

201 KAR 20:057. Scope and standards of practice of advanced practice registered nurses.

RELATES TO: KRS 218A.172, 218A.205(3)(a), (b), 314.011(7), 314.011(8), 314.042, 314.193(2), 314.195, 314.196, National Transportation Safety Board Safety Recommendation 1-14-1.

STATUTORY AUTHORITY: KRS 218A.205(3)(a), (b), 314.131(1), 314.193(2)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.205(3)(a) and (b) require the Board of Nursing, in consultation with the Kentucky Office of Drug Control Policy, to establish by administrative regulation mandatory prescribing and dispensing standards for licensees authorized to prescribe or dispense controlled substances, and in accordance with the Centers for Disease Control and Prevention (CDC) guidelines, to establish a prohibition on a practitioner issuing a prescription for a Schedule II controlled substance for more than a three (3) day supply if intended to treat pain as an acute medical condition, unless an exception applies. KRS 314.131(1) authorizes the board to promulgate administrative regulations necessary to enable it to carry into effect the provisions of KRS Chapter 314. KRS 314.193(2) authorizes the board to promulgate administrative regulations establishing standards for the performance of advanced practice registered nursing to safeguard the public health and welfare. This administrative regulation establishes the scope and standards of practice for an advanced practice registered nurse.

Section 1. Definitions. (1) "Collaboration" means the relationship between the advanced practice registered nurse and a physician in the provision of prescription medication, including both autonomous and cooperative decision-making, with the advanced practice registered nurse and the physician contributing their respective expertise.

(2) "Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Controlled Substances" or "CAPA-CS" means the written document pursuant to KRS 314.042(10).

(3) "Collaborative Agreement for the Advanced Practice Registered Nurse's Prescriptive Authority for Nonscheduled Legend Drugs" or "CAPA-NS" means the written document pursuant to KRS 314.042(8).

(4) "KASPER" means the Kentucky All Schedule Prescription Electronic Reporting system established in KRS 218A.202.

Section 2. (1) The practice of the advanced practice registered nurse shall be in accordance with the standards and functions defined in scope and standards of practice statements adopted by the board in subsection (2) of this section.

(2) The following scope and standards of practice statements shall be adopted:

- (a) AACN Scope and Standards for Acute Care Nurse Practitioner Practice;
- (b) AACN Scope and Standards for Acute Care Clinical Nurse Specialist Practice;
- (c) Neonatal Nursing: Scope and Standards of Practice;
- (d) Nursing: Scope and Standards of Practice;
- (e) Pediatric Nursing: Scope and Standards of Practice;
- (f) Psychiatric-Mental Health Nursing: Scope and Standards of Practice;
- (g) Scope of Practice for Nurse Practitioners;
- (h) Standards of Practice for Nurse Practitioners;
- (i) Scope of Nurse Anesthesia Practice;
- (j) Standards for Nurse Anesthesia Practice;
- (k) Standards for Office Based Anesthesia Practice;

- (l) Standards for the Practice of Midwifery;
- (m) Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and Advanced Practice;
- (n) The Women's Health Nurse Practitioner: Guidelines for Practice and Education; and
- (o) Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives.

Section 3. In the performance of advanced practice registered nursing, the advanced practice registered nurse shall seek consultation or referral in those situations outside the advanced practice registered nurse's scope of practice.

Section 4. Advanced practice registered nursing shall include prescribing medications and ordering treatments, devices, and diagnostic tests, and performing certain procedures which are consistent with the scope and standards of practice of the advanced practice registered nurse.

Section 5. Advanced practice registered nursing shall not preclude the practice by the advanced practice registered nurse of registered nursing practice as defined in KRS 314.011(6).

Section 6. (1)(a) A CAPA-NS and a CAPA-CS shall include the name, practice address, phone number, and license number of both the advanced practice registered nurse and each physician who is a party to the agreement. It shall also include the population focus and area of practice of the advanced practice registered nurse.

(b) Pursuant to KRS 314.196(2), an advanced practice registered nurse shall use the Common CAPA-NS Form.

(2)(a) To notify the board of the existence of a CAPA-NS pursuant to KRS 314.042(8)(b), the APRN shall file with the board the APRN Prescriptive Authority Notification Form.

(b) To notify the board that the requirements of KRS 314.042(9) have been met and that the APRN will be prescribing nonscheduled legend drugs without a CAPA-NS, the APRN shall file the APRN Prescriptive Authority Notification Form.

(c) To notify the board of the existence of a CAPA-CS pursuant to KRS 314.042(10)(b), the APRN shall file with the board the APRN Prescriptive Authority Notification Form.

(3) For purposes of the CAPA-NS and the CAPA-CS, in determining whether the APRN and the collaborating physician are qualified in the same or a similar specialty, the board shall be guided by the facts of each particular situation and the scope of the APRN's and the physician's actual practice.

(4)(a) An APRN with a CAPA-CS shall report all of his or her United States Drug Enforcement Agency (DEA) Controlled Substance Registration Certificate numbers to the board when issued to the APRN by mailing a copy of each registration certificate to the board within thirty (30) days of issuance.

(b) Any change in the status of a DEA Controlled Substance Registration Certificate, including a DEA-X Controlled Substance Registration Certificate, shall be reported in writing to the board within thirty (30) days.

(5) An APRN shall report any changes to a CAPA-CS in writing to the board within thirty (30) days.

(6) If the collaborating physician's license is suspended, the APRN shall follow the procedures set out in KRS 314.196 for a CAPA-NS. The APRN with a CAPA-CS shall cease prescribing controlled substances until the suspension is lifted or a new collaborating physician signs a new CAPA-CS.

(7) An APRN with a CAPA-NS or a CAPA-CS shall report a practice address to the board. A change to the practice address shall be reported to the board within thirty (30) days.

Section 7. Prescribing medications without a CAPA-NS or a CAPA-CS shall constitute a violation of KRS 314.091(1), except when a CAPA-NS has been discontinued pursuant to KRS 314.042(9) or the provisions of KRS 314.196(4)(b) apply.

Section 8. The board may make an unannounced visit to an advanced practice registered nurse to determine if the advanced practice registered nurse's practice is consistent with the requirements established by KRS Chapter 314 and 201 KAR Chapter 20, and patient and prescribing records shall be made available for immediate inspection.

Section 9. Prescribing Standards for Controlled Substances. (1)(a) This section shall apply to an APRN with a CAPA-CS if prescribing a controlled substance. It also applies to the utilization of KASPER.

(b) The APRN shall practice according to the applicable scope and standards of practice for the APRN's role and population focus. This section does not alter the prescribing limits set out in KRS 314.011(8).

(2) Prior to the initial prescribing of a controlled substance to a patient, the APRN shall:

(a) Obtain the patient's medical history, including history of substance use, and conduct an examination of the patient and document the information in the patient's medical record. An APRN certified in psychiatric/mental health shall obtain a medical and psychiatric history, perform a mental health assessment, and document the information in the patient's medical record;

(b) Query KASPER for the twelve (12) month period immediately preceding the request for available data on the patient and maintain all KASPER report identification numbers and the date of issuance of each KASPER report in the patient's record;

(c) Develop a written treatment plan stating the objectives of the treatment and further diagnostic examinations required; and

(d) Discuss with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate:

1. The risks and benefits of the use of controlled substances, including the risk of tolerance and drug dependence;

2. That the controlled substance shall be discontinued when the condition requiring its use has resolved; and

3. Document that the discussion occurred and obtain written consent for the treatment.

(3) The treatment plan shall include an exit strategy, if appropriate, including potential discontinuation of the use of controlled substances.

(4) For subsequent or continuing long-term prescriptions of a controlled substance for the same medical complaint, the APRN shall:

(a) Update the patient's medical history and document the information in the patient's medical record;

(b) Modify and document changes to the treatment plan as clinically appropriate; and

(c) Discuss the risks and benefits of any new controlled substances prescribed with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence.

(5) During the course of treatment, the APRN shall query KASPER no less than once every three (3) months for the twelve (12) month period immediately preceding the request for available data on the patient before issuing a new prescription or a refill for a controlled substance.

The APRN shall maintain all KASPER report identification numbers and the date of issuance of each KASPER report in the patient's record.

(6) These requirements may be satisfied by other licensed practitioners in a single group practice if:

- (a) Each licensed practitioner involved has lawful access to the patient's medical record;
- (b) Each licensed practitioner performing an action to meet these requirements is acting within the scope of practice of his or her profession; and
- (c) There is adequate documentation in the patient's medical record reflecting the actions of each practitioner.

(7) If prescribing a controlled substance for the treatment of chronic, noncancer pain, the APRN, in addition to the requirements of this section, shall obtain a baseline drug screen and further random drug screens if the APRN:

- (a) Finds a drug screen to be clinically appropriate; or
- (b) Believes that it is appropriate to determine whether or not the controlled substance is being taken by the patient.

(8) If prescribing a controlled substance for the treatment of a mental health condition, the APRN shall meet the requirements of this section and KRS 314.011(8)(a) and (b).

(9) Prior to prescribing a controlled substance for a patient in the emergency department of a hospital that is not an emergency situation, the APRN shall:

(a) Obtain the patient's medical history, conduct an examination of the patient and document the information in the patient's medical record. An APRN certified in psychiatric/mental health shall obtain a medical and psychiatric history, perform a mental health assessment, and document the information in the patient's medical record;

(b) Query KASPER for the twelve (12) month period immediately preceding the request for available data on the patient and document the data in the patient's record;

(c) Develop a written treatment plan stating the objectives of the treatment and further diagnostic examinations required; and

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence, and document that the discussion occurred and that the patient consented to the treatment.

(10) For each patient for whom an APRN prescribes a controlled substance, the APRN shall keep accurate, readily accessible, and complete medical records, which include:

- (a) Medical history and physical or mental health examination;
- (b) Diagnostic, therapeutic, and laboratory results;
- (c) Evaluations and consultations;
- (d) Treatment objectives;
- (e) Discussion of risk, benefits, and limitations of treatments;
- (f) Treatments;
- (g) Medications, including date, type, dosage, and quantity prescribed;
- (h) Instructions and agreements;
- (i) Periodic reviews of the patient's file; and
- (j) All KASPER report identification numbers and the date of issuance of each KASPER report.

(11) The requirement to query KASPER shall not apply to:

(a) An APRN prescribing or administering a controlled substance immediately prior to, during, or within the fourteen (14) days following an operative or invasive procedure or a delivery if the prescribing or administering is medically related to the operative or invasive procedure or the delivery and the medication usage does not extend beyond the fourteen (14) days;

(b) An APRN prescribing or administering a controlled substance necessary to treat a patient in an emergency situation; or

(c) An APRN prescribing a controlled substance:

1. For administration in a hospital or long-term-care facility with an institutional account, or an APRN in a hospital or facility without an institutional account, if the hospital, long-term-care facility, or licensee queries KASPER for all available data on the patient or resident for the twelve (12) month period immediately preceding the query within twelve (12) hours of the patient's or resident's admission and places a copy of the query in the patient's or resident's medical records during the duration of the patient's stay at the facility;

2. As part of the patient's hospice or end-of-life treatment;

3. For the treatment of pain associated with cancer or with the treatment of cancer;

4. To assist a patient when submitting to a diagnostic test or procedure;

5. Within seven (7) days of an initial prescription pursuant to subsection (1) of this section if the prescriber:

a. Substitutes a controlled substance for the initial prescribing;

b. Cancels any refills for the initial prescription; and

c. Requires the patient to dispose of any remaining unconsumed medication;

6. Within ninety (90) days of an initial prescription pursuant to subsection (1) of this section if the prescribing is done by another licensee in the same practice or in an existing coverage arrangement, if done for the same patient for the same condition;

7. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federal-wide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health;

8. During the effective period of any disaster or situation with mass casualties that have a direct impact on the APRN's practice;

9. As part of the administering or ordering of controlled substances to prisoners in a state, county, or municipal correctional facility;

10. That is a Schedule IV controlled substance for no longer than three (3) days for an established patient to assist the patient in responding to the anxiety of a nonrecurring event; or

11. That is classified as a Schedule V controlled substance.

(12) Federal regulation 21 C.F.R. 1306.12(b) concerning the issuance of multiple prescriptions for Schedule II controlled substances shall not apply to APRNs in this state.

(13) No less than once every six (6) months, an APRN who has prescribed controlled substances shall review a reverse KASPER report for the preceding six (6) months to determine whether the information contained in KASPER is correct. If the information is incorrect, the APRN shall comply with 902 KAR 55:110 and take the necessary steps to seek correction of the information:

(a) By first contacting the reporting pharmacy;

(b) By contacting law enforcement if suspected fraudulent activity; or

(c) By contacting the Drug Enforcement Professional Practices Branch, Office of the Inspector General, Cabinet for Health and Family Services.

(14) An APRN shall not issue a prescription for hydrocodone combination products for more than a three (3) day supply if the prescription is intended to treat pain as an acute medical condition, with the following exceptions:

(a) The APRN, in his or her professional judgment, believes that more than a three (3) day supply of hydrocodone combination products is medically necessary to treat the patient's pain as an acute medical condition and the APRN adequately documents the acute medical condi-

tion and lack of alternative treatment options which justifies deviation from the three (3) day supply limit on the patient's medical records;

(b) The prescription for hydrocodone combination products is prescribed to treat chronic pain;

(c) The prescription for hydrocodone combination products is prescribed to treat pain associated with a valid cancer diagnosis;

(d) The prescription for hydrocodone combination products is prescribed to treat pain while the patient is receiving hospice or end-of-life treatment;

(e) The prescription for hydrocodone combination products is prescribed as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services;

(f) The prescription for hydrocodone combination products is prescribed to treat pain following a major surgery, which is any operative or invasive procedure or a delivery, or the treatment of significant trauma; or

(g) Hydrocodone combination products are administered directly to an ultimate user in an inpatient setting.

(15) Prescriptions written for hydrocodone combination products pursuant to subsection (14)(a) through (g) of this section shall not exceed thirty (30) days without any refill.

(16) An APRN may prescribe electronically pursuant to KRS 218A.171.

(17) For any prescription for a controlled substance, the prescribing APRN shall discuss with the patient the effect the patient's medical condition and medication may have on the patient's ability to safely operate a vehicle in any mode of transportation.

Section 10. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "AACN Scope and Standards for Acute Care Nurse Practitioner Practice", 2017 Edition, American Association of Critical-Care Nurses;

(b) "AACN Scope and Standards for Acute Care Clinical Nurse Specialist Practice", 2014 Edition, American Association of Critical-Care Nurses;

(c) "Neonatal Nursing: Scope and Standards of Practice", 2013 Edition, American Nurses Association/National Association of Neonatal Nurses;

(d) "Nursing: Scope and Standards of Practice", 2015 Edition, American Nurses Association;

(e) "Pediatric Nursing: Scope and Standards of Practice", 2015 Edition, American Nurses Association/Society of Pediatric Nursing/National Association of Pediatric Nurse Practitioners;

(f) "Psychiatric-Mental Health Nursing: Scope and Standards of Practice", 2014, American Nurses Association/American Psychiatric Nursing Association;

(g) "Scope of Practice for Nurse Practitioners", 2015 Edition, American Association of Nurse Practitioners;

(h) "Standards of Practice for Nurse Practitioners", 2013 Edition, American Association of Nurse Practitioners;

(i) "Scope of Nurse Anesthesia Practice", 2013 Edition, American Association of Nurse Anesthetists;

(j) "Standards for Nurse Anesthesia Practice", 2013 Edition, American Association of Nurse Anesthetists;

(k) "Standards for Office Based Anesthesia Practice", 2018 Edition, American Association of Nurse Anesthetists;

(l) "Standards for the Practice of Midwifery"; 2011 Edition, American College of Nurse-Midwives;

(m) "Statement on the Scope and Standards of Oncology Nursing Practice: Generalist and

Advanced Practice", 2013 Edition, Oncology Nursing Society;

(n) "The Women's Health Nurse Practitioner: Guidelines for Practice and Education", 2014 Edition, Association of Women's Health, Obstetric and Neonatal Nurses/Nurse Practitioners in Women's Health;

(o) "Definition of Midwifery and Scope of Practice of Certified Nurse-Midwives and Certified Midwives", 2011 Edition, American College of Nurse-Midwives;

(p) "APRN Prescriptive Authority Notification Form", 6/2018, Kentucky Board of Nursing; and

(q) "Common CAPA-NS Form", 6/2015.

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