Community Mental Health Partnership of Southeast Michigan/PIHP	*Policy* **Medication Assisted Treatment (MAT)/ Medication for Opioid Use Disorder (MOUD) – Buprenorphine and Naltrexone**
Department: SUD Services	**Regional Operations Committee Review Date 06/27/2022**
Implementation Date 08/28/2022	**Oversight Policy Board Approval Date 07/28/2022**

I. PURPOSE

To have a uniform policy and procedure for all CMHPSM individuals requesting Buprenorphine or Naltrexone for Medication Assisted Treatment (MAT) or Medication for Opioid Use Disorder (MOUD) as a pharmacological support in Opioid Treatment Programs (OTPs) or Office Based Opioid Treatment (OBOT) locations.

II. REVISION HISTORY

DATE	MODIFICATION
June 2021	
December 2021	Information and Language
April 2022	Information and Language
08/28/2022	Information and Language

III. APPLICATION

This policy applies to any individual requesting MAT or MOUD to include Buprenorphine or Naltrexone as a pharmacological support; Opioid Treatment Program (OTP) Providers; and Utilization Review Staff.

IV. DEFINITIONS

Community Mental Health Partnership of Southeast Michigan (CMHPSM): The Regional Entity that serves as the PIHP for Lenawee, Livingston, Monroe and Washtenaw for mental health, developmental disabilities, and substance use disorder services.

Community Mental Health Services Program (CMHSP): A program operated under chapter 2 of the Mental Health Code as a county community mental health agency, a community mental health authority, or a community mental health organization.

Medication Assisted Treatment (MAT)/Medications for Opioid Use Disorder (MOUD) – These terms refer to medications used to treat Opioid Use Disorder (OUD). They are most commonly referred to as MAT, MOUD is a newer term being used to replace MAT in cases when OUD is the primary diagnosis. Naltrexone can also be used to for treatment of Alcohol Use Disorder (AUD).

Office Based Addiction Treatment (OBAT): A program that utilizes evidence-based treatment to address substance use disorders. This approach incorporates pharmacotherapy and counseling-based interventions.

Office Based Opioid Treatment (OBOT): A program that allows primary care or general health care prescribers with a DATA Waiver to dispense or prescribe any Controlled

Substances Act (CSA) scheduled III, IV, V medication approved by the Food and Drug Administration (FDA) for the treatment of Opioid Use Disorder.

Regional Entity: The entity established under section 204b of the Michigan Mental Health Code to provide specialty services and supports.

V. BACKGROUND

The Food and Drug Administration (FDA) approved Buprenorphine hydrochloride (Subutex®) and buprenorphine hydrochloride/naloxone hydrochloride (Suboxone®) on October 8, 2002 for the treatment of Opioid Use Disorder (OUD). There are other forms of these medications also approved by the FDA. Both buprenorphine and buprenorphine/naloxone can be administered in sublingual tablets or films (placed under the tongue) and gradually absorbed, or there are also injectable forms of these medications. Prior to their approval and subsequent scheduling as Schedule III medications, the only prescription medications approved for opioid substitution agents were Methadone and LAAM, both Schedule II medications. Schedule II medications must be prescribed to patients enrolled in OTPs. Because of the numerous federal and state regulations with respect to OTPs, the addition of Schedule III medications as adjunctive treatment greatly increases access to services for potential opioid use disorder treatment individuals because they can now receive medication for opioid use disorder through a qualified physician's office.

Buprenorphine is a partial agonist at the mu opioid receptor which allows for a decreased overall increase in dopamine release thus creating a ceiling effect of the addictive potential of the medication. Buprenorphine has a ceiling effect for toxicity because of its antagonist properties. Once a certain dose or receptor occupancy level is reached, additional dosing does not produce further toxicity. Studies have shown that buprenorphine plateaus at the equivalent of 40 to 60 milligrams of Methadone. Because of the maximum for toxicity, respiratory depression and/or death from overdose are less common than with opioid agonists, such as heroin, oxycodone, or Methadone. Concurrent use of buprenorphine with alcohol, benzodiazepines, or other respiratory depressants can still result in overdose. Naloxone (Narcan) is added to buprenorphine by the manufacturer to prevent diversion because, although the naloxone will have no effect when absorbed under the tongue, crushing and injecting the medication will result in sudden and intense withdrawal symptoms. The ceiling effect also restricts the medication's effectiveness in treating patients who have a need for high levels of opioid replacement medication.

Naloxone and Naltrexone are medications that also block the effects of morphine, heroin, and other opioids. As antagonists, they are especially useful as antidotes. Naltrexone has long-lasting effects, ranging from 1 to 3 days, depending on the dose. The injectable version of Naltrexone (Vivitrol*) lasts for 30 days. Naltrexone blocks the pleasurable effects of opioids and is useful in treating some highly motivated individuals. Naltrexone has also been found to be successful in preventing relapse following periods of abstinence. This medication can also be used for Alcohol Use Disorder.

Although behavioral and pharmacologic treatments can be extremely useful when employed alone, integrating both types of treatments will ultimately be the most effective approach. There are many effective behavioral treatments available for OUD. These can include residential and outpatient approaches. An important task is to match the best treatment approach to meet the particular needs of the individual.

VI. POLICY

Private physicians who have the Substance Abuse and Mental Health Services Administration (SAMHSA) waiver for prescribing buprenorphine/naloxone are limited to managing 30 individuals on buprenorphine at any one time. An OTP physician who has the SAMHSA waiver may prescribe the medication for off-site use as if the physician were in private practice. The maximum number of active individuals would be 30 individuals. Qualified practitioners who undertake required training can treat up to 100 patients using buprenorphine for the treatment of OUD in the first year if they possess a waiver under 21 U.S.C. § 823(g)(2) (i.e., a DATA 2000 waiver) and meet certain conditions (SAMHSA.gov).

One of two conditions must be satisfied for qualified practitioners to treat 100 patients in their first year:

1. The physician holds a board certification in addiction medicine or addiction psychiatry by the American Board of Preventive Medicine or the American Board of Psychiatry and Neurology
2. The practitioner provides medication-assisted treatment (MAT) in a "qualified practice setting." A qualified practice setting is a practice setting that:
    - provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed;
    - provides access to case-management services for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services;
    - uses health information technology systems such as electronic health records;
    - is registered for their State prescription drug monitoring program (PDMP) where operational and in accordance with Federal and State law; and
    - accepts third-party payment for costs in providing health services, including written billing, credit, and collection policies and procedures, or federal health benefits.

After one year at the 100-patient limit, qualifying practitioners who meet the above criteria can apply to increase their patient limit to 275. In addition, 42 CFR 8.655 defines circumstances in which qualifying practitioners may request a temporary increase to treat up to 275 patients to address emergency situations for six months (SAMHSA.gov). The waiver can be found here: https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php

Program Requirements

1. The individual must have a Diagnostic Statistical Manual (DSM) impression of opioid use disorder as determined by the treating provider. All six dimensions of the current American Society of Addiction Medicine (ASAM) Patient Placement Criteria must be used. The individual must meet medical necessity criteria as determined by a physician who has a SAMHSA waiver to prescribe or dispense buprenorphine.

2. Buprenorphine/naloxone must be used as adjunct to opioid treatment throughout the continuum of care (OP, IOP, Residential, sub-acute detoxification, and Methadone adjunctive treatment as part of a detoxification regimen).

3. Toxicology screens must be done at intake and then on a random basis, at least weekly, for the first six months. For a new recipient to a program, the test results must be documented in the individual record prior to the initial dosing. After the first six months of negative screens testing must be done on a random frequency at least monthly. Screens must assay for opioids, cocaine, amphetamines, cannabinoids, benzodiazepines, and Methadone metabolites.

VII. References

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American Society of Addiction Medicine. (2001). *ASAM Patient Placement Criteria for the Treatment of Substance-Related Disorders*, Second Edition-Revised, ASAM UPC-2R, Chevy Chase, Maryland.
Become a Buprenorphine Waivered Practitioner; SAMHSA.gov; https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner

Certification of Opioid Treatment Programs: United States Code of Federal Regulations, Title 42, Part 8, Washington, D.C. (2003).

Drug Addiction Treatment Act of 2000: PL106-310, Section 3502, United States House, 105th Congress, Washington, DC. (October 17, 2000).

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MDHHS Substance Use Disorder Services Policies, Behavioral Health and Developmental Disabilities Administration (BHDDA), OROSC. (2006) *Treatment Policy #3, Buprenorphine*
https://www.michigan.gov/documents/Treatment_Policy_03_Buprenorphine_145923_7.pdf

Office Based Opioid Treatment (OBOT): Indian Health Service, The Federal Health Program for American Indians and Alaska Natives.
https://www.ihs.gov/opioids/recovery/obot/

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Addition of Buprenorphine and Buprenorphine Combination to List of Approved Opioid Treatment Medications: Federal Register, Volume 68, Number 99, pp 27937-27939, Interim final rule, United States Superintendent of Documents. (May 22, 2003).

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