eAppendix Standard Operating Procedure for Treatment in Step-1 Clinics

Treatment of Opioid Use Disorder Using Buprenorphine: For Primary Care, Specialty, and Mental Health Clinicians in an Office-Based Setting, Excluding Specialty Addiction Care[a]

1. **SCOPE/EFFECT:** The following service lines may be affected by this policy: Primary Care, General Mental Health, Specialty Care, Pharmacy Service Line, excluding Specialty Addiction care. This is a new policy.

2. PURPOSE

(a) To facilitate treatment of opioid use disorder (OUD) by removing barriers to care in primary care, specialty care, and general mental health settings.

(b) To establish clear guidelines about who can prescribe buprenorphine for OUD in an office-based setting.

3. POLICIES

(a) Buprenorphine is a proven agent for the treatment of OUD with unique pharmacologic and safety profiles that encourage treatment compliance and reduce risk of overdose.

(b) Consistent with US Department of Veterans Affairs (VA) Connecticut Healthcare System (VACHS) existing buprenorphine policy, only physicians, nurse practitioners, and physician assistants who have completed Drug Enforcement Agency/Substance Abuse Mental Health Services Administration (DEA/SAMHSA) training and hold DEA X-waivers on file with VACHS shall prescribe buprenorphine for OUD in any treatment setting.

4. PROCEDURES

Veterans who meet the following criteria may be treated with buprenorphine therapy in VAHCS by any X-waivered provider.

1. Diagnosis of opioid dependence or diagnosis of OUD as defined by the *Diagnostic and Statistical Manual of Mental Disorders,* 5th edition criteria, and by *International Classification of Disease* 10th revision coding, including maintenance treatment in patients who have initiated buprenorphine in Opioid Reassessment Clinic or other specialty clinics.

2. Willingness to comply with treatment plans and goals associated with buprenorphine treatment, including interval visits and urine drug testing. Psychosocial treatments are available for providers to refer patients to.

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3. Patients who exhibit significant ongoing mental health/substance use issues despite monthly follow-up should have further consultation (either virtual or face to face) with specialty addiction care.

4. Patients who have pain in addition to opioid dependence or OUD are eligible to receive buprenorphine treatment for opioid dependence or OUD.

Providers prescribing treatment for OUD in an office-based setting should adhere to the following recommendations:

1. Providers should consider treatment of OUD in an office-based setting, per VA/Department of Defense guidelines, in the following scenarios:

- Office-based setting provides the needed resources for the patient
- Patient has adequate psychosocial supports
- There are few previous failed treatment attempts with opioid maintenance
- Access issues (mobility, geographic distance) or patient preference would make formal opioid treatment program (OTP) difficult or unattainable
- Patient is not receiving treatment with full agonist opioids
- Co-occurring psychiatric disorder(s) is/are stable
- Co-occurring substance use disorders (SUDs) that pose a significant safety risk are adequately treated
- There is no central nervous system depressant (alcohol, benzodiazepine) dependence
- There has been a previous good response to buprenorphine
- There is an expectation that the patient will be reasonably compliant

2. Providers should consider higher levels of care (OTP, intensive outpatient or residential) for patients who do not meet these criteria. If serious, unstable psychiatric comorbidity, and in the case of pregnancy, providers should intensify care, via the stepped-care model, including referral to specialty addiction care when clinically indicated. Pregnant patients may be treated with buprenorphine therapy in close consultation with a specialty addiction practitioner and Obstetrics/Gynecology services.

3. Providers are responsible to stay within the prescribing limit for their waiver. Qualified providers are initially limited to treating 30 patients concurrently under the original waiver; after 1 year, an application may be filed for approval to treat up to 100 patients at a time, per DEA guidelines. Practitioners are responsible to remain in compliance with this regulation by checking buprenorphine dashboard and/or primary care almanac/opioid therapy risk tool.

4. Appropriate coverage trees will be identified in Primary Care and Mental Health to ensure no interruption of care (in the case of leave/absence of prescribing provider). After-hours access may be obtained through the psychiatric emergency department (ED).

Treatment Course in Ambulatory Care (Office-Based Setting)

1. Initiation phase: Any X-waivered practitioner may initiate induction. Consultation with addiction specialty practitioners (either virtual or face to face) will be available for use when needed.

(a) Induction should be guided by evidence-based protocols. Practitioners are required to use the templated buprenorphine induction note, to ensure that prescribing follows federal and state requirements. This will include clear documentation of rationale for use, assessment for comorbid substance use disorders, naloxone education/distribution, prescription drug monitoring program (PDMP) check, baseline toxicology testing, pregnancy testing in females, baseline liver function testing, signed informed consent, and discussion of proper administration (including timing of buprenorphine induction to avoid precipitated withdrawal).

(b) Follow-up by a designated team member, ideally, should be within 3 days of home induction, and then weekly during the first month of treatment.

(c) Medication during induction phase will be issued by pick-up at pharmacy window only. All prescriptions during the initiation phase should be written for a maximum of a 7-day supply. Each prescription should be of sufficient quantity to last only until the next scheduled appointment with the prescriber.

2. Maintenance phase: Patients on stable dosages of buprenorphine and demonstrating regular adherence to medication dosages and treatment plans may continue to receive this medication from any X-waivered practitioner.

(a) Prescription fills should be on a 28-day cycle, and refills should be requested via telephone contact with a designated team member and documented via templated clinical follow up note. Ideally, face-to-face follow-up with designated team member should be on a at least quarterly basis and should include a PDMP check and urine toxicology, with quarterly follow-up considered only when patients can exhibit regular adherence to medication and treatment plan.

(b) Practitioners are required to use the buprenorphine maintenance note to ensure that federal and state requirements are met, including documentation of rationale for use, confirmation of signed informed consent, documentation of naloxone education/distribution, PDMP checks documented as per state regulation (at least every 90 days), and urine toxicology testing documented at least every 90 days (as per SUD 17 measures), with more frequent checks as clinically indicated, and urine pregnancy testing quarterly, and more often as clinically indicated. In addition, providers will assess for adherence, side effects, aberrancy, other SUDs, psychiatric comorbidity, relapse, and psychosocial stability, via use of templated note.

(c) Should the patient become unstable with respect to buprenorphine treatment, eg, through relapse to illicit pharmaceutical or street opioid use, use of other psychoactive substances (eg, alcohol, cannabis, stimulants, other illicit agents),

poor attendance at scheduled appointments, failure to meet outlined treatment goals, or include a higher risk subgroup (example comorbid mental health disorders or pregnancy), practitioners are encouraged to escalate care, via the stepped-care model; options for care escalation include e-consultation with SUD specialty care, consultation with PCMHI clinicians, referral to the subspecialty SUD clinic, or to a higher level of care such as the psychiatric ED as appropriate.

(d) In the event of needed surgery, short term changes in buprenorphine treatment will be discussed and decided on a clinical case-by-case basis.

(e) Urgent access to clinical assessment can occur through the Detoxification and Addiction Stabilization Service (DASS, ext 5215, 7-East Building 1; Monday-Friday 7:30 AM-3:00 PM). The psychiatric ED may also be utilized for urgent or after-hours access.

3. Discontinuation of buprenorphine

(a) There is no recommended time limit for treatment with buprenorphine.

(b) When the decision is made to discontinue buprenorphine treatment, the daily dose should be decreased gradually over a predetermined period or at a rate decided upon by the patient and prescriber together.

(c) Buprenorphine tapering is generally accomplished over several months.

(d) Withdrawal symptoms may emerge as the buprenorphine dose is decreased. These symptoms can be managed with symptom-driven pharmacotherapy (eg, clonidine for anxiety and restlessness, ibuprofen for muscle aches, dicyclomine for abdominal cramping, etc). Patients should routinely be assessed for continued stability in maintaining a drug-free lifestyle.

(e) Reasons for escalation of care, via the stepped care model, to subspecialty addiction care, may include:

- Diversion of buprenorphine;
- Use of sedatives/other illicit substances that significantly increase risk of overdose or serious adverse event; and
- Nonadherence to treatment plans and follow-up

(f) Termination should not be punitive, rather patients should be provided with additional services and higher level of care, including subspecialty addiction care referral via the stepped- care model

5. RESPONSIBILITY: Primary Care and Mental Health service line managers are responsible for ensuring staff compliance with this policy.

6. REFERENCES:

1. Fiellin DA, Pantalon MV, Chawarski MC, et al. Counseling plus buprenorphine-naloxone maintenance therapy for opioid dependence. *N Engl J Med*. 2006;355(4):365-374. doi:10.1056/NEJMoa055255

2. Fiellin DA, Schottenfeld RS, Cutter CJ, Moore BA, Barry DT, O'Connor PG. Primary care-based buprenorphine taper vs maintenance therapy for prescription opioid dependence: a randomized clinical trial. *JAMA Intern Med*. 2014;174(12):1947-1954. doi:10.1001/jamainternmed.2014.5302

3. Haddad MS, Zelenev A, Altice FL. Buprenorphine maintenance treatment retention improves nationally recommended preventive primary care screenings when integrated into urban federally qualified health centers. *J Urban Health*. 2015;92(1):193-213. doi:10.1007/s11524-014-9924-1

4. Substance Abuse and Mental Health Services Administration. *Medications for Opioid Use Disorder.* Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

DEA Requirements https://www.deadiversion.usdoj.gov/faq/buprenorphine_faq.htm

7. RESCISSION: New

8. REVIEW DATE: 1/17/2019

[a]All mentions of buprenorphine throughout this document refer to sublingual buprenorphine (Subutex) or buprenorphine/naloxone (Suboxone).