

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.

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 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) sponsored 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.

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; or

(c) As an implant-delivered, injectable treatment administered, or observed induction in an APRN's office or other healthcare facility.

(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 an 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 fully 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, which shall at a minimum 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 physical examination of the patient;

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

g. An evaluation by a mental health provider with expertise in addiction and compliance with the recommendations of the evaluator.

2. Obtain the patient's consent and authorizations in order to obtain and discuss the patient's prior medical records.

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

b. If the APRN is unable, despite best efforts, to obtain the patient's prior medical records, the APRN shall 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 objective behavior modification including 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 first submit to a pregnancy test and the APRN shall provide counseling as to the risk of neonatal abstinence syndrome which shall be consistent with patient education material on neonatal abstinence syndrome from the American Congress of Obstetricians and Gynecologists, American Academy of Pediatrics, American Society of Addiction Medicine (ASAM) and the Kentucky Department for Public Health, and offer means to prevent pregnancy.

2. An APRN shall not prescribe Buprenorphine to a patient who is pregnant or breastfeeding

unless the APRN first obtains and documents consultation for an opinion as to whether the potential benefit of Buprenorphine use outweighs the potential risk of use.

3. The consultation shall be obtained from a physician or an APRN as established in subsection (3)(a) of this section.

(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 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 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 is not improving; 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, the APRN shall:

1. Document the previous history of withdrawal;

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

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

(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 of twenty-four (24) milligrams per day.

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

1. The APRN shall see the patient at least weekly for the first two (2) months.

2. If the patient demonstrates objective signs of positive treatment progress after the first two (2) months, the APRN shall see the patient 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 only by the APRN 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 non-compliance 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, at a minimum, screen for buprenorphine, methadone, oxycodone, other 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.

d. 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.

(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:

1. Shall not provide for the automatic replacement of medication prior to the specified interval date; and

2. If the APRN determines that it is necessary to minimize improper or illegal diversion of medications under the circumstances, the APRN shall require the patient to first report the lost or stolen medications to police or other law enforcement agencies and require the patient to provide evidence to the APRN of having so reported.

Section 4. Continuing education. An APRN who has obtained a waiver and registration as issued by the Drug Enforcement Administration (DEA) to prescribe Buprenorphine for the treatment of Opioid Use Disorder shall complete the one and one-half (1.5) contact hours of continuing education required annually by 201 KAR 20:215, Section 5(1)(b) in addiction disorders. (44 Ky.R. 840, 1364, 1507; eff. 1-18-2018; 456 Ky.R. 2159, 2702, 2860; eff. 5-3-2019.)