

#### **Public Policy Statement on the Regulation of Office-Based Opioid Treatment**

#### **Background**

Office-based opioid treatment (OBOT) commonly refers to outpatient treatment services provided outside of licensed Opioid Treatment Programs (OTPs) by clinicians to patients with addiction involving opioid use, and typically includes a prescription for the partial opioid agonist buprenorphine, the provision of naltrexone, or the dispensing of methadone, in concert with other medical and psychosocial interventions to achieve and sustain remission. The initial model of office-based opioid treatment using methadone was first devised as a pathway to expand the reach and capacity of methadone treatment in the 1980's. 1,2 In the United States today, the most common type of OBOT uses the partial opioid agonist buprenorphine and was made possible by the Drug Addiction Treatment Act of 2000 (DATA 2000). The law provided a pathway for qualified physicians to apply for a waiver separate from the Drug Enforcement Administration (DEA) registration requirements that licensed OTPs must meet. DATA 2000 allowed physicians to use certain Schedule III-V controlled substances approved by the Food and Drug Administration (FDA) for the treatment of patients with addiction involving opioid use. In 2002, the FDA approved the use of buprenorphine, a Schedule III opioid, for this purpose and has subsequently approved several different buprenorphine formulations designed to deter its misuse. When compared with methadone maintenance treatment (MMT), OBOT permitted more physicians the opportunity to treat and bill for the treatment of opioid addiction within their regular medical practice. This provided for expanded access to treatment, potential payment mechanisms for physicians in practice as is appropriate for the treatment of chronic diseases, and a more private treatment experience for the patient with an opioid use disorder. The Comprehensive Addiction and Recovery Act (CARA) of 2016 expanded on DATA 2000 to allow nurse practitioners (NPs) and physician assistants (PAs) to become eligible for a waiver as well.

DATA 2000 and CARA have greatly expanded access to evidence-based treatment for patients with addiction involving opioid use. Relative to treatment without medication, office-based opioid treatment with buprenorphine improves six-month treatment engagement, significantly reduces cravings, illicit opioid use and mortality, and improves psychosocial outcomes.<sup>3,4</sup> Importantly, agonist therapy has been shown to decrease mortality by approximately 50% among persons with opioid-use disorder.<sup>5</sup> However, because its use in addiction treatment has increased, concerns have risen about the possible role of OBOT in buprenorphine diversion. In preliminary data from 2016, buprenorphine was the ninth most common drug, and fourth most common prescription opioid, among drugs secured in law enforcement operations and analyzed by federal, state or local forensic laboratories.<sup>6</sup> While the risks of morbidity and mortality are low for buprenorphine, efforts should be made to address diversion, which may possibly be mitigated with some enhanced practices. In fact, studies have shown that the lack of treatment availability is directly linked to the increase in diversion.<sup>3,4</sup>

In 2015, to define and support high-quality treatment for addiction involving opioid use, the American Society of Addiction Medicine (ASAM) released the *National Practice Guideline on the Use of Medications to Treat Addiction Involving Opioid Use* (Practice Guideline). The Practice Guideline covers all FDA-approved medications available to treat addiction involving opioid use and opioid overdose, and aims to help clinicians make evidence-based decisions when prescribing these medications to patients with opioid use disorders. Since studies have shown that lack of treatment access is a risk factor for buprenorphine diversion, and diverted buprenorphine is often used to manage symptoms by persons who cannot access treatment, increasing access to evidence-based treatment as described by the Practice Guideline may be the most effective policy solution to reduce diversion.

To ensure an appropriate quality of care for patients receiving office-based opioid treatment and reduce the diversion of buprenorphine, several states have proposed or begun to regulate the practices of physicians who offer OBOT. The regulatory schemes vary by state, but generally involve a licensing requirement and associated inspections and fees, and may include requirements related to staff training, types of services offered, and/or limits on buprenorphine dosages and formulations. This policy statement aims to inform the creation and implementation of OBOT regulations so that they are evidence-based and do not dissuade clinicians from offering OBOT services, nor create environments unattractive to patients because of unnecessary and unhelpful regulatory burden.

#### **Regulatory Considerations**

ASAM believes that OBOT is a positive development in that it promotes the treatment of addiction in the primary care setting. As such it does not support the exclusive licensing of these sites but rather supports oversight from state medical boards and departments of health as superior to specific licensing. However, ASAM understands that the use of controlled substances to treat the disease of addiction introduces the possibility of misuse and diversion of the very medications used for treatment. Given this, some states may seek to regulate the practices that deliver such treatment to patients with addiction. If a state feels thus compelled, any regulatory framework should be developed from the perspective of what is best for the patient and feasible for the provider while not neglecting the safety of a household or the community at large. Thus, the development of such regulations should include perspective from all of those involved including patients, so that successful balancing can occur between feasibility of implementation and maintenance of safety in these environments. It is vital that timely access to addiction treatment occurs, and thus unnecessary and over-burdensome barriers to treatment should be avoided.

#### **ASAM** recommends:

- States and local jurisdictions should not enact non-evidence-based oversight of OBOT, such as required mandatory medication taper schedules or limits on dosages.
- States seeking to regulate OBOT should consult with addiction specialist physicians in designing regulations which balance treatment effectiveness with patient and public safety.
- States that choose to regulate OBOT should study the effects of its regulations on access to treatment and diversion of buprenorphine.
- Any licensing should be overseen by the state board of medicine and/or department of health.
- Providers that treat 100 or fewer patients should be exempt from any additional regulatory requirements beyond what it is included in the Drug Addiction Treatment Act of 2000, as amended by the Comprehensive Addiction and Recovery Act of 2016.

- Providers who are approved to treat up to 275 patients should be subject to no more than the
  reporting requirements specified by the Substance Abuse and Mental Health Services
  Administration (SAMHSA).
- Clinicians should consider adopting diversion control measures, such as drug testing, reviewing reports from the prescription drug monitoring program (PDMP) and recall visits for pill counts.
- Restrictions on buprenorphine mono-product, if justified, should exclude implantable or depot formulations.

#### **Level of Training**

#### Prescriber (MD, DO, NP, PA)

Delivering addiction treatment can be a complicated process in any environment. In a primary care setting this difficulty can be amplified by the heterogeneity of the patient population and the pace and volume of work. Thus, the training demands on the individual prescribing medication for opioid use disorders should be sufficient but not excessive given time constraints and available resources in what are often challenging clinical settings.

#### **ASAM recommends:**

- Clinicians should obtain training covering buprenorphine, methadone and naltrexone and any
  other topics that align with current federal policy.
- Clinicians should voluntarily continue their knowledge with annual CME focused on treating addiction, including the use of all FDA-approved medications, evidence-based pain treatment and properly addressing behavioral health screening and intervention.

#### Treatment Continuum of Care Including Components, Structure, and Intensity

ASAM recognizes the place that OTPs hold in the continuum of care by providing highly structured treatment environments. The clinical, social, and public health benefits of methadone maintenance administered in federally-licensed and accredited OTPs have been repeatedly demonstrated in clinical research studies and are irrefutable. In addition, recent studies of medical maintenance support both the feasibility and efficacy of transferring stable patients to office-based physician care. If transferred or started on evidence-based medications in the OBOT setting, other major treatment components should be available either directly or through referral. Examples of other major treatment components can include counseling (individual and group), general medical care, psychiatric services, programs for family members, educational/vocational counseling, financial counseling, and legal services, as well as monitoring progress and adherence through laboratory testing and prescription drug monitoring programs. It is important to note that many services are not available in all communities, and that this should not preclude patients from accessing the treatment components that are available. Generally, unstable patients in early treatment require both more structured treatment and greater intensity of such services than patients who are stable and are actively managing their disease. ASAM recognizes that patients who prove unstable in office settings may likely require the level of structure and intensity of integrated services available in an OTP, either with buprenorphine or methadone, if a higher level of structure cannot be obtained in the OBOT setting. 10 However, in areas where such services are not available, such as areas where there are no OTPs, pharmacological treatment alone with support of the treating clinician results in improved outcomes for some patients.<sup>11</sup>

#### **ASAM** recommends:

- That OBOT physicians, affiliated or independent, and OTPs establish a collaborative relationship that permits patients to be referred between programs, providing differing models and intensities of treatment, according to clinical needs.
- Clinicians should document provision of or referral for additional psychosocial treatment if indicated.
- Clinicians should be required to register for their state PDMP and check the PDMP at treatment initiation and once per quarter or per their state requirement thereafter regardless of level of care.
- Clinicians should co-prescribe naloxone to patients receiving OBOT, both as a risk-reduction measure and so that buprenorphine is not incorrectly used to treat opioid overdose, regardless of level of care.

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#### **American Society of Addiction Medicine**

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<sup>&</sup>lt;sup>1</sup> O'Connor PG, Fiellin DA. Pharmacologic treatment of heroin-dependent patients. *Ann Intern Med*.2000; 133:40-54.

<sup>&</sup>lt;sup>2</sup> Salsitz EA, Joseph H, Fran B, et al., Methadone medical maintenance (MMM): treating chronic opioid dependence in private medical practice – a summary report (1983-1998), *Mount Sinai Journal of Medicine* 2000; 67(5-6); 388-397

<sup>&</sup>lt;sup>3</sup> American Society of Addiction Medicine, Treatment Research Institute. (2013). FDA Approved Medications for the Treatment of Opiate Dependence: Literature Reviews on Effectiveness and Cost-Effectiveness. Chevy Chase, MD: American Society of Addiction Medicine. Available at <a href="http://www.asam.org/docs/default-source/advocacy/aaam\_implications-for-opioid-addictiontreatment\_final">http://www.asam.org/docs/default-source/advocacy/aaam\_implications-for-opioid-addictiontreatment\_final</a>.

<sup>&</sup>lt;sup>4</sup> Mattick RP, Breen C, Kimber J, Davoli M. Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. Cochrane Database of Systematic Reviews 2014, Issue 2. Art. No.: CD002207.

<sup>&</sup>lt;sup>5</sup> Schuckit MA. Treatment of Opioid-Use Disorders. *N Engl J Med* 2016; 375:357-368.

<sup>6</sup> U.S. Drug Enforcement Administration, Office of Diversion Control. (2017). National Forensic Laboratory Information System: 2016 Midyear Report. Springfield, VA: U.S. Drug Enforcement Administration. Available at: <a href="https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS\_MidYear2016.pdf">https://www.nflis.deadiversion.usdoj.gov/DesktopModules/ReportDownloads/Reports/NFLIS\_MidYear2016.pdf</a>

<sup>&</sup>lt;sup>7</sup> Lofwall MR and Havens JR. Inability to access buprenorphine treatment as a risk factor for using diverted buprenorphine. Drug Alcohol Depend. 2012; 126:379-383.

<sup>&</sup>lt;sup>8</sup> Yokell MA, Zaller ND, Green TC, Rich JD. Buprenorphine and Buprenorphine/Naloxone Diversion, Misuse, and Illicit Use: An International Review. Current drug abuse reviews. 2011;4(1):28-41.

<sup>&</sup>lt;sup>9</sup> Saxon AJ, Special Issues in Office-Based Opioid Treatment, Chapter 5, *Principles of Addiction Medicine 5<sup>th</sup> Ed. 2014* (*Ries, Fiellin, Miller & Saitz, Ed.s*), pp. 778-795.

<sup>&</sup>lt;sup>10</sup> Mee-Lee D. et al., Eds., *The Asam Criteria 3<sup>rd</sup> Ed.*, 2013, ASAM

<sup>&</sup>lt;sup>11</sup> Fiellin DA, Pantalon MV, Chawarksi MC, et al. Counseling plus Buprenorphine–Naloxone Maintenance Therapy for Opioid Dependence. *N Engl J Med* 2006; 355:365-74.

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## PREFERRED OFFICE-BASED ADDICTION TREATMENT and OPIOID TREATMENT PROGRAM SUPPLEMENT

On April 1, 2017, Virginia's Medicaid program launched an enhanced substance use disorder (SUD) treatment benefit called **Addiction and Recovery Treatment Services (ARTS)**. The ARTS benefit expands access to a comprehensive continuum of evidence-based addiction treatment services for all enrolled fee-for-service and managed care members in Medicaid, Medicaid Expansion, FAMIS and FAMIS MOMS throughout the state, including community-based addiction and recovery treatment services, residential SUD treatment and coverage of inpatient withdrawal management.

The ARTS benefit increases access to medication assisted treatment (MAT), the evidence-based combination of Medication for Opioid Use Disorder (MOUD), psychotherapy, counseling, and psychosocial supports that results in the highest chances of recovery by recognizing Opioid Treatment Programs (OTPs) and Preferred Office-Based Opioid Treatment (OBOT) Providers. The ARTS benefit aligns with the American Society of Addiction Medicine (ASAM) Criteria: Treatment Criteria for Addictive, Substance-related, Co-occurring Conditions, 3rd ed.. DMAS encourages practices that co-locate licensed behavioral health professionals with the buprenorphine-waivered practitioner to reduce barriers for members with opioid use disorder (OUD) in accessing these services.

Per requirements of Section ZZZ the <u>2020 Appropriations Act</u>, DMAS is expanding the OBOT model effective March 1, 2022, to allow for other primary SUDs, referred to herein as Preferred Office-Based Addiction Treatment or Preferred OBAT. Note that OTPs continue to require primary OUD to serve members.

The purpose of this supplement is to provide specific information on the following services:

- OTPs.
- Preferred OBATs,
- MOUD services provided by an in-network buprenorphine waivered practitioners independent from Preferred OBATs and OTP settings.

#### PROVIDER ENROLLMENT

To become an in-network provider with DMAS, its contractor and Managed Care Organizations (MCO), providers must be credentialed and enrolled according to all applicable contractor standards. Providers are subject to applicable Department of Health Professions and Department of Behavioral Health and Developmental Services (DBHDS) licensing requirements. DMAS provider enrollment is located:

https://www.virginiamedicaid.dmas.virginia.gov/wps/portal/WebRegistration.

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Additionally, any licensed practitioner joining a contracted group practice or a contracted organization adding a newly licensed location must also become credentialed with the DMAS feefor-service contractor prior to rendering services. Per §38.2-3407.10:1, the MCOs are required to establish reasonable protocols and procedures for reimbursing new provider applicants, within 30 days of being credentialed by the MCO, for health care services or mental health services provided to covered persons during the period in which the applicant's completed credentialing application is pending. To initiate the application process for contracting and the credentialing process, providers should contact the specific DMAS fee-for-service contractor or MCO. Please note: All participating Medicaid providers are required to complete a new contract agreement as a result of any name change or change of ownership.

In addition to following all general provider requirements outlined in the ARTS Provider Manual Chapter II, providers must also meet the applicable requirements listed below in addition to practicing within the scope of their license/certification/registration with the Department of Health Professions (DHP) (i.e. Board of Medicine, Nursing, Counseling, Social Work, Psychology, etc.). Providers must have the knowledge, skills and abilities (KSAs) for SUD and treatment with applicable experience. Providers may obtain certification for SUD treatment to support having the KSAs, however certification is not required. Attendance in trainings, conferences, classes, etc. that staff participate in to increase their KSAs for SUD treatment and recovery may be kept in their personnel file or records to support this requirement.

All providers for services listed within this supplement must submit the appropriate ARTS Attestation Packet to the DMAS fee-for-service contractor and MCOs to initiate the credentialing process. The ARTS Attestation Forms and Staff Roster and other application forms mentioned below are posted online at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/credentialing/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/credentialing/</a>.

## **Application Process**

- OTP OTPs must submit the "ARTS Attestation Form for Opioid Treatment Programs", "ARTS Staff Roster" and copy of relevant DBHDS license directly to the DMAS fee-for-service contractor and MCOs to begin the credentialing process.
- **Preferred OBATs** Preferred OBATs application process requires several steps including:
  - All licensed practitioners within the program must be credentialed as an in-network provider with DMAS fee-for-service contractor or at least one of the MCOs.
  - Providers must submit the "ARTS Preferred Office-Based Addiction Treatment Program Attestation Form", the "ARTS Preferred OBAT Organizational Staff Roster", and the "ARTS Preferred OBAT Credentialing Checklist" directly to DMAS. The Application Packet is located online at:

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https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/credentialing/ and must be submitted via email to: SUD@dmas.virginia.gov.

- o DMAS will review the Application Packet and determine if it meets the criteria and model of care for the Preferred OBAT status.
- Note: The application should reflect day-to-day operations and staff roles that are specific to the site of the Preferred OBAT application. Providers submitting multiple applications for various sites using a copy and paste method for the application will not be accepted by DMAS. The applications must be unique to the individual site.

Note: Currently approved Preferred OBOTs do not need to take any additional action to be able to serve members with other primary SUD in addition to or without OUD.

Once recognition by DMAS as a Preferred OBAT has been established, DMAS will send the provider a "Preferred OBAT Recognition Letter". The provider must then submit a copy of this letter and a copy of the "ARTS OBAT Organizational Staff Roster" to the DMAS fee-for-service contractor and MCOs and finalize the credentialing process as a Preferred OBAT in order to begin to receive the enhanced reimbursement. Please note the DMAS fee-for-service contractor and the MCOs may require additional documentation to complete the credentialing process.

Continued participation as a Preferred OBAT is contingent on providers maintaining their credentialing or contract status with the DMAS fee-for-service contractor or MCOs, as well as meeting the standards of care and best practices specified in the ARTS Regulations and ARTS Provider Manual.

## **Out-Of-Network Providers**

DMAS strongly encourages the MCOs to transfer members from out-of-network providers who are requiring members to pay out-of-pocket, to in-network Preferred OBATs, OTPs, and other innetwork buprenorphine-waivered practitioners who are within 30 miles in an urban area and 60 miles in a rural area (which meets DMAS network adequacy standards for MCOs) of the member. The MCO will cover all the members' addiction treatment services (e.g., physician visits, laboratory tests, counseling, medication, care coordination, etc.) instead of members needing to pay out-of-pocket to out-of-network providers. Medicaid covers transportation coverage for members to and from their appointments to Medicaid covered services. This increased access to Preferred OBAT Providers and OTPs will ensure that members receive evidence-based MAT including MOUD, medications for alcohol use disorder (AUD), counseling and psychosocial supports, as well as the "high touch" care coordination that will result in the best outcomes.

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#### What Constitutes a Medicaid Provider

Providers are considered Medicaid providers if they are enrolled with DMAS, credentialed with at least one Medicaid MCO or credentialed with DMAS's fee-for-service contractor. Providers who are enrolled with DMAS, credentialed with a Medicaid MCO or the DMAS fee-for-service contractor are considered Medicaid providers in any setting they practice that involves services to individuals enrolled in the Medicaid, Medicaid Expansion, FAMIS or FAMIS MOMS, and for which the provider may receive reimbursement through Medicaid, either directly or indirectly.

The acceptance of payment or anything of value beyond any deductible, coinsurance or copayment required by the member's benefit, by a Medicaid provider outside of the Medicaid reimbursement system for covered SUD treatment services is prohibited and DMAS will take action against any provider who violates this rule. The Agency investigates complaints concerning providers who solicit and receive cash or excess payments from members enrolled in Virginia Medicaid for covered services including office visits, counseling sessions, and MOUD. A Virginia Medicaid provider's solicitation or acceptance of money, or anything of monetary value, in exchange for Medicaid covered SUD treatment services is not permitted. Accepting payment for Medicaid covered-services from an enrolled member is considered "balance billing," which is federally prohibited in accordance with 42 CFR § 447.15, and 12 VAC 30-10-580, as well as the Medicaid Provider Agreements.

# <u>In-Network Buprenorphine Waivered Practitioners Practicing Independently of an OTP and Preferred OBAT</u>

Buprenorphine waivered practitioners must be credentialed by DMAS, its fee-for-service contractor and MCOs. Please note laboratory services that are not covered by the DMAS fee-for-service contractor must be billed to DMAS, practitioners need to be enrolled with DMAS for reimbursement. DMAS will also complete the federal screening requirements as noted in Chapter II of the ARTS Manual.

The ARTS specific procedure codes, reimbursement structure and service authorization requirements for MOUD services delivered independently of a Preferred OBAT or OTP setting are posted online at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/</a> and included as an Appendix to this Supplement.

If not currently enrolled with DMAS, providers must complete a provider enrollment request with DMAS via the online enrollment application on the DMAS Virginia Medicaid web-portal. If a provider is unable to enroll electronically through the web, they can download a paper application from the Virginia Medicaid web-portal and follow the instructions for submission. Please go to <a href="https://www.virginiamedicaid.dmas.virginia.gov">www.virginiamedicaid.dmas.virginia.gov</a> to access the online enrollment system or to download a paper application.

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DMAS encourages providers to enroll or make updates electronically via our web portal. An application for participation submitted on paper will add additional time to the processing of your enrollment and to your request to update your provider file.

Please note: If you are planning to enroll via the paper enrollment process, DMAS will only accept the provider enrollment applications that have the provider screening questions listed. Previous versions of the provider enrollment applications that do not have the provider screening regulation questions will not be accepted and will be rejected with a request to submit the version that is currently posted on the Virginia Medicaid Web Portal at: <a href="https://www.virginiamedicaid.dmas.virginia.gov">www.virginiamedicaid.dmas.virginia.gov</a>.

If you have any questions regarding the online or paper enrollment process, please contact the Provider Enrollment Services at toll free 1-888-829-5373 or local 1-804-270-5105.

All participating Medicaid providers are required to complete a new contract agreement as a result of any name change or change of ownership.

#### PROVIDER OVERVIEW

## **Opioid Treatment Programs (OTPs)**

OTPs are programs certified by the United States Substance Abuse and Mental Health Services Administration (SAMHSA) that engage in supervised assessment and treatment, using methadone, buprenorphine, or naltrexone, of members who have an OUD (12VAC30-130-5020). OTP includes the use of MOUD in addition to the psychotherapy services to treat a member with an OUD. Members must have primary OUD to be treated at an OTP.

## Preferred Office-Based Addiction Treatment (OBAT) Providers

Preferred OBAT Providers, previously known as "Preferred OBOTs", deliver addiction treatment services to members with OUD as well as other primary SUD. Preferred OBAT services are required to be provided by buprenorphine-waivered practitioners working in collaboration and colocated with Credentialed Addiction Treatment Professionals providing psychosocial treatment in public and private practice settings (12VAC30-130-5020). Credentialed Addiction Treatment Professional means: an individual licensed or registered with the appropriate board in the following roles: (i) an addiction-credentialed physician or physician with experience or training in addiction medicine; (ii) physician extenders with experience or training in addiction medicine; (iii) a licensed psychiatrist; (iv) a licensed clinical psychologist; (v) a licensed clinical social worker; (vi) a licensed professional counselor; (vii) a certified psychiatric clinical nurse specialist; (viii) a licensed psychiatric nurse practitioner; (ix) a licensed marriage and family therapist; (x) a licensed professional counselor (18VAC115-20-10), licensed marriage and family therapist (18VAC115-50-10), or licensed substance abuse treatment practitioner (18VAC115-60-10) and is registered with the Virginia Board of Counseling; (xii) a resident in psychology who is under supervision of

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a licensed clinical psychologist and is registered with the Virginia Board of Psychology (18VAC125-20-10); or (xiii) a supervisee in social work who is under the supervision of a licensed clinical social worker and is registered with the Virginia Board of Social Work (18VAC140-20-10).

Additional staff who may practice within the Preferred OBAT setting include but are not limited to: Certified Substance Abuse Counselors (CSAC), CSAC-Supervisees, CSAC-Assistants, Pharmacists, Registered Nurses, Licensed Practical Nurses, and Registered Peer Recovery Support Specialists\*. These staff do not replace the required staff as stated above, but enhance the services delivery for Preferred OBATs.

\*DMAS recognizes that embedded Peer Recovery Support Services can complement interdisciplinary clinical services and function both in conjunction with or independently of the behavioral health care continuum as a core service.

## **In-Network Buprenorphine Waivered Practitioners**

DMAS supports buprenorphine waivered practitioners practicing independently from an OTP or Preferred OBAT site to be in-network with the member's MCO or DMAS's fee-for-service contractor to leverage the available supports for members.

#### MEDICAL NECESSITY CRITERIA

To be eligible for services, the member must be enrolled in Virginia Medicaid and must meet the following medical necessity criteria below:

- For OTPs: The member must have a primary diagnosis of OUD as defined by the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM).
- For Preferred OBATs: The member must have a primary diagnosis of SUD as defined by the most current version of the DSM, with the exception of tobacco-related disorders and non-substance-related addictive disorders.
- The member must be assessed by a Credentialed Addiction Treatment Professional acting within the scope of their practice, who will determine if the severity and intensity of treatment requirements as defined by the most current version of the American Society of Addiction Medicine (ASAM) Treatment Criteria for Addictive, Substance-Related and Co-Occurring Conditions (Third Edition, 2013) is met for this level of care.

Please note that Preferred OBATs and OTPs are required to develop the following within these time frames:

- Initial Individual Service Plan (ISP) within 24 hours from intake;
- Interdisciplinary Plan of Care (IPOC) within 30 calendar days from initiation of treatment; and

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• Update the IPOC, at a minimum, every 90 calendar days.

Providers may use, but are not required to use the DMAS ISP form for Preferred OBATs and the IPOC form for Preferred OBATs and OTPs. The DMAS ISP and IPOC forms are further defined later in this Supplement and posted online at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/policy-and-provider-manual/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/policy-and-provider-manual/</a>.

## **COVERED SERVICES & STAFF REQUIREMENTS**

#### General Evidence-Based Practices for Treatment of OUD and other SUD

DMAS emphasizes the importance of providing care that is responsive to individual patient preferences, needs and values, and supports Medicaid providers' efforts to address the needs of members with OUD and other SUD. DMAS' goals are to minimize treatment barriers for members who have SUD while ensuring these members obtain access to high quality MOUD as appropriate and other proven therapies.

Below is a summary of the current evidence and available coverage through the ARTS benefit that applies to both OTP and Preferred OBAT settings. Nothing in this summary is intended to eliminate the need to follow the Virginia Board of Medicine regulations (18 VAC 85-21-10 et seq.) concerning the prescribing of MOUD for treatment of OUD.

- DMAS encourages same day access and initiation of MOUD for individuals with OUD.
- Remaining in treatment for an adequate period of time is critical to recovery. To best support members in their recovery, **DMAS follows the ASAM Criteria** and the member's level of care shall be based on this versus arbitrary limits of care, regardless of SUD. In addition, **maintenance pharmacotherapy should be prescribed based on the individual's treatment needs**, without arbitrary tapering or time limits.
- No prior authorization is required for the preferred buprenorphine/naloxone product, Suboxone films or the generic buprenorphine/naloxone SL tablets. Evidence exists that some individuals may benefit from buprenorphine doses greater than 16 milligrams per day through higher rates of treatment retention and abstinence from illicit substances. Therefore, DMAS provides coverage for doses up to 24 milligrams per day of Suboxone films and the generic buprenorphine/naloxone SL tablets in alignment with the Virginia Board of Medicine maximum dosage per day. Providers shall continue to follow the Virginia Board of Medicine guidelines regarding dosing during the induction phase as well as maximum prescribing dosages. Please note that the Virginia Board of Medicine requires documentation in the member's record to support prescribed doses of greater than 16 milligrams per day.
- Naltrexone, both Vivitrol and the generic tablets, are also preferred products and do not require prior authorization for both fee-for-service and MCO enrolled members. Naltrexone is approved by the Food and Drug Administration (FDA) for the treatment of OUD and AUD and does not require the buprenorphine waiver to prescribe. Disulfiram

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- and Acamprosate are also FDA approved for the treatment of AUD and do not require prior authorization for fee-for-service and MCO enrolled members.
- DMAS acknowledges that diversion and misuse of buprenorphine/naloxone may still occur but is relatively rare in comparison to diversion and misuse of prescription opioid pain medications. The most commonly cited reason is to manage the negative side effects of opioid withdrawal.
- DMAS requires the **co-prescribing of the overdose reversal agent naloxone with MOUD** since individuals with OUD are at elevated risk for overdose. DMAS also recommends co-prescribing of naloxone for individuals with any SUD as the risks of polysubstance use, whether intentional opioid use or unintentional use if drugs are contaminated with synthetic opioids, increases risk factors for overdose. This is important due to the increasing presence of fentanyl in non-opioid illicit drugs, such as cocaine and methamphetamine. When possible, family members and significant others should also be trained in the use of naloxone. **Medicaid covers naloxone at no cost to the member.**
- DMAS supports the integration and co-location of medical services with addiction services including clinically indicated infectious disease testing such as HIV, Hepatitis A/B/C, syphilis, and tuberculosis testing for members with SUD at initiation of and as indicated during treatment. DMAS provides coverage for the treatment of Hepatitis C and HIV treatment and prevention including pre-exposure prophylaxis (PrEP). Hepatitis C treatment is covered for all Medicaid members with any fibrosis score. Primary care providers can prescribe preferred drugs such as Mavyret (glecaprevir/pibrentasvir) without a referral to a specialist. Members should not be denied treatment for Hepatitis C for the sole reason of SUD. Please see the DMAS Preferred Drug List for more information: <a href="https://www.dmas.virginia.gov/for-providers/prescription-drug-formularies">https://www.dmas.virginia.gov/for-providers/prescription-drug-formularies</a>.
- DMAS supports **integration of reproductive health services including contraception with addiction treatment**. Medicaid covers all family planning medications and devices including long acting reversible contraception (LARC) without a prior authorization.
- DMAS allows and encourages same-day billing of medical and behavioral health services to support integrated medical services and addiction services. Providers should contact the Medicaid MCOs to determine the appropriate modifier to place on claims (such as "GB" or "25") which defines the services as separate and distinct from each other to support billing.
- DMAS supports home inductions of MOUD as clinically appropriate and in accordance with the ASAM National Practice Guideline.
- Recurrence of substance use is a common occurrence among individuals with SUD. DMAS
  encourages providers to use urine drug testing as a therapeutic tool and not to
  discharge patients based on relapse and/or positive drug test results. Upon discovering
  relapse, providers should re-assess a patient's condition, their adherence, their dose of
  pharmacotherapy (for OUD and AUD) and behavioral treatment, and consider
  intensification of care. Additional guidance for urine drug testing is covered later in this
  manual.

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• The introduction of **MOUD** prior to and immediately after release from institutional settings, such as hospitals, inpatient rehabilitation facilities, correctional facilities and jails, can reduce the elevated risk of fatal overdose related to loss of tolerance. Thus DMAS encourages Preferred OBAT and OTP providers to build these relationships and work closely with their community partners to develop linkages for members transitioning to community-based care.

## **Opioid Treatment Programs (OTP)**

OTP providers must be licensed by DBHDS as a provider of Medication Assisted Opioid Treatment and contracted by the MCOs and the DMAS fee-for-service Contractor as an ARTS OTP Provider.

The ARTS specific procedure codes and reimbursement structure for OTP services are posted online at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/</a>.

In addition, OTP providers must meet the following criteria:

1. Staff requirements for OTP programs must meet the licensing requirements of 12VAC35-105-925 et al. The interdisciplinary team must include Credentialed Addiction Treatment Professionals acting within the scope of their practice and trained in the treatment of opioid use disorder including an addiction credentialed physician or physician extenders and as defined in 12VAC30-130-5020.

OTPs may also utilize Certified Substance Abuse Counselors (CSACs) (defined § 54.1-3507.2) and CSAC-Supervisees (defined in §54.1-3507.1 C) within the scope of their practice to provide substance use disorder counseling, psychoeducational services which is further defined in the Board's Guidance Document: 115-11. The CSACs and CSAC-Supervisees may not practice autonomously and must be supervised according to Board of Counseling requirements. Note: A "diagnostic" assessment completed by the appropriately licensed professional and a "multidimensional" assessment, conducted according to the ASAM Criteria, are both required for Medicaid reimbursement for services. CSACs and CSAC-Supervisees are not allowed to do a diagnostic assessment but are allowed to do the multidimensional assessment to make recommendations for a level of care that must then be signed off on or approved by a licensed professional who is supervising the CSAC or CSAC-Supervisee.

OTPs may also utilize CSAC-A's (as defined in §54.1-3507.2) as well as Registered Peer Recovery Specialists\* within their scope of practice (12VAC30-130-5160 et al).

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\*The Centers for Medicare & Medicaid Services (CMS) <u>State Medicaid Director's Letter (SMDL) #07-011</u> state that Peer Recovery Support Services are an evidence-based model of care which consists of a qualified peer support provider who assists individuals with their recovery. Peer Recovery Specialists may deliver services inperson or through telemedicine or audio-only.

2. Staff must be knowledgeable in the assessment, interpretation, and treatment of the biopsychosocial dimensions of alcohol or other SUDs.

A physician or physician extender, as defined in 12VAC30-130-5020, must be available during medication dispensing and clinical operating hours, in-person or by telephone.

OTPs that are dispensing buprenorphine or naloxone products under the authority of the OTP are not required to be a Preferred OBAT provider.

## Service Delivery

Providers must meet the DBHDS regulations for OTPs as defined in 12VAC35-105-925 et al. OTPs must also meet the Medicaid service components and risk management requirements outlined below and as defined in 12VAC30-130-5050.

- Link the member to psychological, medical, and psychiatric consultation as necessary to meet the member's needs.
- Ensure access to emergency medical and psychiatric care through connections with more intensive levels of care.
- Ensure access to evaluation and ongoing primary care.
- Conduct or arrange for appropriate laboratory and toxicology tests including urine drug screenings.
- Ensure appropriately licensed and credentialed physicians are available to evaluate and monitor (i) use of methadone, buprenorphine products, or naltrexone products and (ii) pharmacists and nurses to dispense and administer these medications and who follow the Virginia Board of Medicine guidance for treatment of individuals with buprenorphine for addiction. (Note per the State Opioid Treatment Authority (SOTA), MOUD must be dispensed onsite at OTPs versus issuing a prescription for MOUD.)
- Ensure medication for other physical and mental health conditions are provided as needed either on-site or through collaboration with other providers.
- Provide individualized, patient-centered assessment and treatment.
- Assess, order, administer, reassess, and regulate medication and dose levels appropriate to the member; supervise withdrawal management from opioid analgesics, including methadone, buprenorphine products or naltrexone products; and oversee and facilitate access to appropriate treatment for opioid use disorder.

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- Provide cognitive, behavioral, and other substance use disorder-focused therapies, by a Credentialed Addiction Treatment Professional, reflecting a variety of treatment approaches, provided to the member on an individual, group, or family basis. CSACs and CSAC-Supervisees are recognized to provide substance use disorder counseling in these settings as allowed within scopes of practice as defined in § 54.1-3507.1 of the Code of Virginia.
- Provide optional substance use care coordination that includes integrating behavioral health into primary care and specialty medical settings through interdisciplinary care planning and monitoring individual progress and tracking individual outcomes; supporting conversations between buprenorphine-waivered practitioners and behavioral health professionals to develop and monitor individualized treatment plans; linking individuals with community resources to facilitate referrals and respond to social service needs; and tracking and supporting individuals when they obtain medical, behavioral health, or social services outside the practice.
- Provide onsite screening or the ability to refer for screening for infectious diseases such as Human Immunodeficiency Virus (HIV), hepatitis B and C, and tuberculosis at treatment initiation and then at least annually or more often based on risk factors and the ability to provide or refer for treatment of infectious diseases as necessary.
- Onsite medication administration treatment during the induction phase, which must be provided by a physician, nurse practitioner, physician assistant, registered nurse or licensed nurse practitioner. Medication administration during the maintenance phase may be provided either by a registered nurse or licensed practical nurse. Take-home medications are covered following 12VAC35-105-990.
- Prescription of naloxone for each member receiving methadone, buprenorphine products, or naltrexone products.
- Ability to provide pregnancy testing for individuals of childbearing age.
- For individuals of childbearing age, the ability to provide family planning services or to refer the individual for family planning services.

OTP risk management must include the following activities which must be clearly and adequately documented in each member's record:

- Conduct random urine drug screening for all members, conducted at least one screen per month or if clinically indicated for more frequent, as defined in 12VAC35-105-980.
   Definitive screenings must only be utilized when clinically indicated. Outcomes of the urine drug screening must be used to support positive patient outcomes and recovery instead of punitive approaches, and must be discussed in a nonjudgmental and supportive manner.
- Check the Virginia Prescription Monitoring Program prior to initiation of buprenorphine products or naltrexone products and at least quarterly for all members.
- Provide opioid overdose prevention education, including the prescribing of naloxone.

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- Clinically indicated infectious disease testing such as HIV, Hepatitis A/B/C, syphilis, and tuberculosis testing at treatment initiation and then annually or more frequently depending on the clinical scenario and the patient's risk. Those who test positive must be treated either on-site or through referral.
- Individuals without immunity to the hepatitis B virus must be offered vaccination either on-site or through referral. Individuals without HIV infection must be offered pre-exposure prophylaxis (PrEP) to prevent HIV infection either on-site or through referral.
- Individuals of child-bearing age must be offered onsite or through referral pregnancy testing and contraceptive services.

#### Service Units and Limitations

- The ARTS specific Reimbursement Structure for billing codes and units for OTP services is available online: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/</a>.
- OTPs may bill the H0014 MOUD induction code for three separate inductions per 365 calendar days per member that must be at least 90 calendar days apart. H0014 includes the physician/physician extender services only. This does not cover the medications as part of the induction. The first day of each induction is billed using H0014. Additional physician visits within a 365 calendar day period must be billed using the appropriate evaluation and management code. Thus providers would submit H0014 for day one of induction, and the appropriate evaluation and management code on day two and after. Providers can bill for additional inductions beyond 3 separate inductions per 365 calendar days using the appropriate evaluation and management codes. If a member fails three inductions within a 365 calendar day period in an OTP setting, the provider should consider referring the member to a higher level of care for assessment for treatment.
- Group counseling by Credentialed Addiction Treatment Professionals, CSACs and CSAC-Supervisees shall have a maximum limit of 12 individuals in the group or less depending on the clinical model. Such counseling must focus on the needs of the members served. Group size and composition should be based on the needs of the group members and determined using standards of care.
- The buprenorphine waivered practitioner who is providing physician/physician extender induction services (H0014) and psychotherapy or SUD counseling (H0004 or H0005) within their scope of practice and meet the criteria as a Credentialed Addiction Treatment Professional as defined in Chapter IV of the ARTS Provider Manual, is permitted to bill for the MOUD induction (H0014) and psychotherapy or SUD counseling (H0004 or H0005). Services must be separate and distinguishable and well documented within the member's records.
- A different Credentialed Addiction Treatment Professional can provide opioid counseling and bill for H0004 or H0005 on the same date of service that the buprenorphine waivered practitioner is providing the MOUD induction (H0014). The buprenorphine waivered practitioner who is providing follow up/maintenance physician services (E&M office visit codes) and psychotherapy or SUD counseling (H0004 or H0005) within their scope of

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practice and meet the criteria as a Credentialed Addiction Treatment Professional as defined in Chapter IV of the ARTS Provider Manual, may provide these services on the same day as long as there is documentation supporting services are separate and distinguishable.

• Take home doses have a maximum 28-day limit dispensing at a time and must be approved by the SOTA. OTPs may bill H0020 for the medication encounter for the total number of days' supplied of the take-home medication as allowed by the SOTA.

## **Preferred Office-Based Addiction Treatment (OBAT) Services**

Preferred OBAT services must be provided by a buprenorphine-waivered practitioner and a colocated Credentialed Addiction Treatment Professional and may be provided in a variety of practice settings including primary care clinics, outpatient health system clinics, psychiatry clinics, Federally-Qualified Health Centers (FQHCs), Community Service Boards (CSBs), local health department clinics, and physicians'/physician extenders' offices. DMAS expects Preferred OBAT services to be primarily delivered in-person/on-site and utilize telemedicine as an option to increase access to services as needed. Preferred OBATs services must have regular access to inperson/on-site visits and services shall not be delivered solely or predominantly through telemedicine. The practitioners must be credentialed by DMAS, the DMAS fee-for-service contractor or MCOs to perform Preferred OBAT services. Preferred OBAT providers do not require a separate DBHDS license.

The ARTS specific procedure codes and reimbursement structure for Preferred OBAT services are posted online at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/</a>.

In addition, Preferred OBAT service providers must meet the following criteria.

- 1. The buprenorphine-waivered practitioner licensed under Virginia law must have obtained the waiver to prescribe or dispense buprenorphine for OUD required under the Drug Addiction Treatment Act of 2000 (DATA 2000). The practitioner must have a Drug Enforcement Agency (DEA)-X number issued by the Drug Enforcement Agency that is included on all buprenorphine prescriptions for treatment of OUD. The DEA-X is not required to prescribe naltrexone for OUD nor medications for AUD including acamprosate, disulfiram, and naltrexone.
  - a. As of April 28, 2021, the U.S. Department of Health and Human Services' <u>Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder (OUD)</u>, under 21 U.S.C. 823(f)(2)(B)(i)-(ii), provides eligible physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives, (hereinafter collectively referred to as "practitioners") an exemption from certain statutory requirements that

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allows them to treat up to thirty (30) patients for OUD using buprenorphine without having to meet any training-related certifications and without certifying their capacity to provide counseling and ancillary services. Practitioners seeking to leverage these flexibilities must still meet the following conditions:

- i. Practitioners must be state licensed and obtain (and maintain) a valid DEA registration under 21 U.S.C. 823(f).
- ii. Practitioners must submit a Notice of Intent (NOI) in accordance with current procedures in order to receive a waiver, specifying a patient limit of 30 (allowing them to circumvent training, counseling or other ancillary services requirements otherwise applied under 21 U.S.C. 823(g)(2)(B)(i)-(ii)).

Practitioners utilizing this exemption are limited to treating no more than 30 patients at any one time. Time spent practicing under this exemption will not qualify the practitioner for a higher patient limit under 21 U.S.C. 823(g)(2)(b)(iii).

- iii. Licensed Physician's Assistants or Nurse Practitioners must have completed the 24 hours of training required by SAMSHA and obtained a waiver to prescribe buprenorphine for opioid use disorder from the DEA. Physician Assistants and Nurse Practitioners, who have obtained a SAMHSA waiver, must only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine as in accordance to the Board of Medicine regulations (12VAC85-21-130).
- b. Nurse Practitioners may practice without a practice agreement with a patient care team physician if attestation states that he/she completed the minimum requirements of full-time clinical experience per the Board of Nursing if the proper Board approval is obtained in accordance with the laws and requirements of the Board of Nursing (defined in §54.1-2957). There is no requirement that a collaborating physician be physically located in the same practice site as the nurse practitioner.
- 2. Credentialed Addiction Treatment Professionals must be co-located at the same practice site as the buprenorphine waivered practitioner. The Credentialed Addiction Treatment Professional, under the scope of their practice, provides psychotherapy and counseling within the Preferred OBAT model to support the evidence-based practice for treatment of OUD and other SUDs. The Credentialed Addiction Treatment Professional must work with the buprenorphine-waivered practitioner in an interdisciplinary team setting. The Credentialed Addiction Treatment Professionals may utilize telehealth as an option to increase access to services as needed.

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Preferred OBAT providers may also utilize CSACs and CSAC-Supervisees in their practice to provide SUD counseling and psychoeducational services within their scope of practice which is further defined in the Board's Guidance Document: 115-11. The CSACs and CSAC-Supervisees may not practice autonomously and must be supervised according to Board of Counseling requirements. CSACs are not allowed to do a diagnostic assessment but are allowed to do the multidimensional assessment to make recommendations for a level of care that must then be signed off on or approved by a licensed professional who is supervising the CSAC. CSACs nor CSAC-Supervisees may practice autonomously and must be supervised according to Board of Counseling requirements.

The Credentialed Addiction Treatment Professional must develop a shared care plan with the buprenorphine-waivered practitioner and the patient and take extra steps to ensure that care coordination and interdisciplinary care planning are occurring.

The Credentialed Addiction Treatment Professional must engage in interdisciplinary care planning with the buprenorphine-waivered practitioner including working together to develop and monitor individualized and personalized treatment plans that are focused on the best outcomes for the patient.

- 3. Pharmacists can serve as a member of the interdisciplinary team. Pharmacists may advise buprenorphine-waivered practitioners on the selection of buprenorphine vs naltrexone as treatment options, assist with buprenorphine induction and dose adjustments, contribute to the development of the interdisciplinary treatment plan, and assist with monitoring, communicating with, and educating patients.
- 4. Credentialed Addiction Treatment Professionals must be employed by, have a contractual relationship or an established agreement with the buprenorphine-waivered practitioner or the organization employing the practitioner.
- 5. Ability to utilize Peer Recovery Support Services through employment or contractual relationship. The CMS <u>State Medicaid Director's Letter (SMDL) #07-011</u> states that Peer Recovery Support Services are an evidence-based model of care which consists of a qualified peer support provider who assists individuals with their recovery. Peer Recovery Specialists may deliver services in-person or through telehealth or audio-only.

Service Delivery

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Preferred OBAT service components and risk management requirements must include the following activities. Providers must document the provision of the following activities, as rendered, in the member's medical record.

## Preferred OBAT Service Components

- Develop the initial ISP within 24 hours of initiation of services and complete the comprehensive ISP within 7 calendar days from intake.
- Develop and maintain the DMAS Individualized Plan of Care (IPOC) within 30 calendar days from the ISP assessment date and update it a minimum every 90 calendar days. Providers may use the DMAS IPOC form but the form is not required.
- Ensure rapid initiation of MOUD within 24 to 48 hours from referral for individuals with OUD. Preferred OBAT providers shall complete a screening based on ASAM Criteria and triage members to most appropriate services. If members are medically appropriate and ready to initiate MOUD within the OBAT, this must be done and may be followed with a psychosocial assessment within 7 days. This allows for members to initiate MOUD while coordinating the full psychosocial assessment.
- Preferred OBATs are required to meet a patient's needs for medical or behavioral health emergencies, as well as for individuals with OUD, address MOUD emergencies or needing to start on MOUD within 24-48 hours from referral when they occur outside of their scheduled hours (i.e., weekends, after-hours, days when buprenorphine-waivered practitioner(s) are not on-site).
- Ensure access to emergency medical and psychiatric care. Preferred OBAT clinics shall have procedures for 24-hour responses to member concerns. Members who are experiencing a medical emergency should be encouraged to contact emergency medical services or go to their nearest emergency department. Members who are experiencing a psychiatric emergency and are a danger to themselves and/or others and/or unable to care for themselves due to their mental illness should be encouraged to contact emergency medical services or go to their nearest emergency department.
- Outside of medical and psychiatric emergencies, members may require assistance outside
  of regular clinic hours. Directing members to go to an emergency department when there
  is not a medical or psychiatric emergency is not acceptable as it strains overburdened
  community resources and rarely adequately addresses the member's concerns. Preferred
  OBATs are required to have protocols established that do not default to emergency
  room referrals for non-emergencies.
- Preferred OBATs should have procedures in place to address member concerns outside of regular clinic hours. This may include a call service to contact on-call staff members who can address member needs within a reasonable time. These procedures should be clearly outlined in the OBAT's application and operations manual. These procedures should also be reviewed annually to ensure they are meeting member needs.
- For individuals with OUD or AUD, capability for pharmacotherapy induction, stabilization and maintenance including delivering maintenance pharmacotherapy without arbitrary

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**tapering or time limits** and only discontinuing pharmacotherapy if it is worsening a member's condition or after sufficient time in recovery as cooperatively agreed to by the provider and the member.

- For members with OUD, ensure appropriate dosing of buprenorphine/naloxone for up to 24 mg. per day per the Board of Medicine regulations. There is strong evidence that some individuals may benefit from increased buprenorphine dose >16 mg in terms of treatment retention and abstinence from illicit substance.
- Provide home inductions for pharmacotherapy for OUD or AUD when clinically indicated. Preferred OBATs may utilize telehealth as needed as a resource for home inductions as well as maintenance prescriptions.
- Establish affiliations with more intensive levels of care such as intensive outpatient programs and partial hospitalization programs that unstable members can be referred to when clinically indicated. This includes **active care coordination/warm handoffs** to the receiving provider.
- Provide individualized, patient-centered multidimensional assessment and treatment.
- Assess, order, administer, reassess, and regulate medication and dose levels appropriate to
  the member with OUD or AUD; supervise withdrawal management from opioid analgesics
  or alcohol; and oversee and facilitate access to appropriate treatment for OUD and AUD.
  Note that withdrawal management from specific substances such as such as alcohol
  and benzodiazepines, require close monitoring due to the complicated and potentially
  life threatening symptoms and should be coordinated with emergency services as
  necessary.
- Ensure medication for other physical and mental illnesses are provided as needed either on-site or through collaboration with other providers.
- Ensure buprenorphine products are only dispensed on-site during the induction phase (does not apply to home inductions). After induction, buprenorphine products should be prescribed to the member. Preferred OBATs may also prescribe buprenorphine products during the induction phase. Preferred OBATs must not dispense or prescribe Methadone for treatment of OUD, as this is only allowed by a DBHDS licensed OTP.
- Ensure that buprenorphine monoproduct is only prescribed in accordance with Virginia Board of Medicine rules related to the prescribing of buprenorphine for addiction.
- Provide cognitive, behavioral, and other substance use disorder-focused counseling and psychotherapies, reflecting a variety of treatment approaches, shall be provided to the individual on an individual, group, or family basis and shall be provided by Credentialed Addiction Treatment Professionals working in collaboration with the buprenorphine-waivered practitioner. The Credentialed Addiction Treatment Professional must be co-located at the same practice site and provide counseling in collaboration with the buprenorphine-waivered practitioner.
- DMAS requires individualized SUD counseling and/or psychotherapy to be provided along with pharmacotherapy for OUD and AUD within the Preferred OBAT model. However, DMAS recognizes not all members are ready to engage in counseling or

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- psychotherapy. Providers shall document continuous efforts to engage members in treatment utilizing motivational interviewing techniques, recurrence of substance use prevention strategies, etc.. DMAS strongly supports not discharging members from pharmacotherapy during this period.
- Preferred OBATs may utilize CSACs and CSAC-Supervisees to provide substance use disorder counseling and psychoeducational services within their scope of practice as defined in § 54.1-3507.1 of the Code of Virginia and further defined in the Board's Guidance Document: 115-11.
- The foundation of the Preferred OBAT model is to provide the medical and behavioral health services within the same location, have in-person interactions with the member and provide the high-touch care coordination to support the member in their recovery. DMAS recognizes that there may be situations that telemedicine is necessary to engage the member in treatment and recovery, especially if the member makes this request. Thus Preferred OBAT services may be provided via telemedicine based on the individualized needs of the member and reasons why the in-person interactions are not able to meet the member's specific needs must be documented. The primary means of services delivery shall in-person for the Preferred OBAT model with the exception of telemedicine for specific member circumstances. These circumstances may include but are not limited to: member transportation issues, member childcare needs, member employment schedule, member co-morbidities, member distance to provider, etc.). Where these situations may impede member's access to treatment, telemedicine may be utilized as clinically appropriate and to help to remove these barriers to treatment. Providers delivering services using telemedicine shall bill according to the requirements in the DMAS Telehealth Services Supplemental Manual.
- Provide substance use care coordination, including interdisciplinary care planning between the buprenorphine-waivered practitioner and the treatment team to develop and monitor individualized and personalized treatment plans focused on the best outcomes for the individual. This care coordination includes monitoring individual progress, tracking individual outcomes, linking the individual with community resources to facilitate referrals and respond to social service needs, and tracking and supporting the individual's medical, behavioral health, or social services received outside the practice.
- Provide onsite screening or referral for screening for clinically indicated infectious disease testing for diseases such as HIV; hepatitis A, B, and C; syphilis; and tuberculosis at treatment initiation and then at least annually or more often based on risk factors and the ability to provide or refer for treatment of infectious diseases as necessary.
- **Provide pregnancy testing** for individuals of childbearing age.
- **Provide family planning services** or to refer the individual for family planning services if they are of childbearing age.
- Provide optional onsite medication administration treatment during the induction phase for members with OUD or AUD. The medication dosing shall be provided by a

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physician, nurse practitioner, physician assistant, registered nurse or licensed practical nurse.

- The Board of Medicine requires the buprenorphine-waivered prescriber to see the member weekly during the induction phase for prescribing MOUD. DMAS also recommends the member be seen at least weekly by the Credentialed Addiction Treatment Professional during the induction phase. Note the induction phase is based on the member's stage in recovery, not necessary when they started treatment with a particular provider. These visits shall be in-person/onsite however may be delivered through telemedicine based on the individual needs of the member to ensure access during this critical phase. The member must have documented clinical stability before spacing out visits beyond weekly. This applies to all members regardless of SUD diagnosis. Clinical stability is based on the ASAM Criteria multidimensional assessment and includes, but is not limited to the following:
  - Member is not experiencing suicidal ideations, making suicide attempts or a danger to self;
  - o Member is not a danger to others due to a mental illness;
  - o Member is not experiencing psychotic symptoms;
  - Member is medically stable;
  - Member is not experiencing symptoms of intoxication syndrome or withdrawal syndrome of opioids, alcohol, benzodiazepines or stimulants (i.e., member is not regularly or problematically using these substances);
  - o Member's other needs are stable (e.g., medical, food, housing); and
  - o Member is demonstrating some commitment to working toward their goals.

Once a member is clinically stable, they can continue to be served in the Preferred OBAT setting as long as they require a minimum monthly visit by the buprenorphine waivered prescriber, or the Credentialed Addiction Treatment Professional. Once a member is no longer in need of these monthly visits as a minimum within the Preferred OBAT, they can continue to be served in the ASAM Level 1.0 level of care. The IPOC must be updated to reflect these changes as members stabilize and needs change.

Preferred OBAT must include the following risk management activities which must be documented in each member's record:

• Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the **prescriber must only co-prescribe** these substances when there are extenuating circumstances and must document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed (pursuant to Board of Medicine regulations).

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- Random drug screening, using either urine or blood serums, for all individuals, conducted at a minimum of eight times per year. Drug screenings include presumptive and definitive screenings and shall be accurately interpreted. Definitive screenings shall only be utilized when clinically indicated. Outcomes of the drug screening shall be used to support positive patient outcomes and recovery. See "Urine Drug Testing Guidance" section below.
- A check of the Virginia Prescription Monitoring Program prior to initiation of buprenorphine products or naltrexone products and at least quarterly for all individuals thereafter.
- Periodic monitoring of unused medication and opened medication wrapper counts when clinically indicated.
- Opioid overdose prevention education, including the purpose of and the administration of
  naloxone, including prescribing of naloxone, and the impact of polysubstance use.
  Education shall include discussion of the role of medication assisted treatment and the
  opportunity to reduce harm associated with polysubstance use. The goal is to help
  individuals remain in treatment to reduce the risk for harm.
- Clinically indicated infectious disease testing for diseases such as HIV; hepatitis A, B, and C; syphilis; and tuberculosis at treatment initiation and then annually or more frequently, depending on the clinical scenario and the patient's risk. Those individuals who test positive shall be treated either onsite or through referral.

## Urine Drug Testing Guidance

According to the CMS, current coding for testing for drugs of SUD relies on a structure of "screening" known as "presumptive" testing or "definitive" testing (Gas Chromatography/Mass Spectrometry Combined (GC/MS)) that identifies the specific drug and quantity in the patient. Urine Drug Testing (UDT) is used to monitor patients treated for SUD. Their use should be supportive and non-punitive: providers are encouraged to consider both positive and negative UDT results in shaping and informing current and future treatment to best support their patients. Preferred OBATs may treat recurrence of substance use, such as with Tetrahydrocannabinol (THC) or stimulant use as an opportunity to keep the member in care and intensify services with additional treatment options. The Preferred OBAT model has resources including relationships with other group members, therapists, recovery role modeling among peers, and care coordination to stabilize social determinants of health that may benefit the member who has co-morbid polysubstance use that may show improvement within time engaged in the Preferred OBAT. Drug test frequency is based on the practitioner's best clinical judgment and use of unannounced or random screening schedule rather than a mandated or fixed schedule. If polysubstance use worsens then the practitioner shall consider if higher levels of care as appropriate.

The primary purposes of UDTs in a SUD treatment environment include:

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- To determine if the patient is taking the buprenorphine or naltrexone products as prescribed (Note: this can only be determined through GC/MS testing and should include a test for the presence of buprenorphine and norbuprenorphine, a metabolite of buprenorphine, the presence of which would indicate that the client has taken their medication and metabolized it);
- To assess if the patient is taking medications which have a higher risk of overdose when taken with buprenorphine, such as benzodiazepines; and
- If the patient is not taking their medication but still getting their prescription filled, this may indicate diversion. Likewise, a patient's continued use of benzodiazepines or other substances could suggest a need for a higher level of care.

Results of point of care tests should be considered presumptive. Definitive screening (GC/MS) should be performed prior to changes in clinical care. GC/MS testing provides exact levels of specific substances found in samples, and it is up to the treatment provider, in coordination with the lab, to determine if a sample is 'positive or negative'. This is done by selecting a cut-off level for each substance.

The Virginia Board of Medicine practice guidelines require drug tests or serum medication levels for addiction treatment with buprenorphine at least every three months for the first year of treatment and at least every six months thereafter. A sample schedule for urine screening is initially weekly for four to six weeks but no more than three per week, then biweekly to every three weeks for four to six weeks and then monthly as the patient becomes stable on buprenorphine. On a case-by-case basis, an individualized clinical review might be indicated to determine whether exceeding these limits is justified. High-acuity and high frequency testing should be based on medical necessity and medical records should support services rendered.

The American Society of Addiction Medicine has a Consensus Statement on the best practices for UDT entitled Appropriate Use of Drug Testing in Clinical Addiction Medicine: <a href="https://www.asam.org/docs/default-source/quality-science/appropriate">https://www.asam.org/docs/default-source/quality-science/appropriate</a> use of drug testing in clinical-1-(7).pdf?sfvrsn=2.

Providers should consult with their respective MCOs for Medicaid members if they have additional questions about specific member situations. Services should be based on individual patient needs and may vary.

#### Mobile OBAT

Preferred OBAT Providers of an opportunity to provide OBAT services through a new mode of delivery called "Mobile Preferred OBATs." Note this is separate from the Drug Enforcement Administration (DEA) recent approval in July 2021, of adding a "mobile component" to OTPs certified by SAMSHA. DMAS is working with DBHDS and will follow with updated policies when this is implemented in Virginia.

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The Mobile Preferred OBAT model shall allow Preferred OBAT providers to provide the same services in a Mobile Unit as in a traditional Preferred OBAT setting. As indicated by the Centers for Medicare and Medicaid Services (CMS), and accepted by the Medicaid MCOs and the DMAS fee-for-service contractor, a "Mobile Unit" is designated as place of service (POS) 15 and is defined as a facility or unit that moves from place to place equipped to provide preventive, screening, diagnostic, and/or treatment services: <a href="https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place">https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place</a> of Service Code Set.

Providers using the Mobile OBAT settings shall have the ability to deliver time sensitive screenings, treatment and recovery services to Medicaid members with SUD. Recent studies have shown, that patients treated in a mobile telemedicine treatment unit remained in treatment at 90 days. Longer retention was significantly associated with reduced opioid use. Thus, the goal of the Mobile OBAT is to expand access to evidence-based treatment for members with OUD, but also available to members with other primary SUD, and targets higher-risk, vulnerable populations that have access barriers, including those transitioning from an institutional or hospital setting such as emergency departments, residential, hospital settings as well as prisons, local and regional jails.

## Settings for Mobile Preferred OBATs

The following settings shall be permitted for Mobile Preferred OBATs:

1. A Preferred OBAT shall be allowed to receive approval by DMAS to operate exclusively as a Mobile Unit. To apply to become a Mobile Preferred OBAT, providers must complete the ARTS Preferred OBAT attestation form, organizational staff roster, and credentialing checklist found at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/credentialing/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/credentialing/</a>. All required provider types as well as the Preferred OBAT model of care must meet the traditional Preferred OBAT model, outlined in the this manual, and shall be present in the Mobile Unit for DMAS to consider approval for this setting. Mobile OBATs shall have a physical address attached to the Mobile Unit for billing purposes. When billing for services provided in a Mobile OBAT, the place of service (POS) shall be listed as "015" for a Mobile Unit. Upon recognition by DMAS as a Mobile OBAT, providers must submit the "Preferred OBAT Recognition Letter" from DMAS to the MCOs and Magellan of Virginia to initiate the credentialing process. ARTS Network Relations Contacts at the MCOs and Magellan of Virginia can be found at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/credentialing/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/credentialing/</a>.

Credentialing with the MCOs and the DMAS fee-for-service contractor must occur prior being eligible for reimbursement for services furnished to members in managed care. The MCOs shall follow the Virginia Code §38.2-3407.10:1 that requires MCOs to establish reasonable protocols and procedures for reimbursing new provider applicants of physicians or mental health professionals in its network for services provided to covered persons

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during the period in which the applicant's completed credentialing application is pending (see DMAS Provider memo "Provider Reimbursement for Licensed Mental Health Professionals – December 13, 2019": www.virginiamedicaid.dmas.virginia.gov).

2. A Mobile Unit shall also be permitted to operate as an extension of an established Preferred OBAT's primary location. This shall allow providers at a Preferred OBAT to also provide services in the community using the POS "015" for a Mobile Unit. Providers working in the Mobile OBAT setting shall provide services in-person as well as be permitted to utilize technology to provide telemedicine sessions with providers located at the Preferred OBAT's primary location. Providers delivering services using telemedicine shall follow the requirements set forth in the DMAS Telehealth Services Supplemental Manual. Current Preferred OBAT Providers shall notify the MCOs and the DMAS fee-for-services contractor prior to providing services in a Mobile Unit.

#### Service Units and Limitations

- See ARTS Reimbursement Structure for billing codes and units for Preferred OBAT services available online: https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/.
- Preferred OBAT's physician and physician extender who are buprenorphine waivered may bill the H0014 MOUD induction code for three separate inductions per 365 calendar days per member that must be at least 90 calendar days apart. H0014 includes the physician/physician extender services only. This does not cover the medications as part of the induction. The first day of each separate induction is billed using H0014. Additional physician/physician extender follow up and maintenance visits within a 365 calendar day period must be billed using the appropriate evaluation and management code. Thus providers would submit H0014 for day one of induction, and the appropriate evaluation and management code on day two and after. Providers can bill for additional inductions beyond 3 separate inductions per 365 calendar days using the appropriate evaluation and management codes. If a member fails three buprenorphine or buprenorphine/naloxone inductions within a 365 calendar day period in a Preferred OBAT setting, the provider should consider referring the member to an OTP or higher level of care for assessment for treatment.
- Group counseling by Credentialed Addiction Treatment Professionals, CSACs and CSAC-Supervisees shall have a maximum limit of 12 individuals in the group or less depending on the clinical model. Such counseling must focus on the needs of the members served. Group size and composition should be based on the needs of the group members and determined using standards of care.
- The buprenorphine waivered practitioner **may bill** for MOUD induction (H0014) and psychotherapy or SUD counseling (H0004 or H0005) if **provided by the same practitioner on the same date of service**. Service must be separate and distinct, meaning services may not be provided at the same time and billed as two different services The buprenorphine waivered practitioner who is providing pharmacotherapy induction services

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(H0014) and psychotherapy or SUD counseling (H0004 and H0005) must provider both within their scope of practice and meet the criteria as a Credentialed Addiction Treatment Profession as defined in Chapter IV of the ARTS Provider Manual. The buprenorphine waivered practitioner who is providing follow up/maintenance physician services (E&M office visit codes) and psychotherapy or SUD counseling (H0004 or H0005) within their scope of practice and meet the criteria as a Credentialed Addiction Treatment Profession as defined in Chapter IV of the ARTS Provider Manual, may provide these services on the same days as long as there is supporting documentation.

• Credentialed buprenorphine waivered practitioners at Preferred OBATs do not require service authorizations for the preferred products: buprenorphine SL, Suboxone® film, generic buprenorphine/naloxone tablets, Sublocade™ SQ nor Vivitrol®. Service authorization is required for non-preferred products. DMAS removed service authorization requirement for Sublocade™ SQ effective July 1, 2021. The only prerequisite will be the Risk Evaluation and Mitigation Strategy (REMS) criteria from the specialty pharmacy.

## **Provider Qualifications for Substance Use Care Coordinator:**

- 1. At least a bachelor's degree in one of the following fields (social work, psychology, psychiatric rehabilitation, sociology, counseling, vocational rehabilitation, human services counseling) and at least either (i) one year of substance use disorder related direct experience or training\* or a combination of experience or training in providing services to individuals with a diagnosis SUD or (ii) a minimum of one year of clinical experience or training\* in working with individuals with co-occurring diagnoses of substance use disorder and mental illness; or
- 2. Licensure by the Commonwealth as a registered nurse with at least either (i) one year of direct experience or training\* or a combination or experience and training\* in providing services to individuals with a diagnosis of substance use disorder or (ii) a minimum of one year of clinical experience or training\* or combination of experience and training in working with individuals with co-occurring diagnoses of substance use disorder and mental illness; or
- 3. Board of Counseling CSAC, CSAC-Supervisee or CSAC Assistant under supervision as defined in 18VAC115-30-10 et seq.

\*Direct experience or training may include on the job training or internships.

All Substance Use Care Coordinators must be under the general supervision of a buprenorphine waivered practitioner or Credentialed Addiction Treatment Professional in the OTP or Preferred OBAT setting. Substance Use Care Coordinators must be employed by or have a contractual relationship with either the buprenorphine waivered practitioner or Licensed Credentialed Treatment Professional or the organization employing the buprenorphine waivered practitioner or Credentialed Addiction Treatment Professional.

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## Service Delivery

Substance Use Care Coordination includes activities to ensure that necessary services, including mental health services, are integrated into primary care and specialty medical settings through interdisciplinary care planning and monitoring member progress, tracking member outcomes and reporting back to the buprenorphine-waivered practitioner and the Credentialed Addiction Treatment Professionals. Substance Use Care Coordination supports interdisciplinary care planning meetings between buprenorphine-waivered practitioners and Credentialed Addiction Treatment Professionals to develop and monitor the IPOC. Care coordination includes connecting members with community resources to facilitate referrals, as well as linking members with peer supports and tracking and supporting members when they obtain medical, behavioral health, or other community based services outside the practice.

The Preferred OBAT or OTP must have a designated staff member who performs the following Substance Use Care Coordination functions:

- Meet face-to-face and utilize telephonic/collateral contacts with the member and significant others to facilitate treatment objectives and program goals.
- Act as the primary point of contact for the member and the interdisciplinary team in the Preferred OBAT or OTP setting.
- Ensure that members have access (e.g., a telephone number, e-mail address) to their Substance Use Care Coordinator.
- Engage members in Substance Use Care Coordination activities as identified in the ISP for OTP settings and the ISP/IPOC in Preferred OBAT settings.
- Ensure that members have viable access to emergency services.
- Communicate with the member about their ongoing or newly identified needs on at least a monthly basis (or a frequency as requested by the member), to include a phone call or face-to-face meeting, depending on the member's needs and preferences.
- Notify members who their assigned care coordination contact is and if there needs to be a change, what is the plan for coverage.
- When possible, ensure continuity of care when care coordinator changes are made whether initiated by the member or by the Preferred OBAT or OTP.

The staff member with the primary responsibility for Substance Use Care Coordination must execute the following responsibilities at a minimum to support the monthly billing of Substance Use Care Coordination (G9012):

 Participate in interdisciplinary treatment team meetings for care planning at least once every 30 days for each member that assess the member's needs, planning of services, reviewing and making updates to members goals and objectives as needed to ensure the ISP and the IPOCs are developed and updated as necessary in collaboration with the member;

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- Enhancing community integration through increased opportunities for community access and involvement and enhancing community living skills to promote community adjustment including, to the maximum extent possible, the use of local community resources available to the general public;
- For individuals involved in the pre or post carceral system, care coordinators must establish and maintain coordination with community corrections for members on probation, parole, or participating in a diversion program with appropriate consents;
- Linking the member to those community supports that are most likely to promote the personal rehabilitative, recovery, and life goals of the member;
- Monitoring the provision of services, including outcomes, assessing appropriate changes or additions to services, and facilitating referrals for the member;
- Assisting the member directly to locate, develop, or obtain needed services, resources, and appropriate public benefits through empowerment and the use of self-sufficiency skills;
- Assuring the coordination of services and service planning within a provider agency, with other providers, and with other human service agencies and systems, such as local health and social services departments;
- Ensuring that appropriate mechanisms are in place to receive member input, complaints and grievances, and secure communication among relevant parties;
- Soliciting and helping to support the member's wishes (e.g., health care decisions, prioritization of needs and implementation of strategies, etc.);
- Knowing and monitoring the member's health status, any medical conditions, medications and potential side effects, and assisting the member in accessing primary care and other medical services, as needed; and
- Providing education as needed to support informed decisions and assisting with planning for transitions in the member's life.

#### Service Units and Limits

- Only OTPs and Preferred OBATs can bill for Substance Use Care Coordination.
- The initial and final months of treatment, Substance Use Care Coordination may be billed prior to the initial IPOC being completed, as long as the required activities noted above are provided and documented in the member's medical record for the billing month. The first IPOC must be finalized in the member's medical record within 30 calendar days from the ISP assessment date.
- Medicaid will not reimburse for Substance Use Care Coordination (G9012) if a member is in an ARTS Intensive Outpatient (ASAM Level 2.1), Partial Hospitalization (ASAM Level 2.5) or Inpatient/Acute Care (ASAM Level 4.0) setting.
- OTPs and Preferred OBATs may bill for Substance Use Care Coordination if a member is also receiving Group Home (ASAM Level 3.1) services. Members should be seen at frequency as required earlier in this Supplement.
- Substance Use Care Coordination services are not reimbursable for members while members are residing in institutions, including Residential (ASAM Level 3.3, 3.5, 3.7),

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except that Substance Use Case Coordination may be reimbursed during the month prior to discharge to allow for discharge planning.

- Substance Use Care Coordination services are not reimbursable for members also receiving Substance Use Case Management.
- Care coordination activities must be documented to support the billing of the Substance Use Care Coordination to transition member from residential setting to community and reengagement to the Preferred OBAT or OTP. Documentation of monthly care coordination can be in the form of a monthly progress note.
- Substance Use Care Coordination does not include maintaining service waiting lists or periodically contacting or tracking members to determine potential service needs that do not meet the requirements for the monthly billing. Scheduling transportation rides cannot be the sole activity to support the monthly billing of care coordination.
- Contact with the ARTS Care Coordinator or other health plan care coordination or case management staff do not count towards the monthly Care Coordination service activities.
- The IPOC must be updated at minimum every 90 calendar days or as the member's needs change throughout the course of treatment.

## **MOUD in ASAM Levels 2.1 through 3.7**

Providers within the Preferred OBAT setting may continue to prescribe to members who may require during the course of treatment a higher level of care. Providers should coordinate these services with the new provider to ensure there is no duplication to services. Members who continue to be seen by the Preferred OBAT provider do not require discharging; however changes within treatment setting should be well documented within the IPOC and progress notes.

MOUD can be billed separately from the per-diem ARTS payments in community-based settings providing ASAM Levels 1.0 through 3.7 (excluding inpatient services where it is included in the per diem ARTS payment).

See the MOUD chart in the appendix of this supplement for instructions on how to bill for physician visits, psychotherapy, medication, laboratory tests, and urine drug screens for MOUD inductions and ongoing assessments and monitoring.

## **Buprenorphine Waivered Practitioners Practicing Independently of an OTP and Preferred OBAT Setting**

Buprenorphine Waivered Practitioners must follow the Board of Medicine regulations for provisions for prescribing of buprenorphine for addiction treatment (12VAC85-21-130 to 170) including incorporating recurrence of substance use prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in §54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance use disorder counseling.

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• Buprenorphine Waivered Practitioners do not have a service authorization requirement for preferred product for treatment of OUD, Suboxone® film and generic buprenorphine/naloxone tablets. Claims for the mono-buprenorphine product shall process without prior authorization for members who are pregnant. Sublocade™ SQ, is only be covered by in-network prescribers. Service authorization is required for non-preferred products.

Documentation in the member's medical record must include the following:

- A documented diagnosis of OUD;
- Documentation of ongoing psychological counseling;
- Medical justification for doses greater than 16 mg per day;
- Compliance with the Virginia Prescription Monitoring Program;
- Documentation of person-centered plan of care that is specific to the individual's unique treatment needs, developed with the individual, in consultation with the individual's family, as appropriate.
- Documentation of member's pregnancy if monoproduct is prescribed;
- Documentation of urine drug screens;
- Documentation of co-prescribing naloxone; and
- Documentation to support Non-Preferred agents (if applicable).

The DMAS service authorization form for fee-for-service members are located online at: <a href="https://www.virginiamedicaidpharmacyservices.com">https://www.virginiamedicaidpharmacyservices.com</a>. MCOs have their own service authorization forms posted on their provider websites but will accept the DMAS service authorization forms for the non-preferred agents. The provider records must contain all information as required under the Board of Medicine regulations for provisions for prescribing of buprenorphine for addiction treatment (18VAC85-21-130 through 170) available online:

https://law.lis.virginia.gov/admincode/title18/agency85/chapter21/.

## **DOCUMENTATION REQUIREMENTS**

Providers must be required to maintain documentation detailing all relevant information about the Medicaid members who are in the provider's care. Such documentation must fully disclose the extent of services provided in order to support provider's claims for reimbursement for services rendered. This documentation must be written and dated at the time the services are rendered. Claims that are not adequately supported by appropriate up-to-date documentation may be subject to recovery of expenditures.

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#### **Individual Service Plans (ISP)**

#### Preferred OBATs and the Initial ISP

Preferred OBATs must develop the initial ISP within 24 hours of admission by a Credentialed Addiction Treatment Professional to address the immediate service needs, health, and safety needs of the member at the initial point of contact. Following the SAMHSA Buprenorphine Quick Start Guide the assessment for prescribing MOUD for members with OUD and should include: a patient history including medical, psychiatric and substance use as well as evaluation of family and psychosocial supports; checking the Prescription Drug Monitoring Program; physical examination that focuses on physical findings related to addiction and it's complications; laboratory tests but not delay treatment awaiting laboratory results. A Credentialed Addiction Treatment Professional must sign off on the ISP if developed by a CSAC or CSAC-Supervisee. Preferred OBATS must complete the ASAM multidimensional assessment within seven calendar days from treatment initiation to determine the most appropriate level of care and to support the comprehensive ISP.

The ISP is person-centered, recovery oriented, includes all planned interventions, aligns with the member's identified needs and recovery goals, care coordination needs, is regularly updated as the member's needs and progress change, and shows progress throughout the course of treatment.

The written ISPs must contain, but is not limited to:

- The member's treatment or training needs;
- The member's measurable goals;
- The member's measurable objectives and recovery strategies to meet the identified needs;
- Services to be provided with the recommended frequency to accomplish the measurable goals and objectives;
- The estimated timetable for achieving the goals and objectives; and
- An individualized discharge plan that describes transition to other appropriate services.

For persons with co-occurring psychiatric and substance use conditions, providers are expected to integrate the treatment needs in the member's ISP.

The adult member must sign his or her own ISP and if unwilling or unable to sign the ISP, then the service provider must document the reasons why the member was not able or willing to sign the ISP. The child's or adolescent's ISP must be signed by the parent/legal guardian except in cases where a minor who is deemed an adult for purposes of consenting to medical or health services needed for treatment of substance use disorder services meets requirements per §54.1-2969.

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#### **Comprehensive ISP**

The Comprehensive ISP shall be developed to address needs specific to the member's unique treatment as identified in the multidimensional assessment as applicable to the respective ASAM Level of Care. The Comprehensive ISP shall be person-centered, recovery oriented, outcomes based and includes all planned interventions, aligns with the member's identified needs and recovery goals, care coordination needs, is regularly updated as the member's needs and progress change, and shows progress throughout the course of treatment. The comprehensive ISP shall be developed and documented within 30 calendar days of the initial ISP to address needs specific to the member's unique treatment as identified in the multidimensional assessment. If members are discharged from the service prior to the initial 30 calendar days, the provider is still required to have the ISP documented in the member's medical record.

The Comprehensive ISP shall be contemporaneously signed and dated by the CATP(s) and the physician and/or physician extender, as necessary. A CATP must sign off on the comprehensive ISP if developed by a CSAC or CSAC-Supervisee.

The Comprehensive ISP must be reviewed every 90 calendar days and documented within the member's medical record no later than seven calendar days from the date of the review and signed off within 24 hours as evidenced by the dated signatures of the CATP as noted above, and the member and/or guardian, when a minor child is the recipient (unless meeting §54.1-2969).

The formatting of the Comprehensive ISP may be at the discretion of the provider but must include all required components as stated below:

- The member's treatment or training needs,
- The member's measurable goals,
- Measurable objectives and recovery strategies to meet the identified needs and goals,
- Services to be provided with the recommended frequency to accomplish the measurable goals and objectives,
- The estimated timetable for achieving the goals and objectives;
- An individualized discharge plan that describes transition to other appropriate services; and
- Be based on the ASAM Multidimensional Assessment.

For persons with co-occurring psychiatric and substance use conditions, providers are expected to integrate the treatment needs in the member's Comprehensive ISP.

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#### **Interdisciplinary Plan of Care (IPOC)**

#### Preferred OBATs/OTPs

The IPOC is an essential documentation and planning tool required to bill Substance Use Care Coordination. The IPOC must be developed and documented within 30 calendar days from the initial assessment date prior to billing for Care Coordination services by a Credentialed Addiction Treatment Professional to address needs specific to the member's unique treatment as identified in the assessment and the ASAM Multidimensional Assessment as applicable to the ASAM Level of Care. A Credentialed Addiction Treatment Professional must sign off on the IPOC if developed by a CSAC or CSAC-Supervisee.

The adult member must sign his or her own IPOC and if unwilling or unable to sign the IPOC then the service provider must document the reasons why the member was not able or willing to sign the IPOC. The child's or adolescent's IPOC must be signed by the parent/legal guardian except in cases where a minor has been deemed an adult for purposes of consenting to medical or health services needed for treatment of substance use disorder services meets requirements per §54.1-2969.

The IPOC must be reviewed every 90 calendar days and documented within the member's medical record no later than seven calendar days from the date of the review and signed off within 24 hours as evidenced by the dated signatures of the Credentialed Addiction Treatment Professional as noted above, and the member and/or guardian, when a minor child is the recipient (unless meeting §54.1-2969).

The formatting of the IPOC may be at the discretion of the provider but must include all required components as stated above. Providers may also use the DMAS IPOC form.

The IPOC is person-centered, recovery oriented, includes all planned interventions, aligns with the member's identified needs, including care coordination needs and recovery goals, is regularly updated as the member's needs and progress change, and shows progress and or regression throughout the course of treatment. The documentation contains, but is not limited to:

- The member's treatment or training needs,
- The member's measurable goals,
- Measurable objectives and recovery strategies to meet the identified needs and goals,
- Services to be provided with the recommended frequency to accomplish the measurable goals and objectives,
- The estimated timetable for achieving the goals and objectives;
- An individualized discharge plan that describes transition to other appropriate services; and
- Be based on the ASAM Multidimensional Assessment.

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For persons with co-occurring psychiatric and substance use conditions, providers are expected to integrate the treatment needs in the member's IPOC.

If providers utilize templates other than the standard IPOC template, they should ensure that all required elements are included in order to remain in compliance with documentation requirements.

To streamline provider requirements if the provider is providing Substance Use Care Coordination services the IPOC is considered meeting the Comprehensive ISP documentation requirements if it is reviewed and updated a minimum of every 90 calendar days from the date of the last update. The IPOC must be modified at a minimum of every 90 calendar days or as the needs and progress of the member changes. If the review identifies any changes in the member's progress and treatment needs, the goals, objectives, and strategies of the IPOC must be updated to reflect any changes in the member's progress and treatment needs as well as any newly-identified problems.

The IPOC is an essential documentation and planning tool to use during the interdisciplinary treatment team meetings. While the IPOC must be reviewed monthly during interdisciplinary treatment meetings, the minimum requirement to update the IPOC is at least every 90 calendar days or whenever there is a significant change in the member's treatment goals and objectives.

In Preferred OBOT settings where no single staff member functions as the designated care coordinator and care coordination activities are conducted by multiple members of the care team, the interdisciplinary treatment team meeting may be the only recurring opportunity for team members to come together to share information, and develop a care plan that truly incorporates and addresses the member's ongoing needs.

#### **Interdisciplinary Team Meeting Progress Notes**

Interdisciplinary team meetings may be documented utilizing a monthly progress note. Documentation of the interdisciplinary treatment team meetings must be added to the member's medical record no later than seven days from the calendar date of the review. This will be evidenced by the dated signatures of the Credentialed Addiction Treatment Professional as noted above, and the member and/or guardian, when a minor child is the recipient (unless meeting §54.1-2969).

#### **OTPs**

OTPs must create and update an ISP that meets all criteria contained in the DBHDS Regulations for Licensing Providers (12VAC35-105-20 et all.).

#### **Progress Notes**

Progress notes must disclose the extent of services provided and corroborate the units billed. Claims not supported by corroborating progress notes may be subject to recovery of expenditures.

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Progress notes must be individualized and specific to the particular member's circumstances, treatment, and progress. Progress notes must be signed and dated according to dates services are provided by the professional staff who have prepared the notes.

Progress notes must convey the member's status, staff interventions, and as appropriate, the individual's progress or challenges towards meeting goals and objectives as stated within the treatment plan. The progress notes must include, at a minimum:

- The name of the service rendered;
- The date and time of the service rendered;
- The setting in which the service was rendered,
- The signature and credentials of the person who rendered the service;
- Summary of progression or regression towards goals;
- Observations and orientations of the member's behaviors;
- Any notable changes in the members emotional, mental or behavioral status or affect, and;
- Any recommendations for additional services and or community supports.

The content of each progress note must corroborate the billings for each rendered service. Progress notes must be documented for each service that is billed. Daily progress notes do not require cosignature, but must be reviewed by the supervising staff. Progress notes must be completed within 24 hours following the delivery of services and promptly placed within the member's charts.

#### **Discharge Planning**

Discharge planning should take place throughout the member's treatment, should commence on admission to service, and continue throughout treatment. Discharge planning must be well documented within the member's behavioral health records. When a member is discharged from services, the provider must document the following in the member's records:

- Document the goals stated within the IPOC/Comprehensive ISP that describes members transition within treatment, and;
- Provide a summary of the services provided as well as referrals or follow-up recommendations.

#### **Substance Use Care Coordination**

Substance Use Care Coordination is an optional service available within Preferred OBAT and OTP settings. Preferred OBATs or OTPs may bill for substance use care coordination if they meet all provider and documentation requirements. Provider may choose to utilize a different format than the IPOC, including allowance to document these elements in progress notes; however, all required elements of the IPOC must be present. Separate documentation must be completed to support and

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document activities that meet billing requirements. The following information much be documented:

- Development and monitoring of the individualized IPOC. The IPOC must be reviewed and updated as needed every 90 calendar days. These documents should reflect progress and or regression made toward specific, time limited and personalized goals and reflect the contributions and efforts made on behalf of the member by the interdisciplinary treatment team (including prescribers, Credentialed Addiction Treatment Professionals, allied health care professionals, and other relevant personnel involved in providing and coordinating the member's care). Providers must document activities to address all elements identified in the IPOC that is posted on the DMAS website at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/policy-and-provider-manual/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/policy-and-provider-manual/</a>.
- Interdisciplinary care planning should consist of at least monthly meetings of the interdisciplinary treatment team (including all relevant medical and behavioral health care professionals involved in providing and coordinating the member's care). Updates to the IPOC is only necessary if changes to the member's treatment is determined.

The purpose of the interdisciplinary treatment team meeting includes:

- o Review of the member's complete medical record (including urine drug screens and laboratory tests);
- Discussion of the current status of member's progress toward meeting their goals and objectives as specified in their plan of care;
- Particular attention should be paid to any barriers toward the member's progress in meeting their identified treatment goals as well as the actions which will be undertaken by the treatment team to address those barriers;
- o Identification of any new problems and/or goals and modification of the IPOC action plan accordingly.
- A reassessment of the member's status utilizing the ASAM Criteria's Multidimensional Assessment process and determining if a change in the ASAM Level of Care is required.
- A progress note must be used to document the interdisciplinary meeting and outcomes and to document members treat and outcomes following scheduled member visits.
- Substance Use Care Coordination must include the appropriate use of and facilitation of
  referral to a variety of community based support modalities, including a variety of different
  recovery and wellness pathways, peer recovery services, social service agencies,
  community based resources appropriate to the member's needs, mutual-aid supports and
  other evidence based best practices.. Referrals to community programs and services must
  be documented in progress notes and tracked. All efforts to help the member address any

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barriers to access of appropriate community based referrals such as transportation issues, must be documented as well.

- Substance Use Care Coordination also must include supporting the member's medical, behavioral health, and other health care needs through facilitation of necessary referrals to help meet the overall biopsychosocial needs to the member. This should include addressing needs beyond the member's medical status and include issues such as unstable housing, food insecurity, child care, transportation and other social determinants of health. Subsequent referrals must be documented and tracked along with efforts to assist and educate the member in addressing any barriers to completing the recommended referrals must be documented.
- All contacts with the member regarding the overall care plan should be documented, as
  well as efforts to educate the member regarding treatment planning, the importance of
  treatment plan adherence and timely reporting of all updates and concerns should be
  documented. Safety plans must be documented as well as alternative plans for coverage
  of critical services in the event of provider unplanned unavailability.
- Face-to-face Substance Use Care Coordination is encouraged and should be documented. If for some reason the member is unable to meet face-to-face and other forms of communication are conducted, such as telehealth or telephonic mode of delivery, this too must be documented. If the member continues to be unavailable for face-to-face Substance Use Care Coordination, the member should then be re-evaluated to see if the service is appropriate for the member currently within their treatment process.

#### **Risk Management for Preferred OBAT and OTPs**

Preferred OBAT and OTPs must include the following activities, which must be documented in each member's record:

- Random urine drug screens per the "Urine Drug Testing Guidance" section in this Supplement.
- Virginia Prescription Monitoring Program checked at least quarterly for all members.
- Opioid and other SUD overdose prevention education including the prescribing of naloxone for all members.
- The Board of Medicine requires the buprenorphine-waivered prescriber to see the member weekly during the induction phase for prescribing MOUD. DMAS also recommends the member be seen at least weekly by the Credentialed Addiction Treatment Professional during the induction phase. These visits shall be in-person/onsite however may be delivered through telemedicine based on the individual needs of the member to ensure access during this critical phase. The member must have documented clinical stability as defined earlier in this Supplement before spacing out visits beyond weekly. This applies to all members regardless of SUD diagnosis. The IPOC must be updated to reflect these changes.

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• Periodic monitoring of unused medication and opened medication wrapper counts when clinically indicated.

#### BILLING, PROCEDURE CODES AND REIMBURSEMENT

The licensed behavioral health provider providing the psychotherapy component for SUD treatment must be co-located at the same practice site as the buprenorphine waivered practitioner. This also applies for CSACs providing SUD counseling or psychoeducational activities. Note the telehealth flexibilities indicated earlier in this Supplement. The licensed behavioral health provider in a Preferred OBAT or OTP setting, if billing independently from the buprenorphine waivered practitioner, must submit claims coinciding with the buprenorphine waivered practitioner to support member is receiving the required psychotherapy and SUD counseling services along with the practitioner services. Peer support services billing information may be found in the Peer Recovery Supports Supplemental manual.

The ARTS specific procedure codes and reimbursement structure are documented online at: <a href="https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/">https://www.dmas.virginia.gov/for-providers/addiction-and-recovery-treatment-services/information-and-provider-map/</a>.

#### **Rounding Units**

Providers shall not round up for partial units of service. Providers may accumulate partial units throughout the week for allowable span billing, however, shall bill only whole units. Time billed shall match the documented time rendering the service in the member's clinical record and in accordance with DMAS requirements. Providers should refer to the MCO or the BHSA for information on services that allow span billing.

#### PATIENT UTILIZATION AND SAFETY MANAGEMENT PROGRAM (PUMS)

All contracted Medicaid managed care plans including Medallion 4.0 and Commonwealth Coordinated Care Plus (CCC Plus) are required to have a Patient Utilization & Safety Management Program (PUMS). Note: The fee-for-service Contractor does not have the PUMS requirements. The PUMS program is intended to coordinate care and ensure that members are accessing and utilizing services in an appropriate manner in accordance with all applicable rule and regulations.

The PUMS Program is a utilization control and case management program designed to promote patient safety and support proper medical management of essential health care. Upon the member's placement in the PUMS, the Contractor must refer members to appropriate services based upon the member's unique situation.

#### Placement into a PUMS Program

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Members who are prescribed Buprenorphine containing products may be placed into a PUMS program for a period of twelve (12) months based on an independent review of medical needs by DMAS, or the MCOs. Once a member meets the PUMS placement requirements, the MCO may limit a member to a single primary care provider, pharmacy, controlled substances prescriber, hospital (for non-emergency hospital services only) and/or, on a case-by-case basis, other qualified provider types as determined by the MCO and the circumstances of the member. The MCO must limit a member to providers that are credentialed within their network.

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#### **EXHIBITS**

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Medication Assisted Treatment Table	1
Billing Sheet for Preferred OBAT	2

	Medication Assisted Treatment  Provided Simultaneously and Approved to be Reimbursed Separately from other ASAM Levels of Care	Siv and Appro	Medication A	Medication Assisted Treatment	ment arately from	other ASAM 1	Levels of Care	d	
MAT Services	Procedure Code	ASAM Level 2.1 and 2.5	ASAM Level 3.1 Group Home	ASAM Level 3.3 RTS	ASAM Level 3.5 RTS	ASAM Level 3.5 Inpt Psych Unit	ASAM Level 3.7 RTS	ASAM Level 3.7 Inpt Psych Unit	ASAM Level 4.0 Inpt Psych Unit / Acute Care
Practitioner Induction Day 1	OBAT/OTP -H0014 Non OBAT/OTP = $E\&M$ Codes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Practitioner Visits after Day 1	E&M Codes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Psychotherapy* for MOUD	CPT Psychotherapy Codes	No, included in IOP/PHP rate	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Medications	Prescription filled at Pharmacy or Dispensed on site = HCPCS Codes S0109/J0571/J0572 /J0573/J0574/J0575/J2315	Yes	Yes	Yes	Yes	No	Yes	No	No
Urine drug screens	80305 - 80307	Yes	Yes	Yes	Yes	No	Yes	No	No
Labs	CPT Codes	Yes	Yes	Yes	Yes	No	Yes	No	No
Care Coordination	G9012	No, included in IOP/PHP rate	Yes	No	No	No	No	No	No
Peer Recovery Support Services	T1012 – Individual S9445 – Group	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

\*MOUD psychotherapy must be provided through the provider of ASAM Level of Care 2.1 – 4.0 and requires a Credentialed Addiction Treatment Professional practicing within the scope of their license. This does not replace the minimum requirements for psychotherapy as required in RTS. Professionally qualified practitioners affiliated with RTS providers may bill additional psychotherapy as an ancillary service.

### Appendix

Medication Assisted Treatment (MAT) – Outpatient Settings  Not OTP/OBAT Settings			
Billing Code	Service Name	Authorization or Registration Required	
99202- 99205	Evaluation and management services new patient	No	
99211- 99215	Evaluation and management services established patient	No	
82075	Alcohol Breathalyzer	No	
80305- 80307	Presumptive drug class screening, any drug class	No	
G0480- G0483	Definitive drug classes	No	
86592 86593 86780	RPR Test	No	
86704 86803 86701 86702 86703	Hepatitis B and C / HIV Tests	No	
81025	Pregnancy Test	No	
86580	TB Test	No	
93000 93005 93010	EKG	No	
90832 – alone or GT (w/o E&M)	Psychotherapy, 30 minutes with patient and/or family member	No	
90833 – alone or GT (w/ E&M)	Psychotherapy, 30 minutes with patient and/or family member when performed with an evaluation and management service	No	

## Appendix

Medication Assisted Treatment (MAT) – Outpatient Settings – non OTP/OBAT Settings continued			
Billing Code	Service Name	Authorization or Registration Required	
90834 – alone or GT (w/o E&M)	Psychotherapy, 45 minutes with patient and/or family member	No	
90836 – alone or GT (w/ E&M)	Psychotherapy, 45 minutes with patient and/or family member when performed with an evaluation and management service	No	
90837 – alone or GT (w/o E&M)	Psychotherapy, 60 minutes with patient and/or family member	No	
90838 – alone or GT (w/ E&M)	Psychotherapy, 60 minutes with patient and/or family member when performed with an evaluation and management service	No	
90846 alone or GT	Family psychotherapy (without patient present)	No	
90847 – alone, GT or HF if SA	Family psychotherapy (with patient present)	No	
90853 – alone, GT or HF if SA	Group psychotherapy (other than multi-family)	No	
90863 – alone, GT or HF if SA	Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services	No	
Q3014 – GT	Telehealth originating site facility fee	No	
T1012/S9445	Peer Support Services and Family Support Partner Services (individual/group)	Registration only	



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# Office-Based Opioid Treatment with Buprenorphine (OBOT-B): Statewide Implementation of the Massachusetts Collaborative Care Model in Community Health Centers

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#### **Abstract**

We describe a Massachusetts Bureau of Substance Abuse Services' (BSAS) initiative to disseminate the office-based opioid treatment with buprenorphine (OBOT-B) Massachusetts Model from its development at Boston Medical Center (BMC) to its implementation at fourteen community health centers (CHCs) beginning in 2007. The Massachusetts Collaborative Care Model for the delivery of opioid agonist therapy with buprenorphine, in which nurses working with physicians play a central role in the evaluation and monitoring of patients, holds promise for the effective expansion of treatment for opioid use disorders. The training of and technical assistance for the OBOT nurses as well as a limited program assessment are described. Data spanning 6 years (2007 – 2013) reports patient demographics, prior treatment for opioid use disorders, history of overdose, housing, and employment. The expansion of OBOT to the fourteen CHCs increased the number of physicians who were "waivered" (i.e., enabling their prescribing of buprenorphine) by 375%, from 24 to 114, within 3 years. During this period the annual admissions of OBOT patients to CHCs markedly increased. Dissemination of the Massachusetts Model of the Office-Based Opioid Treatment with Buprenorphine employing a collaborative care model with a central role for nursing enabled implementation of effective treatment for patients with an opioid use disorder at community health centers throughout Massachusetts while effectively engaging primary care physicians in this endeavor.

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#### **Keywords**

opioid agonist therapy; buprenorphine; waivered physicians; nurse care manager; access to treatment; opioid use disorder

#### 1. Introduction

In the United States the number of people with opioid use disorders using prescription opioids increased in 2013 to 1.9 million and for heroin to 517,000. (Substance Abuse and Mental Health Services Administration, 2014b). The 2013 national mortality associated with opioid analgesic overdose exceeded 16,200 deaths (Center for Disease Control and Prevention, 2015). Effective pharmacotherapy exists for people with opioid use disorders but fewer than 24% receive any medication for their addiction. (SAMHSA Center for Behavioral Health Statistics and Quality, 2014).

The contrast of the magnitude of this public health problem with individuals' receipt of efficacious therapy is striking (SAMHSA Center for Behavioral Health Statistics and Quality, 2014). Part of this inadequate response can be explained by the lack of clinical support and infrastructure resulting in difficulty finding a physician who can provide this care (Alford et al., 2011; Walley et al., 2008). Doctors feel that despite appropriate training, the delivery of opioid agonist treatment such as buprenorphine in an office-based setting is difficult (Walley et al., 2008). To address this dilemma, over a decade ago a primary care office-based opioid treatment (OBOT) Collaborative Care Model was created in an academic medical center (Alford et al., 2011). This OBOT approach has been referred to as the Massachusetts model by SAMHSA (Substance Abuse and Mental Health Services Administration, 2014a).

The expansion of the Drug Addiction Treatment Act 2000 allowed a "waivered" physician to prescribe buprenorphine in an office-based setting after a minimum of eight hours of training for up to 30 patients with opioid use disorders. The introduction of the "extended waiver" allowed physicians to apply for approval to treat up to 100 patients per physician after one-year experience with the initial waiver approval. In Massachusetts and nationwide, by 2014, less than 5% of physicians had received such training and were waivered; compounding this physician shortage is that historically, a sizable proportion of the waivered doctors do not prescribe buprenorphine (Kaiser Family Foundation, 2015). Studies on physicians' willingness to treat such patients reveal several barriers to the office-based treatment of opioid use disorders (Barry et al., 2009; Kissin, McLeod, Sonnefeld, & Stanton, 2006; Turner, Laine, Lin, & Lynch, 2005; Walley et al., 2008) (Table 1).

Recognizing these barriers to Office-Based Opioid Treatment with Buprenorphine (OBOT-B), in 2003, a multidisciplinary team at Boston Medical Center (BMC) created a new model of care to increase access to treatment: the Collaborative Care Model of OBOT, subsequently dubbed the Massachusetts Model (Alford et al., 2007; Alford et al., 2011) (Table 1). This program was supported by the Massachusetts Department of Public Health Bureau of Substance Abuse Services (BSAS), the administrative state agency that oversees addiction prevention, treatment and recovery support services. The OBOT-B Collaborative

Care Model at BMC has grown to serve over 450 patients, with nineteen waivered primary care physicians, making this program one of the largest such primary care based programs in the country (Alford et al., 2007). This paper describes the expansion of the Massachusetts model into community health centers (CHCs) throughout the Commonwealth of Massachusetts.

Implementing such a model of care at CHCs has important potential advantages: enables distribution of treatment to a wide geographical area; promotes engagement of marginalized population; and utilizes a facilitative health care reimbursement model. The implementation of this model of care is best explained using the theoretical constructs outlined in the ADAPTS implementation science model (Table 2) (Knapp & Anaya, 2012). We report the process by which this implementation of the OBOT-B Massachusetts Model occurred in CHCs and some metrics of its effectiveness (e.g., annual active admissions, number of waivered physicians).

#### 2. Methods

#### 2.1 State Technical Assistance Treatment Expansion (STATE) OBOT-B

Beginning in 2007, the OBOT-B Collaborative Care Model was implemented in CHCs in Massachusetts (STATE OBOT-B) (Alford et al., 2007; Alford et al., 2011). The goal of the STATE OBOT-B program was to incorporate the OBOT-B Collaborative Care Model into primary care in CHCs, expanding access to buprenorphine treatment. NCMs were hired at CHCs to provide waivered physicians with the clinical support to manage patients on buprenorphine with opioid use disorders. This OBOT-B model was designed to provide treatment to marginalized individuals living in the communities of the CHCs including the homeless, under-insured, uninsured, ethnic and racial minorities and those with co-occurring physical or mental health disorders.

The clinical model consists of four treatment stages: 1) screening and assessment of the patient's appropriateness for office-based treatment; 2) medication induction under a Nurse Care Manager's direct supervision; 3) stabilization; and 4) maintenance. The model adheres to recognized practice standards including SAMHSA's Treatment Improvement Protocol 40 (Center for Substance Abuse Treatment, 2004) and evidence-based treatment guidance for nurses as noted in the Technical Assistance Publications Series 30 (Center for Substance Abuse Treatment, 2009), and practices as described by the Massachusetts Behavioral Health Partnership (Massachusetts Behavioral Health Partnership, 2010).

The Nurse Care Manager (NCM) is central to the OBOT-B Collaborative Care Model (Figure 2). The NCM is usually the initial contact for patients seeking OBOT-B treatment and acts as the primary liaison between the patient and the OBOT physician throughout the treatment process (Figure 1). The NCM performs the initial screening, after which a waivered physician sees the patient to confirm the patient's opioid use disorder diagnosis and appropriateness for OBOT-B. The patient then schedules a medication induction visit with the NCM. Utilizing the Clinical Opioid Withdrawal Scale (Wesson & Ling, 2003), the NCM assesses the patient for withdrawal symptoms following a protocol, and supports the patient through the induction process under the orders of the waivered physician. The patient

and the NCM remain in contact during the first day of induction for support, education, and titration under the direction of the waivered physician. With the NCM as the first point of contact, patients have access to the OBOT-B team for questions, issues or support during induction and as needed throughout treatment. During treatment stabilization, patients are followed closely with weekly or more frequent visits as well as telephone communication to provide support and education, assure adherence, and address other concerns the patient may have. Initially, patients are required to see the NCM weekly for follow-up visits with drug screening and verification of behavioral health counseling, which is provided by the CHC or a nearby addiction treatment clinic. Provided the patient continues to attend weekly counseling and drug screens are negative except for buprenorphine and other prescribed medications, the frequency of follow-up visits with the NCM decreases but can increase based on the patient's needs. This model for treating opioid dependence in a CHC mirrors the model for treating other chronic diseases in that disease management is individualized and includes OBOT-B clinical contacts and referrals to specialized care based on patient need.

The NCM keeps the physician informed at all times primarily via the electronic medical record in which all communications, results, clinical documentation and prescriptions are tracked. As care is provided within a primary care clinic, direct communication among the NCM, the waivered physician who is often but not always the primary care physician, and other clinical team members occurs as befits care of a chronic disease using a chronic care management model (McLellan, Lewis, O'Brien, & Kleber, 2000; Wagner et al., 2001). As not all primary care physicians prescribe buprenorphine, a waivered physician follows patients whose primary care physician is not waivered, for the buprenorphine treatment.

Originally, funding was provided for three years for each site, renewable twice for two additional years, enabling seven years of potential funding. Funding supported one full-time NCM at each site. The expectation was that each NCM would support the care of an active panel of 100 patients. Sites sought to achieve this desired patient caseload over time through a rolling admission process. This process required the induction of two to three new patients into the treatment program each week. To optimize the quality of performance among nurses and other staff involved in the program, a STATE OBOT-B Training and Technical Assistance (TTA) program provided special training and technical assistance. As the program expanded in 2011, its funder, BSAS, increased the caseload requirement to 125 patients per NCM with the addition of a medical assistant to support the NCM.

#### 2.2 STATE OBOT-B Implementation Expectations

To receive STATE OBOT-B grant funding, CHCs, specifically targeting federally qualified health centers (FQHCs), committed to explicit implementation expectations. Specific program goals included the following: integrating buprenorphine treatment into primary care practice; increasing the number of waivered physicians in CHCs; providing accessible buprenorphine treatment to marginalized individuals; and developing expertise in the treatment of opioid use disorders among CHC physicians, nurses and other staff members. To maintain grant funding, CHCs needed to meet expectations including treating the requisite number of patients per NCM, engaging OBOT-B providers in training and

technical assistance, reporting weekly program statistics and complying with site visits as requested by the STATE OBOT-B Program Director (PD) (author - CL).

#### 2.3 STATE OBOT-B Training and Technical Assistance (TTA)

The STATE OBOT-B PD provided training and technical support, which included quarterly nurse trainings, telephone, and confidential email consultations, chart reviews and site visits at the CHCs as needed. In order to optimally support each CHC, the PD first conducted a qualitative assessment of each site via a structured interview to determine the providers' training needs for effective OBOT-B model implementation. Themes that emerged from this assessment are summarized in Table 3.

Mandatory eight-hour training sessions for the CHC NCMs prepared them for their role within the OBOT-B program. The development of these NCM trainings was based on the 8-hour physician waiver training, with more of an emphasis on day-to-day management issues (Figure 3). This core training course was supplemented by quarterly nurse trainings that addressed current and emerging management issues in addiction and OBOT-B treatment including pregnancy, pain, polysubstance use, psychiatric and medical co-morbidities including hepatitis C and HIV, retention, motivational interviewing, compassion fatigue, self-care, drug screening, relapse prevention, harm reduction and current drug trends. These trainings held in Boston also provided a networking opportunity and peer support for OBOT-B nurses at sites around the state given that they did not routinely work among other addiction colleagues. The trainings were designed to mitigate the sense of isolation and build an environment of collaboration and problem-solving among the NCMs. The NCM participants in the quarterly trainings evaluated the course upon completion, providing anonymous feedback.

Clerical, administrative, and non-nursing CHC personnel learned about addiction pharmacotherapy during on-site training with a specific emphasis on stigma of drug addiction. These trainings were provided to help on-site personnel fulfill responsibilities specific to OBOT-B, such as record keeping, confidentiality and collaborative quality care without judgmental or stigmatizing attitudes.

On-site technical assistance included supervision, training, and education to ensure that the following standards were maintained by NCMs: 1) proper incorporation of new knowledge and skills into OBOT-B nursing practice; 2) adherence to established clinical treatment guidelines for buprenorphine use; and 3) compliance of the record-keeping systems with the state and federal requirements. During the first year of OBOT-B implementation, the STATE OBOT-B PD visited each site to provide supervision and support. Site visits facilitated the transfer of knowledge and expertise, and ensured that OBOT-B operations met legal and contractual requirements (Rep Bliley, 2000; SAMHSA, 2015). The PD met with physicians, nurses, and administrative staff to assist in troubleshooting and system management issues. By joining the NCM at patient appointments, the PD helped to integrate academic training into clinical practice and to promote integration of practice standards and quality care.

Technical assistance was offered both on site and remotely. The NCMs had direct access to the STATE-OBOT-B PD by telephone and email as needed. Common needs were addressed in the first year of a CHC program's initiation during established monthly telephone conference calls among the NCMs and STATE OBOT-B PD, in which general support, administrative and clinical updates, networking, and case discussions occurred. In subsequent years, such meetings were held less frequently based on the need of the CHC as assessed by both the PD and the CHC NCM; instead, more frequent phone and email consultations occurred. Additionally, the CHC NCMs were invited to BMC for clinical observation and hands-on training within the flagship's OBOT-B clinical operations. Several sites at program initiation sent physicians, administrative staff and medical assistants to BMC for hands-on experience or group consultations.

#### 2.4 STATE OBOT-B Program Assessment

CHCs completed reporting forms for the state funder assessing patients' social and medical status including current living situation, employment, history of substance use, and mental health. Three types of patient assessments were performed: at enrollment upon program entry; quarterly for each active patient (i.e., patient who stays in the program and follows the prescribed treatment); and at disenrollment. The latter occurs when a patient is discharged, which occurs upon treatment completion or when the patient moves, dies, transfers to higher level of care or is lost to follow-up. This information was tracked by the STATE OBOT Program Manager (author - AB) and entered into the state data reporting system managed by the Massachusetts Executive Office of Health and Human Services. In addition, each site was required to submit to the Program Manager a weekly report with the following data: the number of active patients; the total number of patients treated to date; the number of new enrollments in the previous week; and the number of discharges in the previous week, with reasons for discharge. The data enabled ongoing program assessment about patient enrollment and retention. For technical assistance purposes, this information is shared quarterly with programs so that relative performance is transparent.

#### 2.5 Demographics

Patient demographic and clinical data reflects admissions between August 2007 to December 2013 obtained by self-report at intake. Homeless individuals are those patients who described currently living on the streets or in a shelter.

#### 2.6 CHC Outcomes of Interest

The primary STATE OBOT-B program outcome was the number of CHCs enrolled. Secondary outcomes included number of waivered physicians at participating CHCs, annual active admissions, defined as episodes of an individual initiating buprenorphine at the CHC and duration of treatment in the OBOT-B program.

#### 3. Results

#### 3.1. CHC STATE OBOT-B Expansion

Between 2007 and 2013, nineteen CHCs were enrolled into the STATE OBOT-B program. Five health centers returned the contract for the grant within the first 3–16 months.

Specifically, these health centers demonstrated underutilization of grant funds, including inability to meet the grant caseload requirement (e.g., less than two patients per week) and difficulty adhering to weekly state reporting. The CHCs that opted out of grant participation also had some of the following administrative issues: lack of administrative support; challenges integrating addiction treatment into a CHC setting clinically and administratively; significant lag time integrating treatment; difficulty recruiting and maintaining a full-time NCM; and space restrictions. Fourteen CHCs remained in the STATE OBOT-B program.

Overall annual admissions into the STATE OBOT-B CHC programs increased from 178 in the latter 5 months of the first calendar year of the program (2007) to 1210 in last full year of complete data availability (2012) (Table 4). Prior to the implementation of the OBOT-B program, 24 physicians in the grant-supported CHCs were waivered to prescribe buprenorphine. Three years later, 114 physicians were waivered in these same CHCs. Chronic care for patients in OBOT-B increasingly became the standard. As of 2013, 67% of the patients across all CHC OBOT-B programs were in treatment for more than 12 months. This proportion of patients who were in treatment for more than 12 months increased steadily over the years with 32%, 56% and 65% receiving such treatment in 2010, 2011 and 2012, respectively. Of particular note, 7 of the 14 sites decided to expand program size beyond grant expectations; although the grant only required and funded one full-time NCM, these CHCs hired an additional NCM in order to treat more patients within their OBOT-B program.

The OBOT–B Collaborative Care Model also allowed the funded CHCs to provide a network for the state to assist those patients for whom their physician stopped prescribing buprenorphine. From the implementation of the program through the end of 2013, the STATE OBOT-B program supported patient transfers from fourteen physician practice closures and facilitated a relatively seamless transition of treatment.

#### 3.2 Patient Demographic

Patient characteristics are described in Table 5. A majority of the admissions had each of the following demographic characteristics: white; males; and between the ages of 21 to 39 years. Additionally, 5% were African American, 23% were Hispanic and 7.5% were homeless. One-third of OBOT-B admissions were individuals employed at the time of enrollment (Table 5).

#### 3.4 TTA Nurse Feedback

NCMs involved in the quarterly training sessions rated the sessions using a 5-point Likert scale with 89% strongly agreed the training was helpful (i.e., a score of 5). The NCMs reported the training program allowed them to meet with their nurse colleagues, share ideas, build networks, learn new skills, enhance current knowledge, facilitate problem-solving and review cases. The nurses indicated that they found the activities "stimulating" and "inspiring", and that they felt "supported, energized, and ready to try new things."

#### 4. Discussion

The STATE OBOT-B program utilizing the Massachusetts Collaborative Care Model substantially increased access to treatment for patients with opioid use disorders in CHCs. Within 3 years of implementing the program, the number of waivered physicians (i.e., credentialed to prescribe buprenorphine for opioid use disorders) and the number of annual patient admissions for buprenorphine treatment to the supported CHCs markedly increased. These results demonstrate that a substantial previously unmet demand for the treatment of opioid use disorders was beginning to be addressed by the STATE OBOT-B initiative.

The finding that more than two-thirds of OBOT-B patients in 2013 were in treatment for more than 12 months, a steady increase over time, reflect the maturation and effectiveness of the buprenorphine treatment program. Of note, this data reveals the percentage of program participants at a single point in time in the OBOT program that meet this metric and not a prospective view of the percentage of patients who enter and remain in the program for 12 months or more.

One previous study described delivery of buprenorphine within FQHCs. At 2 sites in Connecticut, programs were able to maintain 62% of the patients in treatment for at least 12 months (Haddad, Zelenev, & Altice, 2013). In the future, it will be important to assess individual outcomes such as patient 12-month retention in the Massachusetts Collaborative Care Model at CHCs.

The STATE OBOT-B program engaged minority populations into treatment (i.e., 5% African American and 23.1% Hispanic). The percentage of enrollments of African Americans and Hispanics in methadone treatment programs in Massachusetts in the same time period was 3.5% and 11.8%, respectively. These findings suggest that the STATE OBOT-B program provided access to minority populations.

The OBOT–B Collaborative Care Model has proven to be highly effective at expanding access to buprenorphine treatment. Implementing the model in the 14 CHCs has increased the uptake of opioid use disorder pharmacotherapy by integrating addiction treatment into the primary care office-based setting. Integrating this model with a central role for the NCM in the provision of OBOT-B enabled the physicians in these community settings to treat complex patients with opioid dependence in primary care practices in community health centers.

The OBOT-B Collaborative Care Model relies heavily on the care of NCMs, who provide complex care management for the patients under the direction of a waivered physician. The NCMs are dedicated full time to the care management of patients with opioid dependence, and thus are more accessible to promptly address urgent issues than the physicians. The model addresses one of the reasons that physicians are reluctant to prescribe buprenorphine, as they have busy primary care practices and the complexities of addiction are challenging with limited support. Although directly involved in patient care, the primary care physicians have limited time for care management, monitoring of urine drug tests, and other complexities of managing the needs of patients with addiction. The central role for nursing

in this model of care enables these functions to get accomplished and is quite compatible with the existing staffing structures of many CHCs.

Another important aspect of the OBOT–B Collaborative Care Model is that the funded CHCs provide a network for the state to assist patients whose physicians stop prescribing buprenorphine. These patients are potentially placed at high risk for relapse unless they can access treatment without interruption. Under the statewide dissemination of the OBOT–B Collaborative Care Model, the patients from the 14 provider practice closures were transferred seamlessly to the funded CHCs to continue receiving appropriate treatment without interruption.

Sustainability is a concern for any new program. CHCs that are federally qualified health centers (FQHCs) are able to bill for nursing visits at a comparable rate as they would for other licensed clinical providers. The billable nature of OBOT-B services allows FQHCs to generate sufficient revenue for the nursing salary and other programmatic costs to sustain the OBOT-B Collaborative Care Model. A review of the OBOT-B program using a cost modeling analysis and reviewed by FQHCs' CEOs and CFOs concluded that this model of care is sustainable over time (MassHealth, 2015; Substance Abuse and Mental Health Services Administration, 2014a). It takes approximately 40 cases per year, at 27 visits per patient per year to fund a full-time NCM position, adjusting for efficiency, and administrative cost. A typical NCM's caseload was initially 100 patients, more than twice the number of cases required to fund the position; after the cost analysis, it was found that a NCM could support a higher caseload of 125 patients with the help of a full-time medical assistant. The additional revenue was used to fund ongoing education, technical support, administrative support, medical assistance, and/or training of more OBOT nurses and physicians to prevent treatment gaps.

The OBOT-B program is an integral part of an effort to engage patients into treatment in their communities throughout Massachusetts. This model has improved access to care for patients that would otherwise be unable to obtain addiction treatment due to the lack of providers or inability to pay. It was effectively implemented by addressing features supportive of effective implementation as noted in Table 2 and described in the ADAPTS theoretical model (Table 2) (Knapp & Anaya, 2012). Specifically the limited access to comprehensive care in the community setting was improved by providing two key structural enabling elements: 1) clinical support to physicians; and 2) training and technical support to nurses and others. As a consequence, it enabled the expansion and integration of opioid addiction treatment with buprenorphine into primary care practice in community settings.

The initiative of the OBOT-B Collaborative Care Model has been particularly successful in the engagement and retention of marginalized patients. Furthermore, the financial sustainability of the OBOT-B program using NCMs allowed seven FQHCs involved in the program to expand beyond grant funding to better serve the needs of their communities.

Given that the STATE OBOT-B program was only implemented in Massachusetts, a potential limitation of the study of this model could be that there might be unforeseen contextual factors that may hinder the adoption of the program into other states. Another

limitation is that it has not considered other parameters used to measure the quality of services delivered by specific standard metrics such as patient specific program retention. Further program evaluation should examine the effectiveness of the STATE OBOT-B program for individual patients. The annual active admission data does not track individuals (i.e. a single patient could have multiple admissions). Thus it gives insight into the magnitude of patients with access to care but not how individual patients fared in treatment. Future study should examine treatment outcomes as well as factors that were associated with successful adoption of the STATE OBOT-B program. Such critical outcome data could be instrumental in facilitating appropriate adoption of the Massachusetts Model beyond that one state in the future.

#### 5. Conclusion

Opioid use disorders are epidemic in the USA, as are the associated opioid overdose deaths. These problems compel us to develop strong and sustainable addiction treatment programs. The highly generalizable OBOT-B Collaborative Care Model developed in Massachusetts addresses key barriers to providing comprehensive health care in community settings by providing a structure in which to deliver multidisciplinary treatment to patients and clinical support to physicians prescribing buprenorphine. This model has enabled the expansion and integration of opioid treatment with buprenorphine into primary care practice settings utilizing a NCM model throughout an entire state within community health centers. This model has displayed successful clinical uptake as well as financial stability as a method of treatment for opioid addiction.

#### **Acknowledgments**

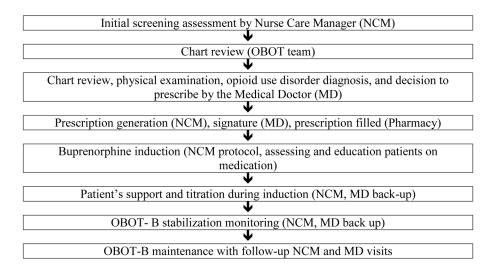
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**Figure 1.** Patient flow in the OBOT-B Collaborative Care Model.

#### Initial screening assessment

- Obtain medical, social, psychiatric history
- Obtain consent and treatment agreement
- Educate patients about program expectations
- Educate patients about buprenorphine
  - What buprenorphine is
  - What to expect from the treatment
  - What the risks and side effects are including potential for withdrawal (precipitated or spontaneous)
- Perform lab testing for the viral hepatitis A^, B & C (HAV^, HBV, HCV), liver function tests, and complete blood count^
- Perform pregnancy tests for all female patients
- Perform HIV testing with verbal consent
- Perform baseline 8-panel drug screening\*\*

#### Buprenorphine induction and monitoring using Clinical Opioid Withdrawal Scale

- Conduct Clinical Opioid Withdrawal Scale assessment
- Provide instruction on taking Buprenorphine
- Perform assessments for side effects and drug interactions

Continuous patient's support, education, and medication titration during the first week under the direction of waivered MD and ongoing through the stabilization and maintenance phases

#### Figure 2.

Role of the nurse care manager (NCM) in the OBOT-B Collaborative Care Model.

- \* Treatment agreements and consents are often employed in the treatment of addiction to make explicit expectations of the patients and their involvement in the treatment process, which is consistent with the Clinical Guidelines in the Use of Buprenorphine Treatment Improvement Protocol 40 SAMHSA.
- ^ Lab tests done for the purposes of primary care of a patient with an opioid use disorder
- \*\* Drug screening is used to assess the patient's ongoing treatment needs and allows the provider to have a conversation with the patient addressing the findings and assisting with appropriate treatment planning.

#### Office based opioid treatment (OBOT)

- Rationale and need
- Legislative authority: Drug Addiction Treatment Act 2000
- Treatment phases

#### General opioid pharmacology

#### **Opioid addiction**

#### Pharmacotherapy treatment options

Physiology and diagnosis criteria

#### **Buprenorphine**

- Pharmacology
- Clinical use
- Potential interactions
- Special populations (homeless individuals, ethnic and racial minorities, persons with co-occurring physical or mental health disorders, pregnant, HIV, Hepatitis C, adolescents, elderly, under-insured and uninsured individuals)
- Pain management: Acute and chronic pain
- Confidentiality
- Safety, efficacy, and diversion

#### Management issues

- Patient treatment responsibilities
- Counseling and referrals
- Treatment consent inclusive of 42CFR Part 2
- Treatment agreements
- Diversion
- Relapse
- Administrative issues
- Department of family and children
- Legal issues

Figure 3.

Topics covered in the OBOT NCM core training program.

 Table 1

 Barriers to treatment and how the STATE OBOT program addressed them.

Barriers	How STATE OBOT program addresses the barriers
Physician competing activities	NCMs meet with patients on a more regular basis and share some of the clinical responsibilities not required to be physician delivered.  NCMs routinely confer with physicians regarding patient issues as the need arises.
Lack of support staff	State supported start up funding and integration of NCMs. Integration of Medical Assistants to work with NCMs. Education and engagement of non-medical staff.
Inadequate addiction expertise	TTA educates the staff on buprenorphine treatment through a day-long Buprenorphine-101 training. Continued support is provided as needed. Ongoing quarterly trainings for NCMs and Medical Assistants. Ongoing educational updates and sharing of information via email
Payment issues	FQHCs are able to bill for nursing visits at a comparable rate as they would for other licensed clinical providers.  Program revenue provides funding for administrative costs.
Administrative obstacles	Education on disease and stigma TTA for administrative staff helps with the implementation. Assisted with systems for: tracking, reporting and visits.

 Table 2

 ADAPTS Implementation Science Model of the STATE OBOT-B program

Step	Action
Assessment	Identified various barriers to physicians regarding providing the office-based treatment of opioid disorders in MA (Walley et al., 2008)  BMC developed the Collaborative Care Model of OBOT and has shown success and need (wait list > 300 patients)  Training and Technical Assistance needs assessment
Deliverables	Policy and procedures manual, visit templates, educational materials Training and Technical Assistance Increased number of prescribers and increased number of patients treated
Activate	Request-for-response was sent to 36 FQHCs in MA to encourage their applying for the grant Site champions: OBOT nurse and physicians
Pretraining	Each FQHC was given the option to make site-specific changes to the implementation to better integrate the program into their individual site
Training	STATE OBOT Training and Technical Assistance provides training and education to staff regarding OBOT-B and opioid use disorders and integration of buprenorphine treatment Provide ongoing training and support as needed
Sustainability	Ongoing support, updates, trainings and check-ins to maintain quality of care Educate about the billing for NCM services for financial sustainability

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 Table 3

 Perceived TTA needs and how the STATE OBOT program addressed them

Perceived TTA needs	How STATE OBOT program addresses the TTA needs
Addiction and buprenorphine treatment education	TTA educates the staff on buprenorphine treatment through a day-long Buprenorphine-101 training. Additionally, knowledge regarding working with individuals with substance use disorders is disseminated, and continued support is provided as needed. Ongoing quarterly trainings address pertinent addiction-related topics for OBOT program staff.
Program initiation and induction process	Education through formalized training and shadowing at BMC's OBOT/buprenorphine clinic, hands-on support is provided at the CHC, ongoing telephone and email support is offered as needed.
Program integration into existing primary care setting	TTA assists program integration into the FQHCs and provides quality control of the programs.
Knowledge of Collaborative Care Model	Formalized training on the model and the policy and procedure manual is provided during initial day-long training. Additionally training is provided to all staff involved in the buprenorphine program.
NCM hiring and training	Assisted with the hiring process via posting through addiction RN list serve distributed to addiction nurses throughout the state.
Policy/procedure development	A buprenorphine treatment policy and procedure manual was developed. This manual was provided to the CHCs in a word document so that each CHC could make site-specific changes and incorporate it into their day-to-day practice.
Staff buy-in	CHC staff are provided trainings related to treating individuals with addiction, ongoing support is offered, ongoing communication with staff facilitates understanding, and site-meetings are scheduled as needed.
Stigma	Education about the disease of addiction is provided to all staff involved and health center wide if agreeable. Sites are supported ongoing when questions and issues arise.
Billing	Educating about utilization of an NCM in a FQHCs in billing.
Limited physician interest	CHC physicians are engaged through education about treating the disease of addiction and the incorporation of this treatment into a primary care setting.

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 $\label{eq:Table 4} \textbf{Enrollment by calendar year from August 1}^{\text{st}} \ \text{in 2007 through December in 31}^{\text{st}} \ \text{in 2012}.$ 

Calendar Year	Enrollments
2007	178 (latter 5 months of the year)
2008	1,499
2009	1,415
2010	1,307
2011	1,184
2012	1,210

Table 5

Demographic characteristics of admissions\* enrolled (n=7722) from August  $1^{st}$  in 2007 through December  $31^{st}$  in 2013.

The state of the s	**
Characteristic	Value (%)**
Gender	
Male	63.4
Female	36.6
Race	
White	72.7
Black or African American	5.0
Asian	<1.0
Native Hawaiian/Other Pacific Islander	<1.0
American Indian/Alaskan Native	<1.0
Multi-Racial	2.7
Refused to answer	<1.0
Other	17.3
Unknown	1.2
Ethnicity	
Hispanic	23.1
Non-Hispanic	76.9
Age (years)	
20 and Under	2.0
21 – 29	29.4
30 – 39	28.3
40 – 49	26.5
50 – 59	12.2
Greater than 59	1.6
Living status	
Homeless	7.5
Not homeless	92.5
Treatment at an opioid treatment facility prior to enrollment	
Yes	56
No	44
History of lifetime overdose	
Yes	34
No	66
Employment status	
Working, full-time	20
Working, part-time	14

CharacteristicValue (%)\*\*Unemployed, looking for jobs44Unemployed, not looking for jobs22

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<sup>\* -</sup> Admissions may reflect a particular individual more than once

<sup>\*\*
-</sup> All characteristics are self-reported



## Boston Medical Center – STATE OBOT-B

★ (/) / Data & Insights (/type/data-insights) / Case Studies (/type/case-studies)

The State Technical Assistance Treatment Expansion Office-Based Opioid Treatment Program with Buprenorphine (STATE OBOT-B) is an innovative, multidisciplinary opioid treatment network that employs addiction-trained nurse care managers who, working alongside waivered physicians, play a central role in the evaluation and monitoring of patients. This collaborative care model was created by Boston Medical Center (BMC), which has led its expansion to community health centers across the state and enabled widespread access to treatment in community health centers under STATE OBOT-B. The model can be used in most treatment settings; however, in community health centers, which often care for underserved populations, it brings insurance-based treatment for addiction to patients. In medical settings that employ nurses, it facilitates multidisciplinary care for a complex disease using nurse care managers.

#### What is it?

The State Technical Assistance Treatment Expansion Office-Based Opioid Treatment Program with Buprenorphine (STATE OBOT-B) is an innovative, multidisciplinary opioid treatment network that employs addiction-trained nurse care managers who, working alongside waivered physicians, play a central role in the evaluation and monitoring of patients. This collaborative care model was created by Boston Medical Center (BMC), which has led its expansion to community health centers across the state and enabled widespread access to treatment in community health centers under STATE OBOT-B. The model can be used in most treatment settings; however, in community health centers, which often care for underserved populations, it brings insurance-based treatment for addiction to patients. In medical settings that employ nurses, it facilitates multidisciplinary care for a complex disease using nurse care managers.

#### Who is it for?

Patients with a substance use disorder in need of medical management.

#### Why do they do it?

More than 129 people a day across the United States die from accidental overdose related to opioids. It is the number one public health crisis. Addiction is a treatable disease that can be managed in a health care practice with the right resources and expertise. Treating one's addiction will allow a patient to engage in preventative care, decreasing emergency department visits and hospital encounters, and promoting wellness. In 2002, the Drug Addiction Treatment Act was passed, enabling physicians who received a waiver from special registration requirements in the Controlled Substances Act to treat addiction with medications that were FDA approved for this purpose in outpatient treatment practices, a desirable alternative to methadone clinics for those seeking privacy with their medical provider. It also brought treatment for addiction into medical care where it belongs, so that medical providers could treat this chronic disease with other medical issues.

Despite its demand and the numerous studies demonstrating its effectiveness, buprenorphine remained underutilized, and there were lengthy waiting lists for individuals seeking treatment. Less than 5 percent of eligible U.S. physicians were waivered to provide it. Among the barriers to uptake identified by physicians surveyed in Massachusetts by the Department of Public Health were lack of clinical nursing support, increased monitoring needs, lack of institutional support and insufficient staff and/or self-knowledge in addiction. Another challenge has been cost. Although Massachusetts has almost universal insurance access, many providers don't take public insurance and may charge cash regardless of insurance. Integration of treatment into community health centers allowed patients with limited means the ability to access treatment utilizing their insurance.

In 2007, the Massachusetts Department of Public Health's Bureau of Substance Abuse Services (BSAS) issued two funding opportunities to increase access to treatment in response to the unmet need for medication-assisted treatment in the state. BMC had already developed a collaborative care model of OBOT utilizing nurse care managers at the hospital's outpatient general medicine practice, which had proved successful in both expanding access to and decreasing costs of opioid addiction. As such, BMC was awarded the grant to partner with BSAS and lead the expansion of its model to 14 community health centers across the state, and to provide the requisite training and technical assistance to get the newly funded sites up and running.

#### **Impact**

Across Massachusetts, the STATE OBOT-B program has: (1) increased access to treatment with buprenorphine; (2) improved outcomes for those struggling with opioid use disorders; (3) reduced the costs associated with substance use; and (4) demonstrated sustainability and replicability. The number of prescribing physicians rose from 24 to 164, a 530 percent increase from 2007 to 2014 in community health centers, where the model was replicated. The number of patients accessing OBOT increased from 327 to 3,000, a nearly 800 percent increase from 2007 to 2014. Since 2007, more than 8,000 patients have accessed buprenorphine treatment through STATE OBOT-B at BMC and at funded community health centers. Further, these sites have been particularly successful in engaging and retaining traditionally underserved black and Hispanic/Latino patients (35 percent) compared with methadone maintenance treatment programs (19 percent).

In the OBOT program at BMC, among 382 patients treated in the first five years, 51 percent remained successfully engaged in treatment one year after starting, and 91 percent of those treated with buprenorphine were abstinent from opioids and cocaine. What is especially striking is that in the 11 years of OBOT at BMC, where 450 patients are being treated at any given time, there have been no overdose deaths while patients have been in treatment. Further, within the first year of implementation, the BMC model of OBOT was adapted successfully for homeless patients at Boston Healthcare for the Homeless Program (BHCHP). Despite greater social instability and comorbidities, BHCHP patients achieved similarly high rates of treatment success at 12 months, with 55 percent retained in care with buprenorphine and 36 percent successfully housed.

Note: The program began as OBOT but has since moved into OBAT (office-based addiction treatment) to be all inclusive since they now have injectable naltrexone, which can be used for both opioid dependence and alcohol use disorders.

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#### **Related Resources**

AHA CENTER FOR HEALTH INNOVATION MARKET SCAN

4 Strategies to Drive Health-Equity Success (/aha-center-health-innovation-market-scan/2023-03-28-4-strategies-drive-health-equity-success)

ADVANCING HEALTH PODCAST

Strategies for Building Powerful Community Partnerships (/advancing-health-podcast/2023-03-15-strategies-building-powerful-community-partnerships)

AHA CENTER FOR HEALTH INNOVATION MARKET SCAN

Transforming Care: Why Leaders Need to Be Radically Collaborative (/aha-center-health-innovation-market-scan/2023-01-24-transforming-care-why-leaders-need-be-radically-collaborative)

CASE STUDIES

Sinai Chicago | Illinois (/case-studies/2023-01-03-sinai-chicago-illinois)

ADVANCING HEALTH PODCAST

Caring for the Family Caregiver Part 2: Gaining Perspective and Supporting the Family Caregiver (/advancing-health-podcast/2022-12-16-caring-family-caregiver-part-2-gaining-perspective-and-supporting-family-caregiver)