201 KAR 20:065. Professional standards for prescribing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone by APRNs for medication assisted treatment for opioid use disorder.

RELATES TO: KRS 314.011, 314.042, 21 U.S.C. 823
STATUTORY AUTHORITY: KRS 314.131
NECESSITY, FUNCTION, AND CONFORMITY: KRS 314.131 authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. This administrative regulation establishes the professional standards for APRNs practicing in Kentucky who prescribe Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone.

Section 1. Definitions. (1) "Advanced Practice Registered Nurse" or "APRN" is defined by KRS 314.011(7).

(2) "Buprenorphine" means the controlled substances Buprenorphine-Mono-Product and Buprenorphine-Combined-with-Naloxone.

(3) "Mental health counseling" means the provision of guidance, by a qualified health professional as defined at KRS 202A.011(12), to the individual through the utilization of methodologies such as the collection of case history data, valid and reliable screening tools, and psychological techniques such as the personal interview.

Section 2. Minimum Qualifications for Prescribing Buprenorphine. An advanced practice registered nurse (APRN) shall not prescribe buprenorphine for opioid use disorder unless that APRN possesses the minimum qualifications established in this section. (1) The APRN shall obtain and maintain in good standing a DATA 2000 waiver and registration as issued by the United States Drug Enforcement Administration (DEA) to prescribe buprenorphine for the treatment of opioid use disorder.

(2) The APRN shall:

(a) Be a DEA-registered prescriber of buprenorphine; and

(b) Have obtained medication assisted treatment education through completion of a Substance Abuse and Mental Health Services Administration (SAMHSA) approved course.

(3) The APRN shall provide to the board a copy of the DEA Controlled Substance Registration Certificate as required by 201 KAR 20:057, Section 6(4).

(4) The APRN shall comply with all federal statutes and regulations pertaining to the prescribing of buprenorphine. This shall include the maximum number of patients, which may be seen by the APRN each year, and the inclusion of the special DEA identification number in addition to the regular DEA registration number on all prescriptions for opioid dependency treatment.

(5) It is not within the scope of practice for an APRN who does not hold a DATA 2000 waiver to conduct a focused examination required to prescribe buprenorphine for the treatment of substance use disorders.

(6) The APRN shall comply with all federal statutes and regulations pertaining to the prescribing of controlled substances via telehealth for medication assisted treatment for opioid use disorder.

(7) The APRN who is at a remote location from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1395m(m) of Title 42, shall comply will applicable federal and state laws.

Section 3. Professional Standards for Prescribing Buprenorphine for Supervised Withdrawal or the Treatment of Opioid Use Disorder. (1) Buprenorphine may be prescribed for supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder in accordance with the standards established by this administrative regulation.

(2) Buprenorphine-Mono-Product shall not be prescribed for supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder, except:

(a) To a pregnant patient, as established in subsection (4)(b) of this section;

(b) To a patient with demonstrated hypersensitivity to naloxone;

(c) As administered under supervision in an APRN's office or other healthcare facility, including hospitals, urgent care settings, surgical care centers, residential treatment facilities, and correctional facilities; or

(d) To a patient transitioning from methadone to buprenorphine, limited to a period of no longer than one (1) week.

(3)(a) Except as provided in paragraph (b) of this subsection, buprenorphine shall not be prescribed to a patient who is also being prescribed benzodiazepines, other sedative hypnotics, stimulants, or other opioids, without consultation of:

1. A physician certified in addiction medicine or psychiatry as required by 201 KAR 9:270;

2. An APRN who is certified in addiction therapy by the:

a. Addictions Nursing Certification Board;

b. American Academy of Health Care Providers in the Addictive Disorders; or

c. National Certification Commission for Addiction Professionals; or

3. A psychiatric-mental health nurse practitioner.

(b) An APRN may prescribe buprenorphine to a patient who is also being prescribed benzodiazepines, other sedative hypnotics, stimulants, or other opioids, without consultation in order to address a documented extraordinary and acute medical need not to exceed a combined period of thirty (30) days.

(4) Each APRN who prescribes buprenorphine for supervised withdrawal or for the treatment of opioid use disorder shall comply with the professional standards established in this subsection.

(a) Prior to initiating treatment, the APRN shall:

1. Obtain, review, and record a complete and appropriate evaluation of the patient, and which shall include:

a. The patient's history of present illness;

b. The patient's history of drug use;

c. The patient's social and family history;

d. The patient's medical and psychiatric histories;

e. A focused physical examination of the patient; and

f. Appropriate laboratory tests, which shall include a complete blood count (CBC), a comprehensive quantitative drug screen, liver function tests, a complete metabolic panel (CMP), HIV screening, and hepatitis serology;

2. Obtain the patient's consent and authorizations in order to obtain and discuss the patient's prior medical records, which shall require:

a. Upon receipt of the medical records, the APRN review and incorporate the information from the records into the evaluation and treatment of the patient; or

b. If the APRN is unable, despite best efforts, to obtain the patient's prior medical records, the APRN document those efforts in the patient's chart.

3. Obtain and review a KASPER or other prescription drug monitoring program (PDMP) report for that patient for the twelve (12) month period immediately preceding the initial patient encounter and appropriately utilize that information in the evaluation and treatment of the

patient;

4. Explain treatment alternatives, the risks, and the benefits of treatment with buprenorphine to the patient;

5. Obtain written informed consent from the patient for treatment;

6. Discuss and document the patient's treatment with the patient's other providers;

7. If the patient is a female of childbearing potential and age, meet the requirements of paragraph (b) of this subsection; and

8. Develop a treatment plan that incorporates an evaluation by a qualified mental health professional as defined at KRS 202A.011(12), with expertise in addiction, and compliance with the recommendations of the evaluator with ninety (90) days initiating treatment, and objective behavior modification including mental health counseling or a twelve (12) step program for the duration of the treatment.

(b) 1. Prior to initiating treatment, the APRN shall require that the patient submit to a pregnancy test and, if pregnant, the APRN shall provide counseling as to the risk of neonatal abstinence syndrome which shall be consistent with current SAMHSA guidance.

2. Prior to prescribing buprenorphine to a patient who is pregnant or breastfeeding, an APRN shall obtain and document consultation with an obstetrician or a maternal-fetal medicine specialist who holds a DATA 2000 waiver that determines the potential benefit of Buprenorphine use outweighs the potential risk of use.

(c) Except as provided by paragraph (d) of this subsection, while initiating treatment with buprenorphine, the APRN shall comply with the following requirements:

1. The APRN shall recommend to the patient an in-office observed induction protocol.

a. Except as provided in clause b. of this subparagraph, the APRN shall conduct or supervise the in-office observed induction protocol.

b. If an in-office observed induction does not occur, the APRN shall appropriately document the circumstances in the patient record and shall implement a SAMHSA-recognized or ASAM recognized home-based induction protocol.

2. The APRN shall document the presence or absence of any opioid withdrawal symptoms before the first dose is given by using a standardized instrument, such as the clinic opioid withdrawal scale (COWS) or other similarly recognized instrument.

3. The APRN shall initiate treatment with a dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet, which:

a. May be followed by subsequent doses if withdrawal persists; and

b. Shall not exceed the dose equivalency of sixteen (16) milligrams buprenorphine generic tablet on the first day of treatment.

(d) If the patient is transferred from another treatment provider and has previously experienced withdrawal without a relapse and has not had a lapse in treatment, the APRN shall:

1. Document the previous history of withdrawal;

2. Educate the patient about the potential for precipitated withdrawal;

3. Continue maintenance treatment of the patient on the same or less dosage as established by the previous treatment provider and then as provided in paragraph (e) of this subsection; and

4. Schedule visits at the same frequency as the previous treatment provider would have been required to or more frequently if deemed necessary by the APRN.

(e) After initial induction of buprenorphine, the APRN shall prescribe to the patient an amount of buprenorphine that:

1. Is necessary to minimize craving and opiate withdrawal;

2. Does not produce opiate sedation;

3. Is able only to supply the patient until the next visit, which shall be scheduled as required by this section; and

4. Does not exceed the FDA-approved dosage limit.

(f) The patient's visits shall be scheduled as follows:

1. The APRN shall ensure that the patient is seen no later than ten (10) days after induction and then at intervals of no more than ten (10) days for the first month after induction and at intervals of no more than fourteen (14) days for the second month after induction.

2. If the patient demonstrates objective signs of positive treatment progress after the first two (2) months, the patient shall be seen at least once monthly thereafter for up to two (2) years.

3. If after two (2) years after initiation of treatment, the patient has demonstrated objective signs of positive treatment progress, including documented evidence that the patient has been compliant with the treatment plan and all treatment directives, then the APRN may require that the patient be seen at least once every three (3) months. The APRN shall:

a. Evaluate the patient to determine whether the patient's dosage should be continued or modified; and

b. Appropriately document that evaluation and clinical judgment in the patient's chart.

4. The APRN shall see the patient in shorter intervals if the patient demonstrates any noncompliance with the treatment plan.

5. If extenuating circumstances arise that require a patient to unexpectedly reschedule a visit, the APRN shall make best efforts to see the patient as soon as possible and document the circumstances in the patient chart.

(g) The APRN shall review compliance with the recommendations of the treatment plan, including review of KASPER or other PDMP reports and drug screens to help guide the treatment plan at each visit.

1. The APRN shall:

a. Incorporate those findings into the treatment plan to support the continuation or modification of treatment; and

b. Accurately document the same in the patient record.

2. Appropriate evaluation may include adjustment of dose strength or frequency of visits, increased screening, a consultation with or referral to a specialist, or an alternative treatment, including consideration of weaning.

3. The APRN shall obtain a minimum of eight (8) drug screens from the patient within each twelve (12) month period of treatment in order to help guide the treatment plan.

a. At least two (2) of the drug screens shall be random and coupled with a pill count. At least one (1) of those two (2) drug screens shall be confirmed by gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry (LC/MS).

b. Each drug screen shall screen for buprenorphine, methadone, opioids, THC, benzodiazepines, amphetamines, alcohol, gabapentin, and cocaine.

c. If a drug screen indicates the presence of any of the drugs screened, the APRN shall:

(i) Incorporate those findings into appropriate clinical evaluation to support the continuation or modification of treatment; and

(ii) Document in the patient record.

(h) Every twelve (12) months following initiation of treatment, if a patient's prescribed daily therapeutic dosage exceeds the dose equivalency of sixteen (16) milligrams buprenorphine generic tablet per day, then the APRN who is not certified in addiction therapy shall:

1. Refer the patient for an evaluation by a physician or an APRN as established in subsection (3)(a) of this section for an opinion as to whether continued treatment and dosage is appropriate; and

2. Document the results of that evaluation in the patient chart.

(i) For patients who have demonstrated objective signs of positive treatment progress for at least two (2) years from the date of initiation of treatment, including documented evidence that the patient has been compliant with the treatment plan and all treatment directives, the APRN shall evaluate for and document every twelve (12) months the medical necessity for continued treatment at the established dose.

(j) The APRN shall document a plan for dealing with any lost or stolen medication, which shall not provide for the automatic replacement of medication prior to the specified interval date. Replacement medication shall not be authorized by the APRN in the absence of an individual assessment, specific consideration of all prior instances of lost or stolen medication, and documented consultation with the patient.

(k) After initial induction, the APRN shall:

1. Implement a treatment plan that requires objective behavioral modification by the patient. The behavioral modification shall include the patient's participation in a behavioral modification program that shall include mental health counseling or a twelve (12) step facilitation; and

2. Require the patient to obtain an evaluation by a qualified mental health professional as defined in KRS 202A.011(12), with expertise in addiction, within ninety (90) days of initiating treatment, and to comply with the evaluator's recommendations..

Section 4. Continuing Education. An APRN who has obtained a waiver and registration as issued by the DEA to prescribe buprenorphine for the treatment of opioid use disorder shall complete a total of four (4) hours annually in addiction disorders, including one and one-half (1.5) contact hours in pharmacology as defined by 201 KAR 20:215, Section 5(1)(c).

Section 5. Use of Transmucosal Buprenorphine for Treatment of Opioid Use Disorder in an Emergency Situation or Inpatient Setting. (1) In an emergency, including in a hospital emergency department or similar outpatient urgent care setting, or in an inpatient setting, an APRN may offer and initiate buprenorphine treatment to patients who present with opioid use disorder, without meeting the requirements established in Sections 2 and 3 of this administrative regulation and to the extent permitted by federal law, if:

(a) The APRN has determined that the use of buprenorphine will not result in a harmful interaction with other medications or substances in the patient's system, including benzodiazepines, sedative hypnotics, carisoprodol, or tramadol;

(b) The APRN obtains and documents written informed consent from the patient specific to risks and benefits of buprenorphine treatment; and

(c) The APRN provides the patient with written instructions and contact information for appropriate follow up care, including bridge-provider services, residential treatment providers, and outpatient treatment providers.

(2) The APRN shall initiate buprenorphine treatment under an observed induction protocol with an initial dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet, which may be followed by subsequent doses, up to a maximum of twenty-four (24) milligrams buprenorphine generic tablet, if withdrawal persists and is not improving.

Section 6. Telehealth. Nothing in this administrative regulation shall be construed to prohibit prescribing buprenorphine via telehealth. The prescribing APRN shall follow the standards set by 201 KAR 20:520. (44 Ky.R. 840, 1364, 1507; eff. 1-18-2018; 456 Ky.R. 2159, 2702, 2860; eff. 5-3-2019; 46 Ky.R. 2984, 47 Ky.R. 525, 1194; eff. 11-19-2020.)