcoming public hearings to monitor public testimony and will keep you apprised of the significant content of testimony and comments regarding the proposed rules and their progress to final rule. Interested parties may attend to provide written or oral comments, or in the alternative, we can provide the written or oral comments to the boards for consideration on your behalf during the public hearings. You may also submit written public comments to the boards at any time prior to the public hearings. You can see a list of the proposed rules, including the closing of the public comment period, by clicking here: http://www.in.gov/pla/3429.htm.

For more information about the proposed rules, please contact Brandon Shirley at bshirley@kdlegal.com.

[1] *See* SEA 534, available at https://iga.in.gov/static-documents/7/0/5/b/705bfac5/SB0534.04.ENRS.pdf.

[2] Ind. Code § 25-22.5-13-3(a).

[3] Ind. Code § 25-22.5-13-2. Version b.

[4] LSA #15-415 amending 844 IAC 5-6-5.

[5] 844 IAC 5-6-3(b).

[6] 844 IAC 5-1-3.

[7] LSA #15-415, IPLA rulemaking docket, available at http://www.in.gov/pla/3429.htm.

[8] The term "health facility" is defined to mean the place for the reception, accommodation, board, care, or treatment extending beyond a continuous 24 hour period in a week of more than four (4) individuals who need or desire such services because of physical or mental illness, infirmity, or impairment.

[9] LSA #15-420, Notice of Public Hearing, http://www.in.gov/legislative/iac/20160601-IR-844150420PHA.xml.pdf.

[10] LSA #15-380, Notice of Public Hearing, http://www.in.gov/legislative/iac/20160525-IR-848150380PHA.xml.pdf.

[11] IPLA Rulemaking Docket, http://www.in.gov/pla/3429.htm.

[12] *See* LSA #15-378, http://www.in.gov/legislative/iac/20160518-IR-828150378PRA.xml.pdf.

[13] *Id*.

[14] *Id*.

[15] LSA #15-378 Notice of Public Hearing, http://www.in.gov/legislative/iac/20160518-IR-828150378PHA.xml.pdf.