ARTICLE 5. PRESCRIPTIVE AUTHORITY FOR ADVANCED PRACTICE NURSING

Rule 1. Prescriptive Authority

848 IAC 5-1-1 Initial authority to prescribe legend drugs

Authority: IC 25-23-1-7
Affected: IC 25-23-1

Sec. 1. (a) An advanced practice nurse may be authorized to prescribe legend drugs, including controlled substances, if the advanced practice nurse does the following:

1) Submits an application on a form prescribed by the board with the required fee, including, but not limited to, the following information:

(A) Complete name, residence and office addresses with zip codes, and residence and business telephone numbers with area codes.
(B) All names used by the applicant, explaining the reasons for any name change or use.
(C) Date and place of birth.
(D) Citizenship and visa status, if applicable.
(E) A complete statement of all nursing education received, including:
   (i) Names and locations of all colleges, schools, or universities attended.
   (ii) Dates of attendance.
   (iii) Degrees obtained or received.
(F) Whether the applicant has ever had any disciplinary action taken against the applicant's nursing license by the board or by the licensing agency of any other state or jurisdiction and the details and dates thereof.
(G) A complete list of all places of employment, including:
   (i) The names and addresses of employers.
   (ii) The dates of each employment.
   (iii) Employment responsibilities held or performed that the applicant had since graduation from nursing school.
(H) Whether the applicant is, or has been, addicted to any narcotic drug, alcohol, or other drugs and, if so, the details thereof.
(I) Whether the applicant has been convicted of any violation of law relating to drug abuse, controlled substances, narcotic drugs, or any other drugs.
(J) Whether the applicant has previously been licensed to practice nursing in any other state or jurisdiction and, if so, the following:
   (i) The names of such states or jurisdictions that previously licensed the applicant.
   (ii) The dates of such licensure.
   (iii) The license number.
   (iv) The current status of such licensure.
(K) Whether the applicant has been denied a license to practice nursing by any state or jurisdiction and, if so, the details thereof, including:
   (i) The name and location of the state or jurisdiction denying licensure.
   (ii) The date of denial of such licensure.
   (iii) The reasons relating thereto.
(L) A certified statement that the applicant has not been convicted of a criminal offense (excluding minor traffic violations) or a certified statement listing all criminal offenses of which the applicant has been convicted. This listing must include the following:
   (i) The offense of which the applicant was convicted.
   (ii) The court in which the applicant was convicted.
   (iii) The cause number in which the applicant was convicted.
(M) All information in the application shall be submitted under oath or affirmation, subject to the penalties for perjury.
(2) Submits proof of holding an active, unrestricted:
   (A) Indiana registered nurse license; or
   (B) registered nurse license in another compact state and having filed a Multi-state Privilege Notification Form with the health professions bureau.
(3) Submits proof of having met the requirements of all applicable laws for practice as an advanced practice nurse in the state of Indiana.
(4) Submits proof of a baccalaureate or higher degree in nursing.
(5) If the applicant holds a baccalaureate degree only, submits proof of certification as a nurse practitioner or certified nurse-midwife by a national organization recognized by the board and which requires a national certifying examination.
(6) Submits proof of having successfully completed a graduate level pharmacology course consisting of at least two (2) semester hours of academic credit from a college or university accredited by the Commission on Recognition of Postsecondary Accreditation:
   (A) within five (5) years of the date of application; or
   (B) if the pharmacology course was completed more than five (5) years immediately preceding the date of filing the application, the applicant must submit proof of the following:
      (i) Completing at least thirty (30) actual contact hours of continuing education during the two (2) years immediately preceding the date of the application, including a minimum of at least eight (8) actual contact hours of pharmacology, all of which must be approved by a nationally approved sponsor of continuing education for nurses.
      (ii) Prescriptive experience in another jurisdiction within the five (5) years immediately preceding the date of the application.
(7) Submits proof of collaboration with a licensed practitioner in the form of a written practice agreement that sets forth the manner in which the advanced practice nurse and licensed practitioner will cooperate, coordinate, and consult with each other in the provision of health care to patients. Practice agreements shall be in writing and shall also set forth provisions for the type of collaboration between the advanced practice nurse and the licensed practitioner and the reasonable and timely review by the licensed practitioner of the prescribing practices of the advanced practice nurse. Specifically, the written practice agreement shall contain at least the following information:
   (A) Complete names, home and business addresses, zip codes, and telephone numbers of the licensed practitioner and the advanced practice nurse.
   (B) A list of all other offices or locations besides those listed in clause (A) where the licensed practitioner authorized the advanced practice nurse to prescribe.
   (C) All specialty or board certifications of the licensed practitioner and the advanced practice nurse.
   (D) The specific manner of collaboration between the licensed practitioner and the advanced practice nurse, including how the licensed practitioner and the advanced practice nurse will:
      (i) work together;
      (ii) share practice trends and responsibilities;
      (iii) maintain geographic proximity; and
      (iv) provide coverage during absence, incapacity, infirmity, or emergency by the licensed practitioner.
   (E) A description of what limitation, if any, the licensed practitioner has placed on the advanced practice nurse's prescriptive authority.
   (F) A description of the time and manner of the licensed practitioner's review of the advanced practice nurse's prescribing practices. The description shall include provisions that the advanced practice nurse must submit documentation of the advanced practice nurse's prescribing practices to the licensed practitioner within seven (7) days. Documentation of prescribing practices shall include, but not be limited to, at least a five percent (5%) random sampling of the charts and medications prescribed for patients.
   (G) A list of all other written practice agreements of the licensed practitioner and the advanced practice nurse.
   (H) The duration of the written practice agreement between the licensed practitioner and the advanced practice nurse.
(8) Written practice agreements for advanced practice nurses applying for prescriptive authority shall not be valid until prescriptive authority is granted by the board.
(b) When the board determines that the applicant has met the requirements under subsection (a), the board shall send written notification of authority to prescribe to the advanced practice nurse, including the identification number and designated authorized initials to be used by the advanced practice nurse.

(c) Advanced practice nurses who have been granted prescriptive authority will immediately notify the board in writing of any changes in, or termination of, written practice agreements, including any changes in the prescriptive authority of the collaborating licensed practitioner. Written practice agreements shall terminate automatically if the advanced practice nurse or licensed practitioner no longer has an active, unrestricted license.

(d) Advanced practice nurses wishing to prescribe controlled substances must obtain an Indiana controlled substances registration and a federal Drug Enforcement Administration registration. *(Indiana State Board of Nursing; 848 IAC 5-1-1; filed Jul 29, 1994, 5:00 p.m.: 17 IR 2876; readopted filed Nov 6, 2001, 4:18 p.m.: 25 IR 940; filed Dec 24, 2003, 10:45 a.m.: 27 IR 1571; readopted filed Nov 17, 2010, 9:50 a.m.: 20101215-IR-848100406RFA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)*

848 IAC 5-1-2 Prescribing legend drugs; use of forms (Repealed)

Sec. 2. *(Repealed by Indiana State Board of Nursing; filed Dec 19, 1996, 10:00 a.m.: 20 IR 1122)*

848 IAC 5-1-3 Renewal of authority to prescribe legend drugs

Authority: IC 25-23-1-7
Affected: IC 25-23-1

Sec. 3. (a) Prescriptive authority for the advanced practice nurse expires on October 31 in each odd-numbered year. Failure to renew the prescriptive authority on or before the expiration date will automatically render the authority invalid without any action by the board.

(b) A notice of expiration and instructions for renewal of the authority to prescribe legend drugs will be mailed in odd-numbered years with the renewal for registered nurse licensure.

(c) Applicants for renewal of the prescriptive authority shall pay a renewal fee in addition to the fee for renewal of the registered nurse license.

(d) The notice of expiration for renewal of the prescriptive authority shall be mailed to the last known address of the licensee. Failure to receive the application for renewal shall not relieve the licensee of the responsibility for renewing the registered nurse license and the authorization to prescribe by the renewal date.

(e) Applicants for renewal of prescriptive authority shall submit the following to the board along with the renewal form and fee:

1. Proof of at least thirty (30) actual contact hours of continuing education during the two (2) years immediately preceding renewal, including at least eight (8) actual contact hours of pharmacology, approved by a nationally approved sponsor of continuing education for nurses.

2. A current signed and dated written collaborative practice agreement that contains all of the information required under section 1 of this rule.

*(Indiana State Board of Nursing; 848 IAC 5-1-3; filed Jul 29, 1994, 5:00 p.m.: 17 IR 2876; readopted filed Nov 6, 2001, 4:18 p.m.: 25 IR 940; filed Dec 24, 2003, 10:45 a.m.: 27 IR 1573; readopted filed Nov 17, 2010, 9:50 a.m.: 20101215-IR-848100406RFA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)*

Rule 2. Limitations of Rules

848 IAC 5-2-1 Limitations of rules

Authority: IC 25-23-1-7
Affected: IC 25-23-1

Sec. 1. No written practice agreement shall be necessary unless the advanced practice nurse seeks prescriptive authority.
Rule 3. Fees for Prescriptive Authority

848 IAC 5-3-1 Fees for prescriptive authority

Sec. 1. (a) The application fee for an advanced practice nurse to receive prescriptive authority shall be fifty dollars ($50).
(b) The fee for renewal of advanced practice nurse prescriptive authority shall be ten dollars ($10).
(c) The fee for a duplicate wall certificate for advanced practice nurse prescriptive authority shall be ten dollars ($10).
(d) The fee for written verification of advanced practice nurse prescriptive authority shall be ten dollars ($10).

Rule 4. Opioid Prescribing Requirements

848 IAC 5-4-1 Scope

Sec. 1. This rule establishes standards and protocols for advanced practice nurses with prescriptive authority in the prescribing of opioid controlled substances for pain management treatment.

848 IAC 5-4-2 Definitions

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.

(Indiana State Board of Nursing; 848 IAC 5-4-2; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)

848 IAC 5-4-3 Triggers for imposition of requirements; exemptions
Authority:   IC 25-22.5-13-3; IC 25-23
Affected:   IC 16-21; IC 16-25; IC 16-28; IC 25-1-9; IC 25-23

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 advanced practice nurse with prescriptive authority may undertake those actions earlier than required if the advanced practice nurse with prescriptive authority deems it medically appropriate and, if those actions meet the requirements, a further initial evaluation is not required. If the advanced practice nurse with prescriptive authority 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. (Indiana State Board of Nursing; 848 IAC 5-4-3; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)

848 IAC 5-4-4 Evaluation and risk stratification by advanced practice nurses with prescriptive authority
Authority:   IC 25-22.5-13-3; IC 25-23-1-7
Affected:   IC 25-1-9; IC 25-23

Sec. 4. (a) The advanced practice nurse with prescriptive authority shall do his or her 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 advanced practice nurse with prescriptive authority'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 advanced practice nurse with prescriptive authority shall utilize nonopioid options instead of or in addition to prescribing opioids. (Indiana State Board of Nursing; 848 IAC 5-4-4; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)

848 IAC 5-4-5 Advanced practice nurse with prescriptive authority discussion with patient; treatment agreement

Authority: IC 25-22.5-13-3; IC 25-23-1-7
Affected: IC 25-1-9; IC 25-23

Sec. 5. The advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority determines that drug monitoring testing is medically necessary.
   C. The advanced practice nurse with prescriptive authority'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 advanced practice nurse with prescriptive authority:
      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 advanced practice nurse with prescriptive authority to conduct random pill counts.
   F. Reasons the opioid therapy may be changed or discontinued by the advanced practice nurse with prescriptive authority.

A copy of the treatment agreement shall be retained in the patient's chart. (Indiana State Board of Nursing; 848 IAC 5-4-5; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)
848 IAC 5-4-6 Patient visits to advanced practice nurse with prescriptive authority

Authority: IC 25-22.5-13-3; IC 25-23-1-7
Affected: IC 25-1-9; IC 25-23

Sec. 6. (a) Advanced practice nurses with prescriptive authority 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 advanced practice nurse with prescriptive authority to achieve optimal management. For patients requiring changes to the medication and treatment plan, if changes are prescribed by the advanced practice nurse with prescriptive authority, 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 advanced practice nurse with prescriptive authority 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. (Indiana State Board of Nursing; 848 IAC 5-4-6; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)

848 IAC 5-4-7 INSPECT report

Authority: IC 25-22.5-13-3; IC 25-23-1-7
Affected: IC 25-1-9; IC 25-23; IC 35-48-7-11.1

Sec. 7. At the outset of an opioid treatment plan, and at least annually thereafter, an advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority's knowledge of the patient's controlled substance use history. (Indiana State Board of Nursing; 848 IAC 5-4-7; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)

848 IAC 5-4-8 Drug monitoring testing

Authority: IC 25-22.5-13-3; IC 25-23-1-7
Affected: IC 25-1-9; IC 25-23

Sec. 8. (a) At any time the advanced practice nurse with prescriptive authority determines that it is medically necessary, whether at the outset of an opioid treatment plan, or any time thereafter, an advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority 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.
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(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 advanced practice nurse with prescriptive authority 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 an advanced practice nurse with prescriptive authority to fail to conduct a review of all eighteen (18) factors listed in subsection (b) if the advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority from performing or ordering a drug monitoring test at any other time the advanced practice nurse with prescriptive authority 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. (Indiana State Board of Nursing: 848 IAC 5-4-8; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)

848 IAC 5-4-9 Morphine equivalent doses above 60; revising of assessments and treatment plans

Authority: IC 25-22.5-13-3; IC 25-23-1-7
Affected: IC 25-1-9; IC 25-23

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 advanced practice nurse with prescriptive authority elects to continue providing opioid therapy at a morphine equivalent dose of more than sixty (60) milligrams per day, the advanced practice nurse with prescriptive authority 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 advanced practice nurse with prescriptive authority elects to provide ongoing opioid treatment. (Indiana State Board of Nursing: 848 IAC 5-4-9; filed Aug 10, 2016, 1:52 p.m.: 20160907-IR-848150380FRA; readopted filed Nov 22, 2016, 12:13 p.m.: 20161221-IR-848160318RFA)