DECLARATORY STATEMENT FOR ADVANCED PRACTICE REGISTERED NURSES PRESCRIBING BUPRENORPHINE FOR THE OFFICE-BASED TREATMENT OF SUBSTANCE USE DISORDERS

Introduction

Evaluating and managing patients with substance use disorders requires specialized knowledge and training prior to the management of such conditions. Section 303 of the Comprehensive Addiction and Recovery Act (CARA) addresses office-based treatment of opioid use disorders with buprenorphine. Advanced Practice Registered Nurses (APRNs) may prescribe buprenorphine containing products for the office-based treatment of opioid use disorders under specific provisos as provided for in 21 USC 823 until October 1, 2021. APRNs authorized to prescribe controlled substances for the treatment of substance use disorders are responsible for understanding and complying with requirements of associated federal and state regulatory agencies including but not limited to the United States Department of Health and Human Services (USDHHS), the Drug Enforcement Agency (DEA), the Louisiana Board of Pharmacy (LBP), the Louisiana Department of Health (LDH), and the Louisiana State Board of Nursing (LSBN).

Authority

Pursuant to L.R.S. 49:963 and LAC 46:XLVII.3321, LSBN is authorized to issue declaratory statements in response to requests for clarification of the effect of rules and regulations or of L.R.S. 37:911 et seq. as revised and amended.

Definitions

Medication Assisted Treatment (MAT) is the use of Food and Drug Administration (FDA) approved opioid agonist medications for the maintenance treatment of opioid use disorders and opioid antagonist medication to prevent relapse to opioid use. MAT is only one aspect of substance use disorder management and is intended to be used in conjunction with evidence based behavioral health interventions.

Maintenance or Maintenance Treatment in the treatment of substance use disorders refers to the use of a substance administered or prescribed by a licensed prescriber over a period of time as an alternative to the substance to which a patient is addicted or dependent.

Detoxification in reference to substance use disorders refers to utilizing interventions in the management of acute physical symptoms of acute substance intoxication and withdrawal associated with discontinuation of the substance.

Dispense means the interpretation, evaluation, and implementation of a prescription drug order as defined in Louisiana's Pharmacy Practice Act. This does not include the prescribing or administration of agents. Only registered practitioners of medicine, dentistry, or veterinary medicine are authorized to compound and dispense drugs in Louisiana in accord with R.S. 37:1201. APRNs in Louisiana are not authorized to dispense.

Office-based opioid treatment or office-based treatment of substance use disorders refers to treatment of opioid use disorders) utilizing controlled substances in schedules III-V in an outpatient office setting that is not otherwise recognized, licensed, or classified as an opioid treatment program *(*OTP). The term addiction is often used interchangeably with or in lieu of "substance use disorder".

Office-Based treatment of substance use disorders refers to a solo practitioner or a group outpatient clinic based practice in which the prescribers possess the required authority, training, and ability to provide clinical evaluation and medical management, including but not limited to maintenance prescriptions, referrals, and follow up, to individuals with substance use disorders.

Opioid Treatment Program (OTP) refers to a licensed program engaged in treatment of opioid addicted patients with approved schedule II opioids (aka methadone clinic).

Qualifying physician as identified in section 303 of CARA is a physician who has been issued and possesses a waiver to prescribe buprenorphine by meeting requirements by either a) holding a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties or b) holding subspecialty board certification in Addiction Medicine from the American Osteopathic Association or c) holding addiction certification from the American Society of Addiction Medicine or d) not holding the aforementioned credentials and therefore otherwise has obtained 8 hours of specified training to meet requirements of the USDHHS and Substance Abuse and Mental Health Services Administration (SAMSHA) for a waiver to prescribe buprenorphine.

Waiver, for the purposes of this statement, refers to documented authorization from the USDHHS issued by SAMSHA under the authority of federal acts, Drug Addiction Treatment Act (DATA) and CARA, that exempts qualified prescribers from select rules that apply to OTPs. The waiver authorizes approved prescribers to prescribe buprenorphine for office-based treatment of substance use disorders.

Key Concepts

1) In 2002, the DATA allowed qualified physicians (but not APRNs) to receive a waiver in order to prescribe and dispense approved buprenorphine containing products in office-based practices for the treatment of opioid use disorders. Subsequently, CARA, signed into law on July 22, 2016, made several changes to DATA including section 303 which addresses office-based treatment of substance use disorders and allows APRNs who are nurse practitioners to receive a waiver to prescribe buprenorphine containing products.

2) Three medications are currently approved for use in MAT for opioid use disorders - methadone, buprenorphine, and naltrexone.

- Naltrexone is not a controlled substance and is therefore not subject to the Controlled Substances Act.
- Methadone is a Schedule II controlled substance, which indicates a higher risk of abuse and can only be administered or dispensed for the treatment of opioid use disorder within an OTP that, in Louisiana, requires licensing through LDH.

- Buprenorphine is a Schedule III controlled substance with lower risk of abuse than schedule II substances.

3) Any APRN who prescribes buprenorphine for substance use disorders before applying for and receiving approval for a waiver will be in violation of federal law.

4) In the first year, approved prescribers may only treat 30 patients at a time with buprenorphine, followed by up to 100 patients in subsequent years after submitting an additional request. Provisions in CARA increased the patient limits to 275 patients at a given time for certain qualified physicians.

Training/Education

APRNs must complete at least 24 hours of specialized training to be eligible for a waiver to prescribe buprenorphine. Such training must include opioid maintenance and detoxification; clinical use of all FDA-approved drugs for MAT; patient assessment; treatment planning; psychosocial services; staff roles; and diversion control. Any exceptions to the training requirements are determined by the USDHHS.

The following organizations are listed in CARA as the professional bodies that can provide the training:

American Academy of Addiction Medicine (ASAM)
American Academy of Addiction Psychiatry (AAAP)
American Medical Association (AMA)
American Osteopathic Association (AOA)
American Psychiatric Association (APA)
American Nurses Credentialing Center (ANCC)
American Association of Nurse Practitioners (AANP)
American Academy of Physician Assistants (AAPA)

LSBN Position Statements

After due deliberation and in accordance with L.R.S. 37:911 et seq. as re-enacted and amended, LSBN supports the following positions in order to safeguard the life and health of the citizens of Louisiana:

1) APRNs prescribing buprenorphine for the treatment of substance use disorders must hold an active license in Louisiana as a Nurse Practitioner and meet the provisions in 21 USC 823 and the following conditions:

a. Be approved by LSBN for prescriptive authority to prescribe legend drugs and controlled substances;

1. including submission of a *collaborative practice agreement* submitted to the LSBN which must include parameters of practice including clinical practice guidelines that are inclusive of current evidence-based practices and professional standards relative to substance use disorder treatment;

2. including having a *collaborating physician* approved by LSBN with whom the APRN collaborates regarding matters relative to evaluation and management of patients with substance use disorders including the management through prescribing of buprenorphine. The collaborating physician must meet the requirements of a "qualifying physician" as defined in 21 USC 823 and if further defined by the Louisiana Medical Practice Act. The collaborating physician must possess approval for a waiver from the USDHHS and the SAMSHA to prescribe buprenorphine;

b. Meet federal requirements including applying with the USDHHS and SAMSHA for the required registration and waiver to prescribe buprenorphine. The DEA then issues an identification number;

1. APRNs must possess their own DEA registration and waiver and applicable identification number in order to prescribe buprenorphine.

2. APRNs are not authorized to delegate their prescriptive authority nor utilize another prescriber's prescribing authority or DEA registration including but not limited to the authority and waiver to prescribe MATs.

c. Practitioners must keep records for controlled substances prescribed and dispensed to patients for maintenance or detoxification treatment per 21 CFR Section 1304.03[c].

2) APRNs in Louisiana are expected to practice in a competent, safe manner at all times including the utilization and prescribing of therapies that are based on current standards of care and evidence-based practices. Current practice relative to substance use disorder treatment includes but is not limited to the following:

a. Substances used for substance use disorders treatment that are prescribed must be approved by the FDA for use in the treatment of substance use disorders in maintenance or detoxification treatment and be prescribed in accordance with approved product labeling;

b. Accessing and utilizing the Prescription Monitoring Program (PMP) upon initially prescribing controlled substances and regularly accessing and utilizing the PMP upon refilling of controlled substances, including buprenorphine to monitor, track, and verify the controlled substance prescriptions that are being filled that are affiliated with the prescriber's assigned DEA registration number in order to clarify patterns, identify potential fraud (including forgery, diversion, etc.), and correct discrepancies;

c. Prior to initiation of buprenorphine, a comprehensive assessment must be completed. Prescribers must personally perform and document a complete history and physical exam including substances use history and mental status exam. Prescribers must also obtain appropriate laboratory testing; ensure that a thorough psychiatric evaluation has been completed if indicated and a copy of such documented evaluation be available in the prescriber's record; review risks and benefits of treatment with buprenorphine with the patient; and review other treatment options with patients. Attention must be given to the potential side effects of buprenorphine as well as consideration to the patients'

environmental and occupational risks when receiving controlled substances such as buprenorphine. Prescribers must ensure that the patient is an appropriate candidate and that office based treatment is the appropriate level of care;

d. Prior to initiation of buprenorphine, a legitimate diagnosis meeting the current Diagnostic and Statistical Manual (DSM) criteria for the indications of buprenorphine must be established and documented;

e. Patients using central nervous system (CNS) depressants, including benzodiazepines, alcohol, barbiturates and other such substances, are not good candidates for MAT and should only be prescribed buprenorphine with great caution;

f. The treatment plan for the patient must be documented and reviewed regularly and include monthly face-to-face visits (at a minimum), concomitant evidence based behavioral health interventions (i.e. counseling by qualified individuals, narcotics anonymous meetings, etc.), and a specific target date for weaning and being drug-free. Transition to naltrexone should be considered.

g. Monitoring for adherence including urine drug screens (UDS), monitoring the PMP, establishing policies for detecting and managing diversion and use of illicit substances. Requiring the use of a single pharmacy for all prescriptions is one strategy in prudent monitoring of patients on MAT;

h. Practice management that provides for accommodation of and resources for the patient limit agreed upon and allowed by law;

i. Referral to appropriate levels of care and resources. Clinicians to whom APRNs refer patients treated with buprenorphine should be actively practicing and trained in the provision of evidence-based therapies known to have effectiveness in the treatment of substance use disorders. Referral to other health care providers is warranted for management of complex or unstable comorbid mental health conditions if the NP is not certified and licensed as a psychiatric mental health NP. Collaboration with or referral to other health care providers is warranted for management of brief episodes of acute pain with controlled substances and management of other complex considerations for patients treated with buprenorphine;

j. Appropriate care and consideration to women of reproductive age including but not limited to contraceptive counseling and pregnancy testing during MAT. Appropriate care and consideration for pregnant and breast feeding women including but not limited to attention to the pregnancy category classification of prescribed substances; evaluation and disclosure of risks of treatment with buprenorphine; co-management of the patient with her obstetric provider(s); addressing and preparing for the potential of neonatal abstinence syndrome; recognizing and managing withdrawal; and provision of additional referral resources;

3) Specific institutional Continuous Quality Improvement (CQI) processes or organizational policy should be developed by and for APRNs and facilities that allow APRNs to prescribe controlled substances for the treatment of substance use disorders. Such policies and processes should ensure that prior to such prescribing there are approved and implemented organizational policies and processes in place that:

a. address and allow for prescribing controlled substances for the treatment of substance use disorders including staff and patient education/training programs;

b. establish and provide for the required data collection and record keeping mandated by federal regulations when controlled substances are prescribed to patients for maintenance or detoxification treatment including reporting the annual caseload by month and the number of patients referred to behavioral health services;

c. provide mechanisms for documenting in writing the training and ongoing competency of the APRN to manage patients with substance use disorders;

d. provide for a plan for monitoring patients' adherence to treatment which may address a structured drug testing strategy (i.e. minimum 8 UDS per year, random pill counts, treatment agreements, informed consent, etc.);

e. provide for a plan or protocol for patient care addressing requirements for abstinence from illicit and diverted substances (i.e. management of lost or stolen medication, positive UDS for illicit substances, multiple pharmacies and/or prescribers of controlled substances on prescription monitoring reports, securing prescriptions, etc.); and

f. address privacy and confidentiality of personal health information.

Exceptions and Limitations.

Nothing within this statement is intended to contradict state and federal regulations applicable to bona fide, certified Opioid Treatment Programs (OTP) and to prescribing controlled substances within such a facility or within a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than substance use disorders.

This statement does not and is not intended to address the use of methadone in the treatment of substance use disorders. Use of methadone treatment for opioid use disorders is restricted to approved treatment facilities that meet specific laws, regulations, and licensing requirements.

LSBN Concluding Statement

When evaluating and managing patients with substance use disorders, including the prescribing of substances to treat opioid use disorders, APRNs must possess the knowledge, skills, and abilities to manage patients with substance use disorders. The decision by an APRN to request to be authorized to prescribe buprenorphine for office-based substance use disorder treatment of opioid use disorders is to be made deliberately with an understanding of the professional accountability that the role requires. The complexity of knowledge and skill required to competently evaluate and manage patients with substance use disorders necessitates that additional education beyond basic advanced practice nursing educational programs be obtained and documented. APRNs are expected to recognize limits of their knowledge and experience,

plan for the management of situations beyond their expertise and consult with or refer patients to other health care providers as appropriate. This statement is not intended to replace clinical judgment or serve as a complete all inclusive "best practice" guideline but rather is intended to clarify and delineate what LSBN considers to be within the boundaries of acceptable professional practice for APRNs.

References

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