ARTICLE 2. OPIOID PRESCRIBING REQUIREMENTS

Rule 1. General Provisions

845 IAC 2-1-1 Scope

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-29

Sec. 1. This rule establishes standards and protocols for podiatrists in the prescribing of opioid controlled substances for pain management treatment. *(Board of Podiatric Medicine; 845 IAC 2-1-1; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)*

845 IAC 2-1-2 Definitions

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-29; 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.

(Board of Podiatric Medicine; 845 IAC 2-1-2; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)

845 IAC 2-1-3 Triggers for imposition of requirements; exemptions

Authority: IC 25-22.5-13-3
Affected: IC 16-21; IC 16-25; IC 16-28; IC 25-1-9; IC 25-29

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 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 podiatrist may undertake those actions earlier than required if the podiatrist deems it medically appropriate and, if those actions meet the requirements, a further initial evaluation is not required. If the podiatrist 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. *(Board of Podiatric Medicine; 845 IAC 2-1-3; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)*

845 IAC 2-1-4 Evaluation and risk stratification by podiatrist

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-29

Sec. 4. (a) The podiatrist shall do the podiatrist'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 podiatrist'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 podiatrist shall utilize nonopioid options instead of or in addition to prescribing opioids. *(Board of Podiatric Medicine; 845 IAC 2-1-4; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)*

845 IAC 2-1-5 Podiatrist discussion with patient; treatment agreement

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-29

Sec. 5. The podiatrist 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 podiatrist 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 podiatrist 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 podiatrist is prescribing to the patient.

(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 podiatrist determines that drug monitoring testing is medically necessary.

(C) The podiatrist'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 podiatrist:

(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 podiatrist to conduct random pill counts.

(F) Reasons the opioid therapy may be changed or discontinued by the podiatrist.

A copy of the treatment agreement shall be retained in the patient's chart.

(Board of Podiatric Medicine; 845 IAC 2-1-5; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)

845 IAC 2-1-6 Patient visits to podiatrist

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-29

Sec. 6. (a) Podiatrists 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 podiatrist to achieve optimal management. For patients requiring changes to the medication and treatment plan, if changes are prescribed by the podiatrist, 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 podiatrist 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. *(Board of Podiatric Medicine; 845 IAC 2-1-6; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)*

845 IAC 2-1-7 INSPECT report

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-26-24-19; IC 25-29

Sec. 7. At the outset of an opioid treatment plan, and at least annually thereafter, a podiatrist prescribing opioids for a patient shall run an INSPECT report on that patient under IC 35-48-7-11.1(d)(4) *[IC 35-48-7 was repealed by P.L.51-2019, SECTION 21, effective April 18, 2019. See IC 25-26-24-19.]* and document in the patient's chart whether the INSPECT report is consistent with the podiatrist's knowledge of the patient's controlled substance use history. *(Board of Podiatric Medicine; 845 IAC 2-1-7; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)*

845 IAC 2-1-8 Drug monitoring testing

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-29

Sec. 8. (a) At any time the podiatrist determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, a podiatrist 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 podiatrist 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 podiatrist and any other treating podiatrists.

(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 podiatrist 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 podiatrist to fail to conduct a review of all eighteen (18) factors listed in subsection (b) if the podiatrist 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 podiatrist from performing or ordering a drug monitoring test at any other time the podiatrist 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. *(Board of Podiatric Medicine; 845 IAC 2-1-8; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)*

845 IAC 2-1-9 Morphine equivalent doses above 60; revising of assessments and treatment plans

Authority: IC 25-22.5-13-3
Affected: IC 25-1-9; IC 25-29

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 podiatrist elects to continue providing opioid therapy at a morphine equivalent dose of more than sixty (60) milligrams per day, the podiatrist 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 podiatrist elects to provide ongoing opioid treatment. *(Board of Podiatric Medicine; 845 IAC 2-1-9; filed Jul 15, 2016, 10:27 a.m.: 20160810-IR-845150416FRA)*

*