GENERAL GOVERNMENT CABINET

Board of Nursing

(Amendment)

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

RELATES TO: KRS 218A.010, 218A.170, 314.011, 314.042, 21 U.S.C. 823, 42 U.S.C. 1395

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) "Consultation" means the process by which an APRN directs the patient to a physician, APRN, or other specialist, as required by Section 3(3)(a), Section 3(4)(b)2., or Section 3(4)(g)2. of this administrative regulation to render an opinion with regard to the prescribing of

Buprenorphine to the patient, and includes the requirements as established in Section 8 of this administrative regulation.

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~~] and an active PDMP account as defined by administrative regulation 201 KAR 20:057, Section 1(7).

(2) The APRN shall:

(a) Be a DEA-registered prescriber[~~-of Buprenorphine~~]; and

(b) Have completed an eight (8) hour continuing education training on managing and treating opioid and other substance abuse disorders as required by administrative regulation 201 KAR 20:215, Section 5(2)[~~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), via the KBN Nurse Portal[~~APRN Update online portal~~] at https://kbn.ky.gov[~~/aprn_practice/Pages/aprn_update.aspx~~].

(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.

(6[~~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 42 U.S.C. 1395m(m), 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, 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 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. If an appropriate justification for initiation of treatment in advance of the review of laboratory tests is documented by the APRN, this subsection shall be satisfied though the documentation of a plan for obtaining and reviewing the laboratory tests required by this subsection within thirty (30) days of initiating treatment.

2. Document a plan to obtain the patient's consent and authorizations in order to obtain and discuss the patient's prior medical records within thirty (30) days of initiating treatment, which shall require:

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; or

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 the patient's participation in a behavioral modification program, which may include counseling or a twelve (12) step facilitation.

(b)1. Prior to initiating treatment, the APRN shall recommend that female patients of child bearing age and ability 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. The APRN shall document a patient's decision to decline to take a pregnancy test and the stated rationale for the patient's decision.

2. Prior to prescribing buprenorphine to a patient who is pregnant or breastfeeding, an APRN who is not an obstetrical care provider shall have a plan to obtain and document consultation with an obstetrical care provider to co-manage the patient's care. The APRN shall document a patient's decision to decline consultation referenced in this subsection, and the stated rationale for the patient's decision.

(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 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) After initial induction of Buprenorphine, the APRN shall review compliance with the recommendations of the treatment plan and drug screen results at each visit to help guide the treatment plan. Current [~~KASPER and other~~] relevant PDMP reports shall be obtained no less frequently than once every three (3) months, to help guide the treatment plan.

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 of continued Buprenorphine prescribing shall include documented consideration of initial laboratory test results as specified in subsection (4)(a)1.f. of this section, subsequent laboratory test results, and the patient's prior medical records. Appropriate evaluation of continued Buprenorphine prescribing shall also include, if appropriate and relevant, 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, if weaning is clinically appropriate.

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.

b. At least one (1) of those two (2) drug screens shall be confirmed by either gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry (LC/MS).

c.[~~b~~]. Each drug screen shall screen for buprenorphine, methadone, opioids, THC, benzodiazepines, amphetamines, alcohol, and cocaine.

[~~c. The two (2) drug screen[s] confirmed by either gas chromatography/ mass spectrometry (GC/MS) or liquid chromatography/ mass spectrometry (LC/MS) shall screen for buprenorphine, methadone, opioids, THC, benzodiazepines, amphetamines, alcohol, gabapentin, and cocaine.~~

d. 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 discussion with the patient.

(k) After initial induction, the APRN shall:

1. Implement a treatment plan that requires objective behavioral modification by the patient.

2. The behavioral modification plan shall include the patient's participation in a behavioral modification program that shall include counseling or a twelve (12) step facilitation.

Section 4. Continuing Education. An APRN who [~~has obtained a waiver and registration as issued by the DEA to~~] prescribe<u>s</u> buprenorphine for the treatment of Opioid Use Disorder shall complete <u>continuing education</u> [~~a total of four (4) hours annually in addiction disorders, including the one and one-half (1.5) contact hours in pharmacology as defined by~~] <u>pursuant to</u> 201 KAR 20:215, Section 5(1)([~~c~~]<u>b</u>). [~~The pharmacology hours shall be on the dual subjects of addiction disorders and pharmacology.~~]

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.

Section 7. Documented Deviation from Professional Standards for Prescribing Buprenorphine. If an APRN is unable to conform to professional standards for prescribing Buprenorphine as set forth in this administrative regulation due to circumstances beyond the APRN's control, or the APRN makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the APRN shall document those circumstances in the patient's record and only prescribe Buprenorphine to the patient if the patient record appropriately justifies the prescribing under the circumstances and in accordance with SAMHSA guidelines.

Section 8. Consultation Requirements. (1) Consultation shall not require an in-person visit.

(2) It may include a discussion by the APRN and the consultant by telephone or other appropriate electronic communication.

(3) The consultant may recommend further evaluation which may be either in-person, by telehealth, or a records review.

(4) It is the responsibility of the APRN to initiate a consultation and to communicate clearly to the consultant that the APRN is seeking a consultation.

(5) A consultation may involve the consultant providing advice and information to the APRN or patient.

(6) It is the responsibility of the APRN to provide all relevant client records to the consultant, including a written summary of the client's history and presenting problem, as deemed appropriate by the consultant.

(7) Consultation shall be fully documented in writing by the APRN in the patient's record, including the consultant's name, date of service, and the consultant's findings, opinions, and recommendations.

(8) The APRN shall discuss the consultant's recommendations with the patient.

Amended Administrative Regulation

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

Adopted: August 24, 2023.

Audria Denker, DNP, RN, FAADN

Audria Denker, President
Kentucky Board of Nursing

August 24, 2023
Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held on November 21, 2023 at 10:00 AM at Kentucky Board of Nursing, 312 Whittington Parkway, Ste 300, Louisville, KY 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by November 14, 2023, five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through November 30, 2023. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON:
Jeffrey R. Prather, General Counsel
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Or submit a comment at:
https://secure.kentucky.gov/formservices/Nursing/PendReg

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 20:065
Contact Person: Jeffrey Prather
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Email: Jeffrey.prather@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation sets standards for advanced practice registered nurses (APRN) to prescribe buprenorphine for treatment of opioid use disorder.

(b) The necessity of this administrative regulation: It is necessary to promulgate this regulation to establish standards for APRN prescribing of Buprenorphine for the treatment of opioid use disorder in the Commonwealth of Kentucky.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by setting standards.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by setting standards for APRN prescribing of Buprenorphine for the treatment of opioid use disorder.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments do the following:

- Removes references to the X-waiver;
- Require that an APRN who prescribes Buprenorphine shall have an active DEA registration and Prescription Drug Monitoring Program (PDMP) account;
- Requires that an that an APRN who prescribes Buprenorphine shall have eight hour continuing education training on managing and treating opioid and other substance abuse disorders, as well as continuing education, see also 201 KAR 20:215, currently in promulgation;
- Updates “KASPER” to “PDMP”, see 201 KAR 20:057, currently in promulgation; and
- Clarifies the patient drug screening requirements.

(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to keep the standards current.

(c) How the amendment conforms to the content of the authorizing statutes: The Board is authorized to set standards governing APRN prescribing of Buprenorphine.

(d) How the amendment will assist in the effective administration of the statutes: By having current and appropriate standards.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The Kentucky Board of Nursing currently

licenses approximately Kentucky APRNs who are authorized to prescribe of controlled substances, approximately 2334, in the treatment of substance use disorder.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: APRNs who prescribe Buprenorphine in the treatment of opioid use disorder will be required to comply with the new standards.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no additional costs.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): They will be in compliance with the new standards.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional costs.

(b) On a continuing basis: No additional ongoing costs are directly attributable to the amendments to this regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Agency funds.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: None.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: It does not.

(9) TIERING: Is tiering applied? The changes will apply equally, there is no tiering.

FISCAL NOTE

201 KAR 20:065
Contact Person: Jeffrey Prather
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(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Board of Nursing.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. Kentucky Revised Statutes 314.131.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.

(c) How much will it cost to administer this program for the first year? No additional cost.

(d) How much will it cost to administer this program for subsequent years? No additional cost.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? None.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? None.

(c) How much will it cost the regulated entities for the first year? None.

(d) How much will it cost the regulated entities for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]* This administrative regulation will not have a major economic impact.