

Guidance Document on Best Practices:

Key Components for Delivering Community-Based Medication Assisted Treatment Services for Opioid Use Disorders in New Hampshire

Second Edition

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ACRONYMS AND ABBREVIATIONS

42 CFR, Part 2 – Title 42, Part 2 of the Code of Federal Regulations
ASAM – American Society of Addiction Medicine
ASI – Addiction Severity Index
ATTC – Addiction Technology Transfer Center
BDAS – Bureau of Drug and Alcohol Services
CARA – Comprehensive Addiction and Recovery Act
CBT – Cognitive Behavioral Therapy
CHC – Community Health Center
CMS – Centers for Medicare & Medicaid Services
COWS – Clinical Opiate Withdrawal Scale
DATA 2000 – Drug Addiction Treatment Act of 2000
DEA – Drug Enforcement Administration
DHHS – Department of Health and Human Services
DSM-5 – Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
DUR – Data Utilization Review
FDA – Food and Drug Administration
HIPAA – Health Insurance Portability and Accountability Act of 1996
IM – Intramuscular
IOP – Intensive Outpatient Program
IV – Intravenous
LADC – Licensed Alcohol and Drug Counselor
MAT – Medication Assisted Treatment
MCO – Managed Care Organization
MET – Motivational Enhancement Therapy
MLADC – Master Licensed Alcohol and Drug Counselor
NCM – Nurse Care Manager
NHHPP – NH Health Protection Program
OBOT – Office-Based Opioid Treatment
OOWS – Objective Opiate Withdrawal Scale
OTP – Opioid Treatment Program
OUD – Opioid Use Disorder
PAP – Premium Assistance Program
PCP – Primary Care Provider
PDL – Preferred Drug List
PDMP – Prescription Drug Monitoring Program
PHP – Partial Hospitalization
PO – By Mouth
PRSS – Peer Recovery Support Services
QHP – Qualified Health Plan
QSO – Qualified Service Organization
SAMHSA – Substance Abuse and Mental Health Services Administration
SES – Socioeconomic Status
SOWS – Subjective Opiate Withdrawal Scale
SUD – Substance Use Disorder
TAP – Technical Assistance Publication
TIP – Treatment Improvement Protocol

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY	5
II. INTRODUCTION	7
III. OVERVIEW OF OPIOID USE DISORDER MEDICATIONS	8
IV. SERVICE DELIVERY AND CLINICAL CONSIDERATIONS	12
A. Staffing	17
B. Training & Resources	23
C. Billing	27
D. Evaluation	30
E. Treatment Planning	36
F. Induction	40
G. Psychosocial Treatment & Recovery Support Services	43
H. Drug Testing	48
V. OTHER CONSIDERATIONS	50
A. Confidentiality - 42 CFR Part 2	52
B. Communications	55
C. Stigma	57
VI. APPENDICES	58
Appendix I: MAT Quality Planning Tool	59
Appendix II: Objective Opiate Withdrawal Scale	65
Appendix III: Subjective Opiate Withdrawal Scale	66
Appendix IV: Clinical Opiate Withdrawal Scale	67
Appendix V: Sample Treatment Agreement	69
Appendix VI: Consent Form	70

EXECUTIVE SUMMARY

In 2016, New Hampshire (NH) recorded 485 drug overdose deaths, a 10% increase from 2015. In the past year, an estimated 87% (424) of those deaths involved fentanyl, heroin, or other/unknown opioids (other opioids may include prescriptions such as oxycodone based medications; unknown opioids are currently unable to be investigated or classified), as compared to 90% (397) of deaths involving those substances in 2015. In 2016, there were 6,084 opioid-related emergency room visits and 2,896 naloxone (Narcan) administrations through the NH Bureau of Emergency Medical Services. As of December 7, 2017, 350 individuals have died as a result of a drug overdose, with 311 (89%) of those attributable to opiates/opioids.¹

In response to the opioid crisis, NH has passed legislation and executed several initiatives including: allowing physicians to prescribe naloxone to anyone who may be in a position to help someone experiencing an opioid-related overdose (House Bill 271); providing protection from civil, criminal and professional liability to the prescriber, dispenser and administrator of naloxone, also known as the Good Samaritan Law (House Bill 270); not requiring a renewal of a prior authorization more frequently than once every 12 months if substance use disorder (SUD) services are a covered benefit under a health plan (Senate Bill 158); implementing screening, brief intervention and referral to treatment (SBIRT) in all community health centers to identify problem alcohol and drug use; making naloxone kits available to patients of ten community health centers at no cost; supporting community education and naloxone access events through the state's regional public health network system; and launching an opioid awareness and public education campaign. As a companion to these addiction prevention, early identification and overdose prevention initiatives, the state is making a concerted effort to expand the availability of addiction treatment through investment in and promotion of medication assisted treatment (MAT) for opioid use disorders (OUDs). Specifically, the state offers buprenorphine waiver trainings at no cost for physicians, nurse practitioners, and physician assistants and contracts with community health centers and practices part of hospital networks to initiate and expand MAT.

Similar to many other states across the country, MAT services are limited and desperately needed in NH. The need for expanded MAT is evident in the high rates of opioid misuse reflected in the sharp increases in emergency room visits, ambulance calls and in the administration of naloxone.²

To address the lack of capacity to treat OUDs, the NH Department of Health and Human Services (DHHS), Bureau of Drug and Alcohol Services (BDAS) convened a panel of practitioners from health care, behavioral health and specialty SUD treatment services, and the NH Medical Society to review existing MAT models in New Hampshire and other states and to identify key components and best practices to develop this compendium of recommendations and resources for implementing and delivering MAT.

¹ NH Attorney General Department of Justice, Office of Chief Medical Examiner. 2016 & 2017 Drug Death Data.

² NH Attorney General Department of Justice, Office of Chief Medical Examiner. 2016 & 2017 Drug Death Data.

GOAL: To initiate and expand MAT capacity to serve more patients with OUDs across a variety of treatment settings.

OBJECTIVES:

1. Increase the number of waived buprenorphine prescribers;
2. Increase office-based access to MAT programs through multiple settings, including primary care offices and clinics, specialty office-based (“stand alone”) MAT programs, and traditional addiction treatment programs offering medication; and
3. Increase awareness of and access to extended-release injectable (depot) naltrexone and other medications by prescription.

INTRODUCTION

This compendium of best practice recommendations and resources has been developed to provide guidance and support to initiate and expand MAT services for OUDs for patient populations in a variety of service settings as requested by health care and behavioral health professionals. This document is not intended to replace best practice resources such as the *American Society for Addiction Medicine (ASAM) National Practice Guideline For the Use of Medications in the Treatment of Addiction Involving Opioid Use* or the *Substance Abuse and Mental Health Services Administration's (SAMHSA) Treatment Improvement Protocols (TIPs) and Technical Assistance Publications (TAPs)*, but is rather a compilation of resources and recommendations identified from these and other sources.

The development of this compendium is based on several key principles:

- The disease of addiction is a complex biopsychosocial disease that is chronic in nature and is often characterized by periods of relapse and remission;
- Methadone and buprenorphine have been determined by research to be highly effective in short-term withdrawal management; and these two medications and naltrexone are shown to be effective in longer term/chronic management of OUD³;
- Access to medication for those experiencing addiction is limited in NH;
- Only 30% of SUD treatment programs offer medications for OUD⁴; and
- Medical professionals from a range of primary care and specialty practices have expressed interest in delivering MAT to existing patient populations and/or to MAT-targeted patients provided they are able to access adequate training, technical assistance, and professional mentoring.

MAT can be delivered in a variety of service settings with the proper integration of specific components.

These settings include:

- Primary care
- Behavioral health/specialty addiction treatment
- MAT-specific treatment programs

Each of these settings exist in New Hampshire, and representatives from each were contacted to help the panel understand and consider the models used and the strengths, challenges, and opportunities. Examples will be shared throughout the document to better describe the different models and are not intended for promotional purposes.

³ The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015.

⁴ The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015.

OVERVIEW OF OPIOID USE DISORDER MEDICATIONS

According to SAMHSA's Addiction Technology Transfer Center (ATTC) Network, *MAT is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders.* MAT is linked to many positive outcomes including:^{5,6,7}

- Decreasing mortality;
- Increasing retention in treatment;
- Reducing medical and SUD treatment costs;
- Reducing opioid overdose among patients in treatment;
- Increasing abstinence from opioids; and
- Lowering a person's risk of contracting HIV or hepatitis C.

Three medications are approved by the U.S. Food and Drug Administration (FDA) for treating OUDs -- methadone, buprenorphine, and naltrexone -- with several products/formulations available for each of these medications. While all three pharmacotherapies are approved options with different indications and contraindications, this compendium will focus primarily on the following medications:

- Buprenorphine (e.g., Suboxone®, Subutex®, Zubsolv®, Bunavail®, Probuphine®, Sublocade®)
- Naltrexone (extended-release injectable/depot/XR-NTX: Vivitrol®)

These medications were selected because they may be prescribed in an office-based setting, unlike methadone which, per federal regulation, must be dispensed at certified opioid treatment programs (OTPs). Additionally, this guidance document focuses on depot naltrexone, specifically Vivitrol, the only commercial product currently available, rather than oral naltrexone (ReVia®, Depade®) because poor medication adherence has resulted in lower retention rates when compared to depot naltrexone.⁸ Prescribers are strongly advised, however, to have a thorough understanding of each therapeutic medication and the different products and formulations available in an effort to, in agreement with the patient, identify which pharmacotherapy will be the best treatment option.

Sampling of Research Findings Associated with Buprenorphine, Naltrexone and Methadone

Research outcomes relative to these medications are important to review as medications are considered.

For example, in an examination of buprenorphine maintenance versus placebo or methadone maintenance, which included 31 trials and 5,430 participants, findings indicated that buprenorphine retained fewer participants than methadone when dose intervals are flexible and at low fixed doses.

5. Connery, H. Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions. 2015. Harv Rev Psychiatry. 23(2):63-75.

6. The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015.

7. Kakko, J. et. al. 1-year retention and social function after buprenorphine-assisted relapse prevention treatment for heroin dependence in Sweden: A randomised, placebo-controlled trial. The Lancet. February 22, 2003; (361)662-66

8 The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015.

However, at medium to high doses no differences were seen. Additionally, based on the literature reviewed, no difference was observed between methadone and buprenorphine for reducing criminal activity or mortality rates. Specifically, this research found the following:

- Low fixed-dose studies indicated that methadone (≤ 40 mg) was more likely to retain participants than low-dose buprenorphine (2 - 6 mg), (3 studies, 253 participants, RR 0.67; 95% CI: 0.52 to 0.87);
- No difference in retention was observed between medium-dose buprenorphine (7 - 15 mg) and medium-dose methadone (40 - 85 mg), (7 studies, 780 participants, RR 0.87; 95% CI 0.69 to 1.10); and
- No difference in retention was observed between high-dose buprenorphine (≥ 16 mg) and high-dose methadone (≥ 85 mg), (RR 0.79; 95% CI 0.20 to 3.16).⁹

Another study looked at the long-term (18-month) outcomes of office-based treatment with buprenorphine/naloxone and the impact of socioeconomic status (SES) and other characteristics. Of the 176 patients with an OUD who were on buprenorphine/naloxone and receiving intensive outpatient counseling, 110 completed the follow-up interview with 77% of those reporting that they remained on the medication. Individuals who were still on buprenorphine/naloxone were more likely to report abstinence, involvement with recovery programs, and to be employed. No differences were observed between high and low SES groups.¹⁰

In a randomized, comparative effectiveness trial of 24 weeks of treatment – following an acute inpatient detoxification admission, done at typical community-based treatment programs across the U.S., 570 participants were randomized to receive treatment with either extended-release injectable naltrexone (XR-NTX) (283) or buprenorphine-naloxone (BUP-NX) (287) and were intended to be treated. 474 participants were successfully inducted, with XR-NTX significantly more difficult to initiate than BUP-NX patients. Among patients that were successfully inducted, 24-week relapse events were similar across XR-NTX patients (52%) and BUP-NX patients (56%). Overall, if induction to either medication is successful, XR-NTX and BUP-NX were comparably effective and safe options.¹¹

In a recent study, 308 patients were randomly assigned to treatment; outpatient (N=201); short-term inpatient (N=59); and long-term inpatient (N=48) as usual (TAU) (N=155) or TAU + injection naltrexone (depot naltrexone; XR-NTX) (N=153). Five weeks after randomization, patients being treated with XR-NTX+TAU that initiated the study on short-term inpatient experienced little relapse (7%); however, those assigned to TAU experience a high rate of relapse (63%). By the end of the study (26 weeks) there was continued relapse across treatment conditions and settings; however, relapse rates were lower among the XR-NTX+TAU condition patients across treatment settings. The XR-NTX exerted a protective effect among outpatient, reducing the relapse rate to 38% as compared to short-term inpatient (59%) and long-term inpatient (46%).¹²

According to the results of a retrospective, longitudinal study comparing patients who received MAT versus those who did not receive medication to support recovery, of 10,513 patients who received one of the four approved

9 Mattick RP, Breen C, Kimber J, Davoli M. *Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence (Review)*. Copyright © 2014. The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

10 Parran et. al. Long-term outcomes of office-based buprenorphine/naloxone maintenance therapy. *Drug and Alcohol Dependence*. 106 (2010) 56–60.

11 Lee, J. et. al. Comparative effectiveness of extended-release naltrexone versus buprenorphine-naloxone for opioids relapse prevention (X:BOT): A multicentre, open-label, randomized controlled trial. *The Lancet*. November 2017. Retrieved from: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)32812-X/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32812-X/fulltext)

12 Nunes, E.V., et. al. Relapse to opioid use disorder after inpatient treatment: Protective effect of injection naltrexone, *Journal of Substance Abuse Treatment* (2017). Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmed/28473233>

medications for the treatment of OUDs (depot naltrexone, n=156, 1.5%; oral naltrexone, n=845, 8.3%; buprenorphine, n=7,596, 72% or methadone, n=1,916, 18.2%), the per-patient mean cost associated with treatment including inpatient, outpatient and pharmacy costs was \$10,710 vs. \$6,791 for patients receiving no drug treatment. However, six-month risk-adjusted outcomes indicated lower total healthcare costs by 29% for patients who received a medication for their opioid use disorder. Specifically, treatment with depot naltrexone was associated with significantly fewer opioid and non-opioid related hospitalizations and fewer emergency department visits than patients who received methadone. It is important to note that the cost of depot naltrexone is much higher in comparison to other medications for OUDs. In looking at total costs, this medication is not significantly different compared to oral naltrexone or buprenorphine, but is significantly lower than methadone.¹³

Additional References

1. Connery, H. Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions. *Harvard Review of Psychiatry*. Volume 23, Number 2: March/April 2015.
2. Bart G. Medication Maintenance for Opiate Addiction: The Foundation of Recovery. *J Addict Dis*. 2012 July; 31 (3): 207-225.
3. Watkins K, Ober A, Lamp K. Collaborative Care for Opioid and Alcohol Use Disorders in Primary Care. *JAMA Intern Med*. 2017;177(10):1480-1488. Retrieved from: <http://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2652574>.
4. Korthuis, P.T. et. al. Primary Care-Based Models for the Treatment of Opioid Use Disorder: A Scoping Review. *Ann Intern Med*. 2017 February 21; 166(4): 268–278. doi:10.7326/M16-2149.
5. Jones et. al. Neonatal Abstinence Syndrome After Methadone or Buprenorphine Exposure. *New England Journal of Medicine*. December 2010. 363;24.
6. Lee et. al. Extended-Release Naltrexone to Prevent Opioid Relapse in Criminal Justice Offenders. *N Engl J Med*. 374 (13), March 31, 2016.

¹³ Baser O, Chalk M, Fiellin DA, Gastfriend DR. Cost and utilization outcomes of opioid dependence treatments *Am J Manage Care*. 2011;17:S235-248.

The following chart provides a brief overview of the differences between the three medications. For more detailed prescribing information, please refer to the ASAM National Practice Guidelines.

OPIOID USE DISORDER MEDICATION DIFFERENCES ^{14,15,16,17}			
PRESCRIBING CONSIDERATIONS	METHADONE	BUPRENORPHINE	NALTREXONE
Product/Formulation		E.g., Suboxone,* Subutex, Zubsolv,* Bunavail,* Probuphine, Sublocade	Extended-release injectable/depot/XR-NTX; Vivitrol
Mechanism of Action	Full Agonist: Binds to and activates receptors. Long-acting, providing steady blood levels which avoid reward (euphoria) due to peak effects and avoids withdrawal or craving due to low blood levels.	Partial Agonist: Binds to and partially activates opioid receptors. Long-acting, providing steady blood levels which avoid reward (euphoria) due to peak effects and avoids withdrawal or craving due to low blood levels.	Antagonist: Binds and competitively blocks opioid reward effects.
Uses of Medication	Withdrawal and Treatment	Withdrawal and Treatment	Treatment
Route of Administration	Oral tablet or liquid	Sublingual tablet, sublingual or buccal film, implant, injection	Intramuscular (IM) injection
Frequency of Administration	Daily	Based on formulation and clinical needs of the patient.	Monthly
Dosage	Based on formulation and clinical needs of the patient.		
Regulatory Context	May only be dispensed at a certified opioid treatment program (see He-A 300 rules, part 304). ¹⁸	Any licensed prescriber with a DEA registration and a buprenorphine waiver.	Any healthcare provider who has a license to prescribe (e.g., physician, nurse practitioner, physician assistant).
Typical Visit Requirement	Initial: Daily	Initial: Weekly <i>Interval may change based on course of treatment</i>	Monthly
Cost of Medication	Low	Depends on product	High
Controlled Substance Schedule	Schedule II	Schedule III	Not a Scheduled Medication
Diversion Value	High	High	Low
Discontinuation of Medication	Tapering Required	Tapering Required	No Tapering Required

* Suboxone, Zubsolv, and Bunavail contain both buprenorphine and naloxone. Naloxone is an antagonist and is used to decrease potential for diversion and misuse. If used intravenously a person will experience immediate withdrawal as a result of the naloxone.

14 The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015.

15 National Council for Behavioral Health. Webinar: Making the Case: How MAT Improves Mental Health Care for those with OUDs held by Dr. Hilary Connery on October 6, 2015.

16 Retrieved from Substance Abuse and Mental Health Services Administration (SAMHSA). An Introduction to Extended-Release Injectable Naltrexone for the Treatment of People With Opioid Dependence. Winter 2012. Volume 11. Issue 1, http://www.integration.samhsa.gov/Intro_To_Injectable_Naltrexone.pdf.

17 The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015.

18 He-A 300 Certification and Operation of Alcohol and Other Drug Disorder Treatment Programs, Part He-A 304 Operational Requirements for Opioid Detoxification and Methadone Maintenance, Treatment, and Rehabilitation Programs, http://www.gencourt.state.nh.us/rules/state_agencies/he-a300.html

SERVICE DELIVERY AND CLINICAL CONSIDERATIONS

There are many components related to the development, implementation, and integration of a MAT program for the treatment of OUD. An overview of each element will be described in the following sections. Federal and state requirements and best practice recommendations and resources will be identified throughout this guidance document to assist with the initiation or expansion of office-based opioid treatment (OBOT) programs. Formal structuring of office systems to support best practices in MAT is strongly encouraged to facilitate efficient patient care and reduce system stress.

Many different service models can be used to deliver MAT within each setting. The following chart provides an overview of the models that can be used in a primary care clinic or office, behavioral health/specialty addiction treatment program, and a MAT-specific setting.

Overview of Buprenorphine and Naltrexone Service Delivery Models				
	Primary Care Clinic or Office-Based	Behavioral Health/ Specialty Addiction Treatment Program	MAT-Specific Treatment Programs	
			Free-Standing MAT Clinic	Opioid Treatment Program (OTP)/ Methadone Clinic
General Description	Engages existing PCP to become waived Prescribes buprenorphine and/or naltrexone Arranges psychosocial treatment and recovery support services	Provides psychosocial treatment and recovery support services Employs or contracts with buprenorphine and/or naltrexone prescribers	Establishes clinic specifically to provide buprenorphine and/or naltrexone Engages prescriber, psychosocial treatment provider and care coordinator Provides or refers to recovery support services	Expands services to include prescribing of buprenorphine and/or naltrexone Engages waived prescribers and utilizes existing psychosocial treatment provider and care coordinator Provides or refers to recovery support services
Prescriber Roles - Diagnoses opioid use disorder - Inducts onto MAT - Prescribes - Provides routine follow-up visits	Employs waived prescriber May link to other waived prescriber for cross coverage	Employs Medical/ Psychiatric Director or other waived prescribers Partners with waived prescriber in community	Employs waived prescriber	Employs waived prescriber

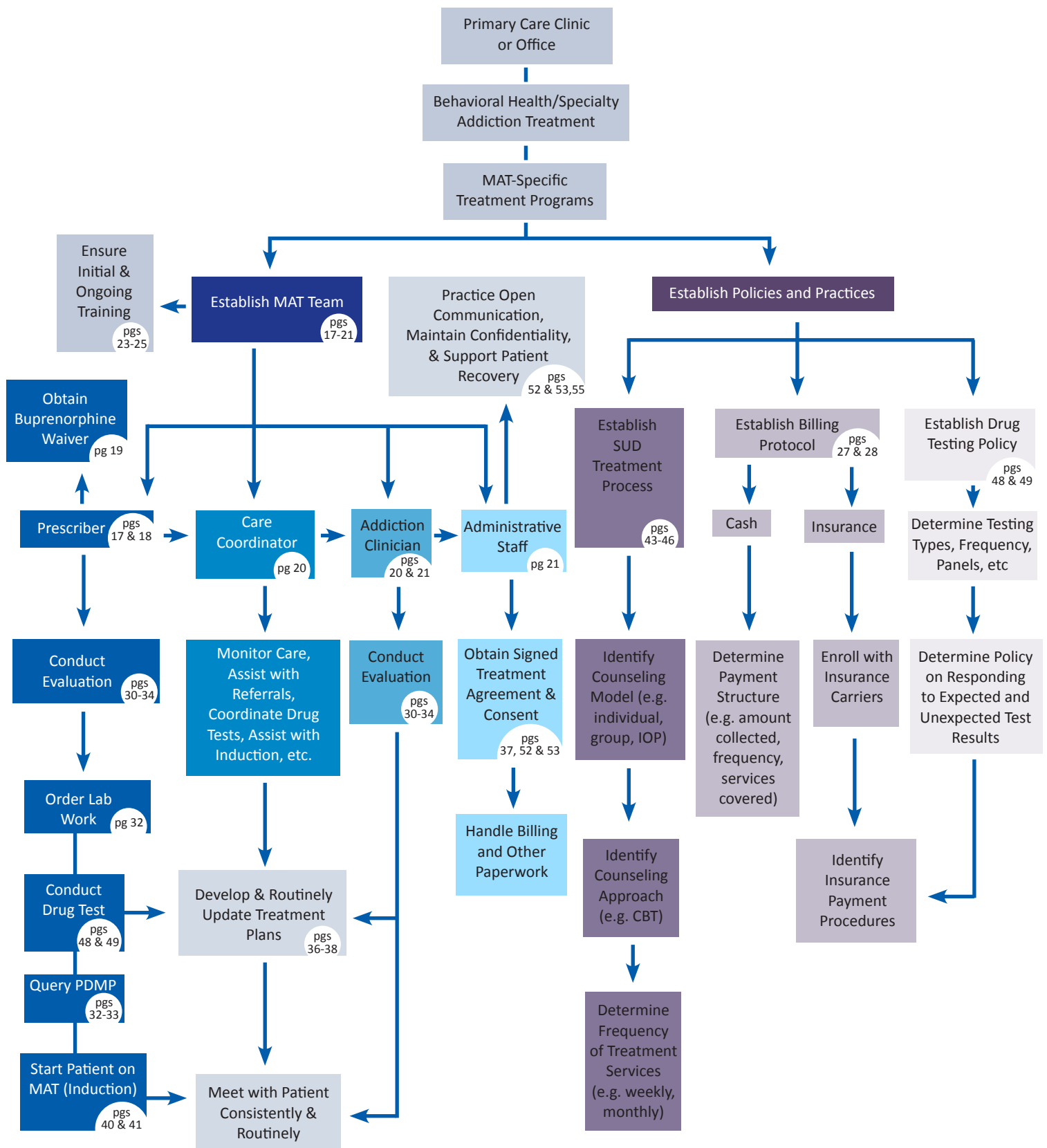
Overview of Buprenorphine and Naltrexone Service Delivery Models				
	Primary Care Clinic or Office-Based	Behavioral Health/ Specialty Addiction Treatment Program	MAT-Specific Treatment Programs	
			Free-Standing MAT Clinic	Opioid Treatment Program (OTP)/ Methadone Clinic
Counselor Roles - Provides SUD counseling - Group - Individual - Provides counseling for co-occurring disorders as needed - Encourages and refers to recovery support	Embed addiction counselor or contracts with outside provider	Designates counseling staff	Designates counseling staff	Designates counseling staff
Care Coordinator Roles - Facilitates communication between prescriber, counselor, and patient - Provides routine support to patients outside of office visits - Conducts drug testing and pill/ film counts - Links with recovery support services	Role may be assumed by various positions (e.g., nurse, medical assistant, counselor).			

The following chart references the federal and state requirements and the best practices that are strongly encouraged by the state of New Hampshire. The simplest form of MAT with buprenorphine which meets federal and state regulations involves a waived prescriber writing a prescription for a patient who meets criteria for an OUD, providing regular office visits, documenting care properly and ensuring capacity to refer patients for appropriate counseling and other appropriate ancillary services.

In addition to these requirements, the state is promoting additional best practices to support the successful delivery of MAT. Some of these recommendations include querying the Prescription Drug Monitoring Program (PDMP) each time a prescription is written, conducting routine and random drug testing and pill/film counts and practicing timely communication among the prescriber, the patient and other providers.

Federal & State Requirements	New Hampshire Recommendations
- Obtain buprenorphine waiver to prescribe - Physician (MD/DO) (eight hour waiver training) OR - Nurse Practitioner/Physician Assistant (24 hours of training including the 8 hour waiver training) - Conduct full evaluation and medical exam - Verify that patient meets criteria for an opioid use disorder - Verify that patient is deemed appropriate for MAT and medication - Provide regular office visits - Document care properly (e.g., treatment plans, confidentiality) - Ensure capacity to refer patients for appropriate counseling and other appropriate ancillary services	- Establish a core team of qualified staff to deliver MAT - Provide initial and on-going training and resources to all staff - Query the PDMP each time a prescription is written - Enroll and credential with managed care organizations (MCOs), qualified health plans (QHPs), and other insurers - Perform routine and random drug tests - Perform routine and random pill/film counts - Practice timely communication among the prescriber, the patient and other providers

To further outline the MAT requirements and recommended best practices, a visual representation is provided below and a Quality Planning Tool is available in Appendix I to help MAT programs review and assess their progress related to the development and implementation of the recommended best practices. Periodic use of this tool is encouraged to inform continual quality improvement. Programs can anticipate that the first one to two years after implementation will involve assessing and adjusting programming and service delivery as necessary.



IV.

A. STAFFING: Establish a Core Team

A. STAFFING: Establish a Core Team

Establishing a core team dedicated to patient care and service coordination specific to MAT is fundamental for an organized MAT setting.¹⁹ This team may involve clinic staff exclusively or may include partnering providers to provide comprehensive treatment services to meet patient needs.

To establish a team, it is important to identify or recruit interested and qualified staff who encompass the attitudes, values, and competence associated with treating patients with OUDs. It is recommended that the team consist of, at a minimum, a prescriber, a care coordinator, a licensed alcohol and drug counselor (LADC) or behavioral health provider with training in the treatment of SUDs, and non-clinical, administrative staff. Each of the recommended positions are described in more detail in this section.

Prescriber

Buprenorphine: Physicians (MD or DO), Nurse Practitioners (NPs), and Physician Assistants (PAs) who have received a waiver through the DEA (Drug Enforcement Administration) can prescribe buprenorphine.

Physicians have been able to prescribe buprenorphine since October 2002 when the FDA approved buprenorphine for clinical use in treating OUDs. The eight-hour DATA-waiver course is required in order to apply to prescribe to up to 30 patients in the first year and to increase the limit to 100 patients thereafter. Physicians who have prescribed buprenorphine to 100 patients for at least one year can apply to increase their patient limits to 275 patients under new federal regulations. As of February 27, 2017, prescribing of buprenorphine was extended to NPs and PAs per the Comprehensive Addiction and Recovery Act (CARA). 24 hours of training including the 8 hour waiver training is required in order to apply to prescribe to up to 30 patients.

Naltrexone (NR-NTX): This medication may be prescribed by any healthcare provider (e.g., NPs, PAs) who is licensed to prescribe medications. There is no limit on the number of patients for whom this medication may be prescribed.

Approved in October of 2010, extended-release injectable naltrexone is the most recent drug authorized for the treatment of OUDs.

Methadone: For the treatment of pain, methadone can be prescribed by any prescriber with a DEA registration, but for OUDs this medication can only be dispensed at a licensed opioid treatment program (OTP)/methadone clinic. If methadone is determined to be the most appropriate medication for a patient, primary care offices and clinics, behavioral health/specialty addiction treatment programs, and free-standing MAT clinics, can refer patients to one of the eight licensed OTPs in New Hampshire.

The following table recommends prescriber models by setting and medication.

¹⁹ Center for Substance Abuse Treatment. Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

OVERVIEW OF PRESCRIBER MODELS BY SETTING			
	PRIMARY CARE CLINIC OR OFFICE	BEHAVIORAL HEALTH / SPECIALTY ADDICTION TREATMENT PROGRAM	MAT-SPECIFIC TREATMENT PROGRAM
Buprenorphine	Recruit interested prescriber(s) in practice to obtain buprenorphine waiver, prescribe medication, and oversee patient care.	Have prescriber obtain buprenorphine waiver. Establish a working relationship with a prescriber(s) in the community waived to prescribe buprenorphine.	Hire prescribers to obtain buprenorphine waiver.
Naltrexone (XR-NTX)	Identify existing healthcare providers to prescribe naltrexone and oversee patient care.	Have existing healthcare provider prescribe naltrexone. Establish a working relationship with a healthcare provider(s) in the community to prescribe naltrexone.	Have existing provider prescribe naltrexone. Hire or subcontract with a licensed healthcare provider to prescribe naltrexone and to participate in oversight of patient care.
If methadone is determined to be the most appropriate medication for patients, providers can establish care coordination plans with one of the state's eight methadone clinics. For a list of OTPs, visit the NH Alcohol and Drug Treatment Locator, www.nhtreatment.org .			

Buprenorphine Waiver Process

TO QUALIFY FOR A BUPRENORPHINE WAIVER, A PRESCRIBER MUST:

1. Be a licensed physician (MD or DO), nurse practitioner, or physician assistant
2. Meet and verify any one or more of the following criteria:
 - a. Complete DATA-waiver course on the management and treatment of patients with opioid use disorders as provided by an approved vendor. NPs and PAs are required to complete 24 hours of training including the 8 hour waiver training.
 - b. Hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
 - c. Hold an addiction certification from the American Society of Addiction Medicine.
 - d. Hold a subspecialty board certification in addiction medicine from the American Osteopathic Association.
 - e. Have participated as an investigator in one or more clinical trials leading to the approval of a narcotic medication in Schedule III, IV, or V for maintenance or detoxification treatment.
 - f. Have other training or experience that the state medical licensing board or Health and Human Services considers a demonstration of the physician's ability to treat and manage patients with opioid dependency.
3. Submit notification of intent to SAMHSA.
<http://buprenorphine.samhsa.gov/forms/select-practitioner-type.php>

SAMHSA will send a letter within 45 days with approval status. If approved, a DEA identification number will be provided to treat up to 30 patients for the first year.

Physicians who have prescribed buprenorphine for a year can submit a second letter of intent to treat 100 patients. After treating at this patient limit for a year, physicians can apply to increase to 275 patients.

For more information: <https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management>

BUPRENORPHINE WAIVER TRAININGS

Training must be obtained from one of the following approved training providers. Different learning formats are offered at varying costs.

Providers' Clinical Support System for Medication Assisted Treatment (PCSS-MAT) - FREE training
(<https://pcssmat.org/education-training/mat-waiver-training/>)

American Academy of Addiction Psychiatry (AAAP)
(<https://www.aaap.org/education-training/buprenorphine/>)

American Society of Addiction Medicine (ASAM)
(<https://www.asam.org/education/live-online-cme/buprenorphine-course>)

American Osteopathic Academy of Addiction Medicine (AOAAM)
(<http://www.aoaam.org/?page=PCSSMAT&hhSearchTerms=%22PCSS-MAT%22>)

Care Coordinator

Care coordination is a critical component for effective delivery of MAT and patient care. How care coordination is provided often varies from program to program, but there are components of care coordination that are consistent across different styles, approaches and practice settings.

Care coordination often involves a range of tasks and responsibilities specific to medication assistance, including but not limited to, coordinating induction, administering drug tests, and lab screens and monitoring results, collaborating with other providers in compliance with Title 42, Part 2 of the Code of Federal Regulations (42 CFR, Part 2), and assisting patients with accessing treatment, recovery support services, and other ancillary services. Depending on the structure and capacities of the MAT setting, a case manager, medical assistant, physician's assistant, nurse, or another staff member may assume the role of care coordinator.

The most central component of successful MAT models is care coordination for patients.

Example: Using Nurses to Coordinate Patient Care

In 2003, Boston Medical Center (BMC) created the Collaborative Care Model of Office-Based Opioid Treatment also known as the Massachusetts Model in an effort to expand access to buprenorphine treatment. The model utilizes Nurse Care Managers (NCMs) to provide clinical support to waived physicians. Specifically, the NCM is the initial contact for patients and serves as the main liaison between the patient and physician throughout treatment. The NCM is responsible for conducting the initial patient assessment to better understand the patient's medical, social, and psychiatric history; works with the patient through the induction process; provides stabilization and maintenance support through weekly appointments and telephone check-ins; and conducts urine toxicology screens and verifies behavioral health counseling. Additionally, NCMs are responsible for relapse prevention, overdose education and support for patient self-management.¹ Since the program's inception, BMC has grown to serve over 500 patients with twenty-four waived primary care physicians.

In 2007, this model was implemented in community health centers through support provided by the Massachusetts Bureau of Substance Abuse Services (BSAS). By 2017, thirty-three health centers, in addition to BMC, were enrolled in the State Office-Based Addiction Treatment-Buprenorphine Program and the number of waived physicians in Massachusetts increased from 24 to over 600.² Since the grant was disseminated across the Commonwealth over 10,000 patients have been served. Each NCM has a caseload of 125 patients (8-12 patients per day) and receives assistance from a medical assistant. Additionally, as of 2013, 67% of the patients stayed in treatment for more than twelve months and 50% for more than five years.³

Information obtained from Colleen LaBelle, M.S.N., RN – B.C., C.A.R.N., Director of Boston Medical Center's OBAT on February 9, 2018.

1. LaBelle, C. T.; Bergeron, L. P.; Wason, K.W.; and Ventura, A. S. Policy and Procedure Manual of the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders. Unpublished treatment manual, Boston Medical Center, 2018.

2. Substance Abuse and Mental Health Services Administration. Number of DATA-Certified Physicians. (2018). Retrieved from https://www.samhsa.gov/medication-assisted-treatment/physician-program-data/certified-physicians?field_bup_us_state_code_value=MA

3. Labelle, C. et. al. Office-Based Opioid Treatment with Buprenorphine (OBOT-B): Statewide Implementation of the Massachusetts Collaborative Care Model in Community Health Centers. Journal of Substance Abuse Treatment. (2015).

The credentials held by care coordinators is secondary to their understanding of the nature of addiction and behaviors associated with this disease, in combination with a caring and problem solving approach to challenges.

Many existing MAT programs distribute responsibilities across available staff. However, treatment retention and compliance can be vastly improved through identifying one or more positions to coordinate care for all MAT patients. For MAT settings in which all services are not co-located, care coordination becomes even more critical.

Behavioral Health/Addiction Clinician

MAT combines medication assistance with behavioral health and/or SUD treatment and recovery support services such as recovery coaching and community-based support groups. Studies have found that programs providing regular, structured, SUD focused counseling had better outcomes than programs providing little or no counseling.²⁰ Having an on-site LADC/MLADC or a behavioral health clinician with training in the treatment of SUDs will help to encourage behavior change and will also hold patients accountable in, thereby receiving the support they will need in recovery. If the MAT program does not have SUD treatment services on-site, it will be crucial that formal agreements be established with several treatment providers offering different levels of care in an effort to support a patient's recovery. Additionally, it will be important for the care coordinator to consistently monitor treatment attendance based on program expectations and routinely provide and obtain updates from the external providers. Please refer to Section G: Psychosocial Treatment and Recovery Support Services which describes the levels of care and suggested programming.

Administrative Staff

Non-clinical and administrative staff are often responsible for obtaining patient intake information and consents, handling the billing and other accounting procedures, and most importantly, they are the first person the patient comes in contact with. Thus, it is important that these personnel receive the same education and training as clinical staff to include addiction as a disease, pharmacotherapy and stigma-related issues. Staff should also receive on-going record keeping and confidentiality training. Ensuring that the patient is welcomed into the program beginning at intake can positively influence the treatment experience.

INCENTIVES & SUPPORTS FOR RECRUITING AND RETAINING STAFF:

- Establish shared collegial patient care
- Provide on-going supervision
- Provide initial and on-going training
- Pay training and registration fees
- Ensure for practical caseloads
- Offer competitive wages

20 Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

IV.

**B. TRAINING & RESOURCES:
Provide Initial and On-Going
Training & Resources**

B. TRAINING & RESOURCES: Provide Initial and On-Going Training & Resources

...the attitude of staff members, is probably the next most important determinant of treatment effectiveness...

(Bell 1998, p. 168)

Patient outcomes are influenced by a variety of factors. Staff can play a significant role. It is important to ensure that the attitudes, values, and competence around MAT and interactions with patients among all staff are conducive for delivering MAT services. All staff should have on-going access to training and supervision, current literature and other resources. The following is a list of resources related to MAT best practices and service delivery models as well as resources by medication and topic area and information for accessing SUD treatment and recovery support services and other resources for patients, families and friends.

MAT BEST PRACTICE RESOURCES

The ASAM National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use

- Guidelines - <https://asam.org/resources/guidelines-and-consensus-documents/npg>
- Pocket Guide - <https://asam.org/resources/guidelines-and-consensus-documents/npg/pocket-guide-and-app>

SAMHSA TIP 63: Medications for Opioid Use Disorders

- TIP - <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorders-Full-Documents-Including-Executive-Summary-and-Parts-1-5-/SMA18-5063FULLDOC>

SAMHSA Medication Assisted Treatment of Opioid Use Disorder

- Pocket Guide - <https://store.samhsa.gov/shin/content/SMA16-4892PG/SMA16-4892PG.pdf>

American Hospital Association, Stem the Tide: Addressing the Opioid Epidemic

- Guideline - http://www.aha.org/content/17/opioid-toolkit.pdf?utm_source=eblast&utm_medium=email&utm_content=AHA_opioidtoolkit&utm_campaign=eblast-newtoolkit-11-06-17

Providers' Clinical Support System For Medication Assisted Treatment

- www.pcssmat.org

MATx Mobile App by SAMHSA

- <https://store.samhsa.gov/product/MATx-Mobile-App-by-SAMHSA/PEP16-MATAPP>

RESOURCES ON MAT MODELS

Agency for Healthcare Research and Quality, Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings

- Technical Brief - <https://www.ncbi.nlm.nih.gov/books/NBK402352/>

Primary Care-Based Models for the Treatment of Opioid Use Disorder: A Scoping Review

- Article - Korthuis, P.T. et. al. Ann Intern Med. 2017 February 21; 166(4): 268–278. doi:10.7326/M16-2149.

RESOURCES BY MEDICATION	
BUPRENORPHINE	SAMHSA TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction - TIP - https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf - Quick Guide – https://store.samhsa.gov/shin/content/KAPT40/KAPT40.pdf
	Buprenorphine Treatment: Training for Multidisciplinary Addiction Professionals Training - http://attcnetwork.org/projects/buptx.aspx
NALTREXONE	Clinical Use of Extended Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide Guide – https://store.samhsa.gov/shin/content//SMA14-4892R/SMA14-4892R.pdf
METHADONE	SAMHSA TIP 43: Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs - TIP - https://store.samhsa.gov/shin/content//QGCT43/QGCT43.pdf - Knowledge Application Program Key - https://store.samhsa.gov/shin/content//SMA12-4108/SMA12-4108.pdf Recovery-oriented Methadone Maintenance - Monograph - http://www.williamwhitepapers.com/books_monographs/
RESOURCES BY TOPIC AREA	
Screening	Screen and Intervene: NH S · BI · RT Playbook Version 2.1 http://sbirtnh.org/playbook/
	Institute for Research, Education, & Training in Addictions www.ireta.org
Assessment	SAMHSA TIP 42: Substance Abuse Treatment for Persons With Co-Occurring Disorders - TIP - https://store.samhsa.gov/shin/content//SMA13-3992/SMA13-3992.pdf - Quick Guide - https://store.samhsa.gov/shin/content//SMA10-4531/SMA10-4531.pdf
Induction	The ASAM National Practice Guidelines for the Use of Medications in the Treatment of Addiction Involving Opioid Use Guidelines - https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24
	Withdrawal Scales - Clinical Opiate Withdrawal Scale (COWS) - http://www.naabt.org/documents/cows_induction_flow_sheet.pdf - Objective Opiate Withdrawal Scale (OOWS) - https://www.ncbi.nlm.nih.gov/books/NBK143183/ - Subjective Opiate Withdrawal Scale (SOWS) - http://www.buppractice.com/node/5775
Confidentiality	Substance Use Disorder Privacy Workbook: 42 CFR Part 2 Workbook - https://chhs.unh.edu/sites/chhs.unh.edu/files/departments/institute_for_health_policy_and_practice/pdfs/sud_privacy_part_2_idn_workbook_unh_1017.pdf
Diversion Control	Diversion Control Protocol Template for Opioid Use Disorder Treatment Providers http://media.campaigner.com/media/33/333080/MAT-PDOA%206-28-17/MAT_PDOA_DiversionControlTemplate.pdf

RESOURCES BY TOPIC AREA (CONTINUED)

Drug Testing	Appropriate Use of Drug Testing in Clinical Addiction Medicine http://1viuw040k2mx3a7mwz1lwva5.wpengengine.netdna-cdn.com/wp-content/uploads/2017/11/appropriate_use_of_drug_testing_in_clinical-1-7.pdf
	Urine Drug Testing in Clinical Practice http://1viuw040k2mx3a7mwz1lwva5.wpengengine.netdna-cdn.com/wp-content/uploads/2017/07/2012-GourlayHeit-UDT-monograph.pdf
	The ASAM Appropriate Use of Drug Testing in Clinical Addiction Medicine Webinar Series - https://elearning.asam.org/drugtestingwebinars

NH SUBSTANCE USE DISORDER TREATMENT RESOURCES

NH Statewide Addiction Crisis Line 1-844-711-HELP (4357)
NH Alcohol and Drug Treatment Locator www.nhtreatment.org
NH Department of Health and Human Services, Bureau of Drug and Alcohol Services Resource Guide - State-funded SUD Treatment Services - https://www.dhhs.nh.gov/dcbcs/bdas/documents/resource-guide-treatment.pdf - State-funded Recovery Support Services - https://www.dhhs.nh.gov/dcbcs/bdas/documents/recovery-resource-guide.pdf

RESOURCES FOR PATIENTS, FAMILY AND FRIENDS

SAMHSA Decisions in Recovery: Treatment for Opioid Use Disorder https://archive.samhsa.gov/MAT-Decisions-in-Recovery/Default.aspx
ASAM Opioid Addiction Treatment: A Guide for Patients, Families and Friends http://eguideline.guidelinecentral.com/i/706017-asam-opioid-patient-piece/0?
Family Resource Center http://www.familyresourcectr.org/

IV.

**C. BILLING:
Establish Billing Protocol**

C. Establish Billing Protocol

Services can be covered through different payer/payment mechanisms to include cash and third-party payers. While cash can be collected to cover the services that are delivered, it is recommended that office-based opioid treatment programs credential with third-party payers in an effort to better support patients and their ability to access available services.

Non-Insurance Payment Model: Establish a payment structure to identify the cost of services and when and how payment will be collected. Policies on how to address late payments and patients who may not be able to pay for services in full are strongly recommended.

Third-Party Payer Reimbursement Model: Enroll and credential with managed care organizations (MCOs), qualified health plans (QHPs), and other insurers. The MCOs and other third-party carriers use specific strategies to help manage the prescribing of addiction medicines. It is strongly recommended that MAT programs familiarize themselves with the requirements of each carrier, and the time it takes to meet requirements prior to prescribing medication to ensure that the patient does not become responsible for unpaid claims.

For more information about third-party reimbursement, please visit:

NH Health Insurance Marketplace - http://www.nh.gov/insurance/consumers/mp_plans.htm

Premium Assistance Program (PAP) - <http://www.dhhs.state.nh.us/ombp/pap/>

NH Health Protection Program (NHHPP) - <http://www.dhhs.nh.gov/ombp/nhhpp/>

INSURANCE STRATEGIES FOR MANAGING MEDICATION ASSISTED TREATMENT ²¹

Preferred Drug List (PDL)	Prior Authorization	Medical Necessity: Quantity and Duration Limits
<i>Identify if a medication is on the PDL.</i> 	<i>If a prescribed medication is not on the PDL, the provider will need to obtain a prior authorization before the medication will be paid for.</i> 	<i>A provider should be aware of utilization guidelines for each medication prescribed in that restrictions may be placed on the amount prescribed and the frequency of the prescription.</i>

Drug utilization reviews (DURs) may be initiated by a MCO or third-party carrier in which claims documentation is reviewed against a clinical database to identify patient prescribing discrepancies (e.g., duplication of prescriptions, incompatibility with other prescriptions).

Legislation (Senate Bill 158) was passed on July 3, 2017, and went into effect on August 28, 2017, to “declare that if substance use disorder services are a covered benefit under a health benefit plan, a health carrier that has authorized or approved medication assisted treatment for such services shall not require a renewal of a prior authorization more frequently than once every 12 months.”²² A sunset clause is not in place and is, therefore, indefinite unless repealed. This legislation applies to all medication products and formulations for the treatment of opioid and alcohol use disorders.²³

To file a complaint and to initiate an emergency appeal process, contact the Consumer Services Unit at 603-271-2261 or submit a complaint online at: <https://www.nh.gov/insurance/complaints/index.htm>.

²¹ Retrieved from CMS, SAMHSA, CDC, NIH Informational Bulletin - <http://www.medicare.gov/federal-policy-guidance/downloads/cib-07-11-2014.pdf>.

²² NH State Legislature, Senate Bill 158. Retrieved from: <https://legiscan.com/NH/bill/SB158/2017>.

²³ Technical assistance regarding SB 158 provided by Michele Merritt, Esq., President & CEO of New Futures, Inc.

IV.

D. EVALUATION:

**Establish a Process for
Assessing Patients**

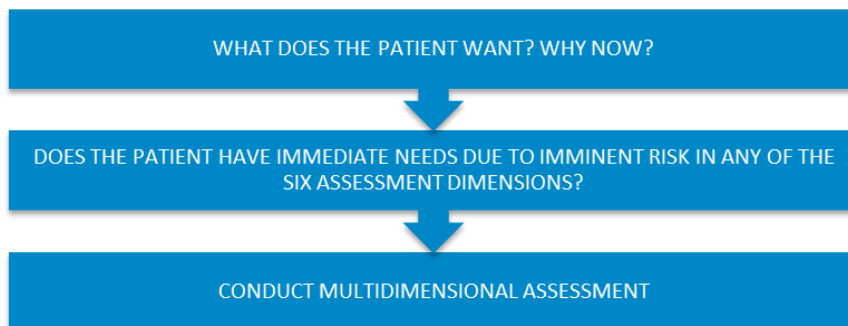
D. EVALUATION: Establish a Process for Assessing Patients

Prior to prescribing medication a thorough evaluation should be conducted with the patient to identify if he/she is an appropriate candidate for MAT and, if so, the type of medication that would be most suitable.

A clinical and medical assessment is needed to determine the level of care the patient meets. Understanding the patient's medical history, past and current use of alcohol and/or drugs, family background, environment and other factors, will help identify which medication and psychosocial treatment will be most appropriate.

It is recommended that the behavioral health clinician and prescriber be involved with the evaluation process. The following indicates the steps for conducting a thorough evaluation.²⁴

1. **Conduct Patient Assessment:** Utilize evidence-based tools such as the Addiction Severity Index (ASI)²⁵, a semi-structured assessment tool available on the public domain, to evaluate an individual.
 - a. Evaluate the patient's physical, mental, and emotional health, past and current substance use, and medical history.
 - b. Identify current and past medications, allergies, pregnancy status, personal history of infectious diseases such as hepatitis, HIV, and TB, and social and environmental factors.
 - c. Engage the patient in treatment by asking open-ended questions to identify his/her treatment goals.
 - d. Utilize information gathered, including how patient's overall assessment aligns with ASAM criteria to assess level of care.



Sample Open-Ended Questions:

- What was your first exposure to opioids?
- Tell me about your use?
- How do you use opioids?
- What other substances do you use?
- What prescribed medicines do you take regularly?
- What medical conditions do you have or have you been treated for?
- Is there a chance you could be pregnant?
- What are your goals for treatment?
- What services and supports have been helpful to you in the past?
- What services and supports would be helpful to you?
- Who is a support to you?

²⁴ The American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, May 27, 2015.

²⁵ Retrieved from the Treatment Research Institute - <https://www.tresearch.org/products/assessment-and-evaluation>.

The table below lists appropriate observations for each ASAM dimension that would qualify an individual for needing opioid pharmacotherapy as a component of overall treatment.

ASAM Dimensions	Observation
DIMENSION 1: Intoxication and/or Withdrawal Potential	Physiologically dependent on opiates and requires some form of treatment to assist in alleviating withdrawal symptoms. It is possible that patients will qualify for MAT without being physically dependent on opioids (i.e., diagnosis of OUD without recent use but risk of use based on cravings or environment, or periodic use in setting of addiction).
DIMENSION 2: Biomedical Conditions and Complications	None or manageable with outpatient medical monitoring
DIMENSION 3: Emotional/Behavioral/Cognitive Conditions and Complications	None or manageable in an outpatient structured environment
DIMENSION 4: Readiness to Change	Ready to embark on changes associated with abstinence
DIMENSION 5: Relapse/Continued Use/Continued Problem Potential	At risk of relapse/continued use and willing to engage in structured treatment to promote treatment progress
DIMENSION 6: Recovery Environment	Has supportive recovery environment and/or options for a stable living environment

2. **Conduct Physical Exam:** An exam should be performed by either the prescribing physician or another healthcare provider prior to prescribing medication. The exam should include identifying physical signs of opioid use, intoxication, withdrawal, and other complicating signs of SUD (e.g., abscesses, cellulitis) as well as overall physical health including nutritional status. Several opioid withdrawal scales are available to help a clinician identify and quantify OUDs. These scales include:
 - a. Objective Opiate Withdrawal Scale (OOWS)²⁶ – Tool for determining level of withdrawal (see Appendix II: *Objective Opiate Withdrawal Scale (OOWS)*).
 - b. Subjective Opiate Withdrawal Scale (SOWS)²⁷ – Self-reporting tool for identifying opiate withdrawal (see Appendix III: *Subjective Opiate Withdrawal Scale (SOWS)*).
 - c. Clinical Opiate Withdrawal Scale (COWS)²⁸ – Tool for identifying signs and symptoms which integrates subjective and objective items (see Appendix IV: *Clinical Opiate Withdrawal Scale (COWS)*).

²⁶ Retrieved from the National Institutes of Health - <http://www.ncbi.nlm.nih.gov/books/NBK143183/>.

²⁷ Retrieved from buppractice - <http://www.buppractice.com/node/5775>.

²⁸ Retrieved from The National Alliance of Advocates for Buprenorphine Treatment - http://www.naabt.org/documents/cows_induction_flow_sheet.pdf.

3. **Conduct Laboratory Tests/Drug Tests:** The following should be considered at the time of initial evaluation:
- infectious disease (tuberculosis, hepatitis A, B, C, sexually transmitted diseases and HIV);
 - pregnancy test;
 - blood count;
 - drug testing; and
 - liver function testing.

Depending on the results of these tests further follow up may be required.

Opioid Use Disorder Severity Classifications:

Mild: 2 – 3 symptoms

Moderate: 4 – 5 symptoms

Severe: 6 – 11 symptoms

4. **Determine Diagnosis:** A diagnosis of OUD must be identified before prescribing a medication. The assessment, physical exam, drug testing, and other information gathered during the evaluation process will be essential to determine the diagnosis. A patient must be diagnosed with at least a “mild” OUD, two of eleven criteria indicated in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) met by the patient within the last twelve months. A non-medical clinician can determine this diagnosis; however, the prescriber should confirm the diagnosis. The diagnosis of an SUD/OUD is followed similar to any chronic illness. It is important to review continued drug and alcohol use with patients, symptoms of craving, physical symptoms that may occur with cessation of drug use and side effects of prescribed medications. For more details, see Section E. Treatment Planning.

5. **Query PDMP:** The NH PDMP grants access to system accounts to practitioners and approved delegates so that they may enter and review controlled substance dispensing information on their patients. Per NH law, it is a requirement that prescribers review data prior to prescribing an opioid when treating or managing a patient for pain. It is essential that all prescribers review data prior to prescribing scheduled medications in an effort to ensure appropriate prescribing.

Per NH law, each dispenser is required to submit information into the PDMP regarding each prescription dispensed for a Schedule II, III, or IV controlled substance. In accordance with transmission methods, information is to be submitted daily by the close of business on the next business day from the date the prescription was dispensed. Veterinarians shall submit the information no more than 7 days from the date the prescription was dispensed. Dispensers who have a federal DEA license, but who do not dispense controlled substances may request a waiver from the requirements of having to report to the PDMP from the board.

To register in the NH Prescription Drug Monitoring Program:

1. Open an Internet browser window and navigate to the following URL: <https://newhampshire.pmpaware.net/login>
 - a. Click “Create an Account”
 - b. Enter a current, valid email address
 - c. Select and enter a password twice for validation (a password must contain at least 8 characters, including 1 capital letter and 1 special character (such as !, @, #, \$))
 - d. Click “Save and Continue”
2. At the role selection screen, expand the role categories to select the role that best fits your profession.
 - a. Click “Save and Continue”
3. A message is temporarily displayed stating that an email has been sent to your email address for verification.
 - a. The email will arrive in your inbox within a few minutes
 - b. Within this email, click the link to verify that your email address is valid and current.
4. After validation, you will be redirected to the demographics screen.
 - a. Enter your name, date of birth, employer information, and other information as configured by the PDMP Administrator (required fields are marked with a red asterisk).
 - b. Please enter all active DEA numbers associated with your NH license, if applicable.
 - c. Click “Submit Your Registration”
5. You will be taken to a landing page notifying you that your account is pending approval.
 - a. Additional validation documents are not required, as is indicated by the “None Required” message in the “Validation Documents Required” column.

PDMP administrators will process the registration within 24 hours. If approved, notification will be sent via email to set up a password. If the request is not approved, an email with an explanation as to why registration was not approved will be sent. Please contact 603-271-6978 if you have not received some type of communication after you have submitted an application for registration.

The following table provides recommendations for when and by whom each evaluation component may be initiated.

Evaluation Components	Staff Responsible for Component	Initiation of Evaluation Component
Assessment	Behavioral Health/Addiction Clinician Strongly recommended that prescriber conduct an abbreviated assessment	Assessment may be completed over a period of a few sessions; however, a shortened version is essential at intake to identify patient history and needs necessary to prescribe the appropriate pharmacotherapy.
Physical Exam	Prescriber or other health care provider	Prior to prescribing pharmacotherapy
Lab/Drug Tests	Prescriber or other healthcare provider may order May be conducted in-house or an outside lab may be used	Prior to prescribing pharmacotherapy and ongoing
Diagnosis	Behavioral Health/Addiction Clinician Prescriber must confirm diagnosis	Prior to prescribing pharmacotherapy
PDMP Check	Prescriber or other approved designee	Prior to prescribing pharmacotherapy

Example: Promoting Individualized Care through Comprehensive Evaluation

A wide array of services to include primary care, addiction medicine and psychiatry are offered at one practice. The addiction program offers individual and group counseling and office-based opioid treatment. Prior to prescribing medication, an evaluation of the patient is conducted which takes approximately three hours. The patient meets with the intake and project coordinator who conducts a 1.5 – two-hour assessment, a half hour is spent with the addiction medicine physician who also performs a physical exam, and a one-hour psychiatric consult is provided. This comprehensive evaluation allows the care team to identify the appropriate treatment needed. The model this practice utilizes, in which all services are available, assists with the evaluation process, and also allows for patients to receive specialized and coordinated care.

Information obtained from Dr. Mark Logan, Green Mountain Family Practice Medicine, Rutland, VT in September 2015.

IV.

**E. TREATMENT PLANNING:
Monitor Patient Progress**

E. TREATMENT PLANNING: Monitor Patient Progress

After the patient has been evaluated, the prescriber will determine the appropriate medication based on information collected from the patient related to his or her history, and based on medical and social factors. A behavioral health clinician can assist with developing a plan for psychosocial treatment. The plan should be the result of shared decision-making with the patient, and may include supportive family or friends if the patient chooses.

To determine the best plan, the prescriber and clinician collaboratively review the following:

- Co-morbid medical conditions
- Socioeconomic factors (e.g., transportation, child care, employment/education)
- Medication adherence
- Setting/Level of care (e.g., more structure, frequency of visits)

If the prescriber and the clinician are not considerate of these factors, medication and psychosocial treatment adherence may be adversely affected and the patient's recovery compromised. Two respective treatment plans, one for monitoring MAT and one for behavioral health treatment, can be developed. One inclusive plan is acceptable for settings that provide both services.

The following highlights recommended components to include in the medication treatment plan and provides examples that may be included under each component. Plans should be individualized to meet the needs and goals of the patient.

MAT Treatment Plan Components	
Components	Considerations/Examples
Diagnosis	This diagnosis will be made with the assistance of behavioral health professionals familiar with the DSM-5 criteria for use disorders; other co-morbid diagnoses may exist and also need to be documented and addressed within the context of integrated care. (e.g., Opioid Use Disorder, severe, dependence)
Goals of Treatment	• Abstinence from illicit opioids or substances • Cessation of tobacco products • Abstinence from use of needles • Treatment completion of hepatitis C infection (if appropriate)
Treatment Objectives (over a defined period of time)	• By X week on MAT drug tests will be negative for illicit opioids
Medication Plan	• Medication prescription (type of medication, dose, and other instructions) • Participate in weekly in-person visits for first four weeks followed by... • Every other week visits with prescriber alternating with nurse care coordinator • Check-in calls once a week
Counseling Plan	• Varies by patient and site • Level of care will be determined by prescriber and behavioral health clinician

MAT Treatment Plan Components	
Recovery Support Expectations	• Participate weekly in mutual help/12 step programs • Participate in other community-based supports
Plan for Patient Participation (including for non-adherent patients, voluntary discharge, treatment completion)	• More frequent visits • Referral to higher level of care • Reduction in dose of buprenorphine • Meeting with provider and team to determine next steps

Additionally, an agreement and informed consent for medication, release of information for any agencies and other physicians and providers, induction to include labs, drug testing at each visit, and querying of the PDMP prior to visit to evaluate adherence are necessary. Completion of these components may be documented in the treatment plan at the discretion of the program.

In the event that a patient does not follow the plan and/or relapses, it is recommended that the prescriber and clinician review and revise treatment plans accordingly, rather than summarily discharging a patient. In addition to the treatment plan, a treatment agreement can be a helpful tool to clarify treatment goals, identify and reinforce expectations and promote medication adherence. A sample treatment agreement²⁹ for the prescribing of opioid medications is provided in Appendix V: Sample Treatment Agreement.

The length of time that a medication is prescribed for a use disorder is not defined by best practices other than to note that the longer one is treated with medication, the longer the person typically remains abstinent. There are times that the patient and the prescriber will discuss changes to the original regimen. This might be the case when the patient has made changes in his or her life compatible with recovery (avoiding triggers, involvement with healthy activities, etc.). At other times it may be necessary to make changes because the medication is not effective or causing side effects. The prescriber and the clinician can work collaboratively to determine the best way to support the patient and the regimen that will suit the individual.

There are times that family members, friends or others in the person's sphere exert pressure on the individual based on preconceived notions, opinions and inaccurate understanding of MAT. Best practice does not support weaning medication once it is started unless reviewed with the prescriber and patients' team of caregivers and all understand the risk and benefit involved.

²⁹ Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004. Appendix H Sample Treatment Agreement/Contract.

Sample Treatment Timeline	
Week 0	Intake, Diagnosis, Treatment Plan Development and Patient Expectation Discussion
Week 1	Induction
Week 2	Stabilize Patient
Week 3	Conduct Labs
Week 4	Review Treatment Plan
Week 6	Review Patient Progress • Drug testing should show absence of illicit substances. • If unexpected opioid noted and confirmed, then consider 1) a change in dose of buprenorphine, 2) a change in medication or 3) a higher level of care. • If other illicit substance found, recommend a higher level of care (e.g., IOP, PHP, residential). It is not recommended to discharge the patient from care nor stop medication altogether. • Review patient record (includes infectious disease review) and refer for any treatment needed (hep C, further medical work up for co-morbid diseases)
12 Weeks	Review Patient Progress • If abstinent, change diagnosis to OUD, severe (mild, moderate) in early remission.
Every 2 Weeks	Check-In Visits • Schedule 15-minute visits with counselor, recovery coach or care coordinator. • Schedule 5 -15 minutes with prescriber (longer if office does not have counselor, coach or coordinator). • Document progress on components consistent with treatment plan: ▪ Patient report of wellness/recovery ▪ Current living/housing/transportation or other potential barriers to care ▪ Psychosocial treatment progress ▪ Mutual help participation ▪ Medication adherence, side effects ▪ Substance Use (Opioids, Benzodiazepines, Alcohol, Stimulants, Other) ▪ Other substance use and plan (include nicotine use and readiness to change) ▪ Primary care follow-up needs (e.g., physical, immunizations) ▪ Co-morbid psychiatric disease ▪ Co-morbid medical issues ▪ Infectious disease
Monthly	Conduct Drug Testing
Twice Per Year	Conduct Random Drug Testing and Film/Pill Count
At 6 Months	Test for Liver Enzymes
At 12 Months	Recheck for Infectious Disease

IV.

F. INDUCTION:

Start Patients on Buprenorphine

F. INDUCTION: START PATIENTS ON BUPRENORPHINE

- There should be a sufficient interval (range: 6-12 hours) between the last opioid use and the first buprenorphine/naloxone dose.
- If a long-acting opioid has been used, i.e. methadone, MS Contin, or other long-acting opioid, a longer interval of at least 48 hours should be used to avoid precipitating withdrawal with buprenorphine.
- **NOTE: Starting buprenorphine while one is taking an opioid (prescribed or illicit) or if the timing is too soon after last dose of an opioid agonist, can precipitate withdrawal.**

The goal of the induction phase is to find the dose of buprenorphine that relieves the patient of craving and withdrawal symptoms. A waived prescriber is responsible for evaluating and monitoring the patient during the induction phase. The induction phase has been described as an observed event in an office setting though many experts site home induction as effective and safe in appropriate cases.³⁰

Before induction the patient should not have any signs of intoxication or sedation; drug testing needs to correlate with patient self-report. Symptoms of opioid withdrawal need to be documented. This can be evaluated using the Clinical Opiate Withdrawal Scale (COWS) (Appendix IV).

There may be situations in which induction with buprenorphine is conducted even though a patient has been free of opioids for some time and is not in acute opioid withdrawal (for example: post-detox, post-hospitalization, post-incarceration). In these cases, the COWS need not be utilized to determine timing of dosing.

Some patients may already be taking daily buprenorphine illicitly with no other opioids, as documented by drug test results. Induction may not be necessary in these cases as per the discretion of the prescriber.

Dosing of Buprenorphine:

1. The typical first dose of buprenorphine is 2/0.5 to 4/1mg and the sublingual tab/film should be observed to have dissolved completely under the tongue (this can take as long as 15 minutes).
2. Have patient demonstrate proper medication administration:
 - a. Tab/film placed under tongue
 - b. No food/drink during administration
 - c. Allow saliva to pool in front of mouth
 - d. Spit out saliva once tab/film dissolved
3. After the first dose, patients will need to wait in the office or waiting room and be checked after 30-60 minutes for adverse effects (i.e., change in mental status, difficulty breathing, hives, sedation) and to repeat the COWS to evaluate symptoms.
4. A repeat dose of 2/0.5-4/1 mg can be used 1-2 hours after the first dose if withdrawal symptoms are still present. A total first day dose of buprenorphine/naloxone should not exceed 16/4mg.
5. After the first day's induction dose the patient should be contacted and/or observed in office by designated staff.

30 Lee, J., Vocci, F., Fiellin, D. Unobserved "home" induction onto buprenorphine. Journal of Addiction Medicine. 8(5):299-308, September/October 2014.

6. Dosing should be based on the experience from induction.
 - a. If symptoms were relieved, then the dose should be kept at the total dose used for induction.
 - b. If symptoms were not relieved, then buprenorphine can be titrated in increments of 2/0.5-4/1 mg daily.
7. Stabilization/maintenance dosing is variable but rarely exceeds a total daily dose of 16/4 mg.

IV.

G. PSYCHOSOCIAL TREATMENT & RECOVERY SERVICES:

Identify How Substance Use Disorder Services Will Be Delivered

G. PSYCHOSOCIAL TREATMENT & RECOVERY SUPPORT SERVICES: Identify How Substance Use Disorder Services Will Be Delivered

There are three important parts to MAT: medication, SUD treatment and recovery support services and care coordination. Studies have found that programs providing regular, structured, SUD-focused counseling had better outcomes than programs providing little or no counseling.³¹ Additionally, to maintain a buprenorphine waiver, the prescriber must be capable of referring patients for counseling and other ancillary services.

The following chart highlights key considerations for ensuring patients receive psychosocial services.

DELIVERY OF PSYCHOSOCIAL SERVICES	
ON-SITE	OFF-SITE
• Hire a LADC/MLADC or behavioral health clinician who has training in the treatment of SUDs • Identify the type of treatment that will be provided (e.g., individual, group, intensive outpatient counseling) • Identify the psychosocial approaches that will be used (e.g., CBT, MET) • Determine the frequency of services • Review psychosocial treatment expectations and responsibilities with patient • Develop and routinely update treatment plan collaboratively with patient • Refer to recovery support and other ancillary services	• Establish strong working relationships or formal agreements with providers offering different levels of treatment and recovery support services • Review psychosocial treatment expectations and responsibilities with patient • Obtain signed consent form from patient to approve open communication • Routinely provide and obtain updates from the external provider to consistently monitor treatment attendance and progress

Below are the most common treatment options used in conjunction with MAT. MAT can be provided during any level of care. Advantages of group counseling over individual counseling include the opportunity for patients to interact and problem solve with their peers³².

- **Individual Outpatient Counseling** – Service provided by a clinician to assist an individual in achieving treatment objectives through the exploration of SUDs and their effects, including an examination of attitudes and feelings, and considering alternative solutions and decision-making with regard to alcohol and other drug-related problems.
- **Group Outpatient Counseling** – Service provided by a clinician to assist two or more individuals and/or their families/ significant others in achieving treatment objectives through the exploration of SUDs and their effects, including an examination of attitudes and feelings, and considering alternative solutions and decision-making with regard to alcohol and other drug-related problems.
- **Family Counseling** – Provides education, allows family members to express their feelings and concerns, and helps secure the family's support for the person in recovery.
- **Intensive Outpatient Services** – Structured individual and group alcohol and/or other treatment services and activities that are provided according to an individualized treatment plan. Services for adults are provided at least nine hours per week and services for adolescents are provided at least six hours per week.

31 Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

32 Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

The following are additional treatment options available in NH.

- **Partial Hospitalization(PHP)** – *Combination of 20 or more hours per week of group and individual sessions in conjunction with, either directly or through referral, medical and psychiatric services, psychopharmacological services, addiction medication management, recovery support services and 24-hour crisis services.*
- **Residential Services** – *Program providing 24-hour support and services where an individual lives full time at the program and receives individual and/or group counseling, educational sessions and introduction to self-help groups.*

Group medical visits have been used in some MAT practices in an effort to provide treatment services more efficiently. These involve the prescriber and behavioral health/addiction clinician co-facilitating a group with a ten-minute individual medical appointment preceding or following the group.

Example: Utilizing Group Medical Visits to Provide Substance Use Disorder Treatment

An independent OBOT program uses a group medical visit approach for delivering psychosocial and medical treatment. This program is designed to be between 18-24 months. Each week patients are required to participate in a group visit which is facilitated by an addiction clinician, be involved with treatment planning, and complete a urine drug test which tests for 12 substances, including buprenorphine. The group structure is based on evidenced-based curriculum as well as some elements taken from 12 step programs. A prescriber is present during the group once a month (every 30 days) to answer and discuss any medical-related questions. Each group consists of no more than twelve people to ensure adequate opportunity for everyone to share. Before or after the group, the prescriber meets with each patient for a ten-minute check-in to review treatment plan goals, discuss medication adherence, side effects, treatment progress and concerns. This treatment model provides patients with the opportunity to problem solve and gain support from their peers while also being able to discuss medical concerns directly with the prescriber.

Information obtained from Groups, Heather Prebish, Clinical Director, on December 7, 2017.

Different treatment interventions can be used to initiate behavior change. Some approaches utilize positive reinforcement while others capitalize on readiness to change. The box to the right lists some of the more commonly used treatment interventions.

Regardless of the type of treatment or approach used, several topics are essential including:³³

- Education about addiction and the effects of substances;
- Education about relapse prevention strategies to learn skills to attain and maintain recovery;
- Education on opioid-related health issues (e.g., HIV, Hepatitis);
- Providing linkages to existing family support systems; and
- Providing referrals to community supports.

Examples of Treatment Interventions:

- Cognitive behavioral therapy
- Motivational enhancement therapy
- Contingency management/ motivational incentives
- Community reinforcement approach
- Behavioral couples counseling

In addition to treatment services, recovery support services can be made available during any stage of a patient's recovery. Specifically, Peer Recovery Support Services (PRSS) are non-clinical services designed to help people achieve and maintain their recovery provided by people with lived experience of addiction and recovery. Many of these services can be accessed at community-based Recovery Centers.

Peer Recovery Support Services include:

Telephone Peer Recovery Support Services: Scheduled and as needed telephone contact that provides peer support and encouragement as well as information about community resources, mutual support groups and other supports that may be available to individuals in or seeking recovery.

Peer Recovery Coaching: Services provided by trained peers who serve as guides and mentors to individuals seeking or in recovery in order to assist those individuals with developing a recovery plan and removing barriers to recovery.

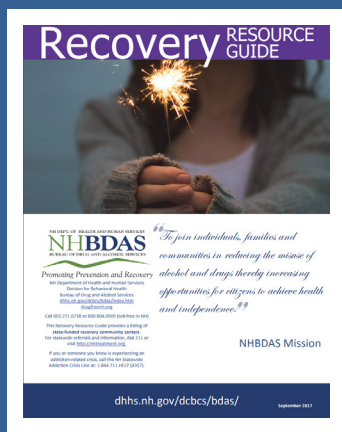
Wellness Activities: Activities vary by Recovery Center and may include gardening, yoga and meditation, financial literacy, goal setting, work readiness training and more.

Mutual Support Group Meetings: Every Recovery Center makes space available for a variety of recovery groups including Alcoholics Anonymous, Narcotics Anonymous, Al-Anon, and family support groups.

33 Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. HHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.



The NH Alcohol and Drug Treatment Locator is an online directory for locating alcohol and drug treatment and recovery support service providers in New Hampshire who offer evaluation services, withdrawal management, outpatient counseling, residential treatment, recovery support services and other services by location, service type, population/specialties served, and/or payer.



The Treatment and Recovery Resource Guides list treatment and recovery support services funded by the NH Department of Health and Human Services, Bureau of Drug and Alcohol Services. These resource guides can be accessed at: <https://www.dhhs.nh.gov/dcbcs/bdas/guide.htm>.

Example: Supporting Patient Needs by Offering Multiple Pharmacotherapy and Psychosocial Treatment Options

One OTP offers a full array of SUD services to include most products and formulations of methadone, buprenorphine, and naltrexone and a variety of psychosocial treatments including residential treatment. These services are made available to patients depending on multiple factors including physiological aspects, socioeconomic factors, setting (e.g., more structure, frequency of visits), and medication adherence. Patients are required to participate in one group session per month, brief psychosocial counseling with a physician monthly, and are encouraged to participate in recovery support groups.

Information obtained from Stephen Straubing MD, DABAM, Meridian Behavioral Healthcare, Gainesville, FL. on October 8, 2015.

IV.

**H. DRUG TESTING:
Establish Policies and Procedures**

H. DRUG TESTING: Establish Policies and Procedures

Drug testing is a tool that uses a biologic sample to detect presence or absence of a specific drug as well as specific metabolites of drugs within a specified window of time. The use of drug testing provides a source of information to complement self-report, collateral reports, and provider assessments. Drug testing should be considered therapeutic and NOT punitive and used for treatment planning assistance. In addition, it can be helpful in exploring denial, motivation, and actual substance use behavior. It is important for a physician or other provider to understand the various testing techniques, their sensitivity and specificity, and cost to the medical system, insurance, and patient. It is strongly recommended that providers utilize the expertise of toxicologists or local certified Medical Review Officers (MROs) for any questions arising for their patients' individual situations.

Testing Types: Urine is the biological sample that is most widely used though tests utilizing other samples (e.g. saliva, hair, blood) are becoming more available and popular.

Testing Categories: There are two categories of drug testing: definitive and presumptive. Presumptive tests have lower sensitivity and/or specificity compared to definitive testing.

	Definitive Drug Testing (Quantitative)	Presumptive Drug Testing (Qualitative)
Test setting	Lab	Point of Care
Analytical method	Gas or Liquid Chromatography	Immunoassay
Purpose	Confirmation	Screening - <i>Any dispute of results should be definitively evaluated, especially in cases where the result may effect clinical care, legal status, or change in medication</i>
Advantages	Gold standard method but can take more time to obtain results and can cost more	Immediate results at the cost of being less accurate
For both presumptive and definitive testing it is important to understand the cut off concentrations for the substances to provide the best clinical utility.		

Documenting/Reporting Testing: The proper reporting of a drug that is prescribed and present in the test is documented as “expected”. A substance that is not prescribed and present is documented as “unexpected”. It would also be unexpected if a prescribed medication is not definitively detected.

Recommendations for Appropriate Use of Drug Testing in Clinical Addiction Medicine³⁴ (these recommendations are not intended to substitute for independent clinical judgment)

1. The frequency of testing should be determined based on patient situation (usually more frequent at beginning of treatment).
2. Testing should be based upon clinical indication for a broad panel of drugs; knowledge of local drug use trends can guide the choice of panels.
3. Use random drug testing over routine visit testing.
4. Use different matrices (samples) depending on the patient situation (i.e., dry mouth, shy bladder, etc.).
5. Improved sample collection and detection technologies can reduce sample adulteration and substitution.
6. Consider cost to value ratio.
7. Consider the medical necessity of test results.

Recommended Resources

Appropriate Use of Drug Testing in Clinical Addiction Medicine

- http://1viuw040k2mx3a7mwz1lwva5.wpengengine.netdna-cdn.com/wp-content/uploads/2017/11/appropriate_use_of_drug_testing_in_clinical-1-7.pdf

Urine Drug Testing in Clinical Practice

- <http://1viuw040k2mx3a7mwz1lwva5.wpengengine.netdna-cdn.com/wp-content/uploads/2017/07/2012-GourlayHeit-UDT-monograph.pdf>

The ASAM Appropriate Use of Drug Testing in Clinical Addiction Medicine

- Webinar Series - <https://elearning.asam.org/drugtestingwebinars>

³⁴ “Smarter Drug Testing” strategies as published in a Consensus Statement: Appropriate Use of Drug Testing in Clinical Addiction Medicine by an expert panel selected by ASAM, 2017.

OTHER CONSIDERATIONS

In addition to the service delivery and clinical considerations described in the previous sections, there are several overarching components to consider when providing office-based MAT. Practices are strongly encouraged to integrate these components in all aspects of service delivery in an effort to offer a successful model of care.

V. A. Confidentiality/42 CFR, Part 2

A. Confidentiality/42 CFR Part 2³⁵

42 CFR Part 2 (“Part 2”) are the federal SUD confidentiality regulations issued by the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA) to protect the confidentiality of SUD treatment records. The purpose of Part 2 is to protect patients from unintended bias associated with SUDs. SAMHSA amended the Part 2 regulations effective March 21, 2017 in an effort to support integrated behavioral health models of care. SUD treatment providers must handle treatment information about SUD patients with heightened confidentiality. The Part 2 non-disclosure requirements are more strict than the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and some of these same confidentiality requirements have been adopted into New Hampshire law. In most cases, to share treatment information with a third-party (e.g. pharmacist, family, social service agencies), a SUD provider must obtain written consent from the SUD patient.

The following provides a brief summary of the Part 2 confidentiality requirements and the key issues MAT providers must think about if they need to disclose patient SUD treatment information.

Please refer to the Substance Use Disorder Privacy Workbook: 42 CFR Part 2 developed by the Health Law and Policy Programs at UNH School of Law, Institute for Health Policy and Practice, and the NH Citizens Health Initiative: (https://chhs.unh.edu/sites/chhs.unh.edu/files/departments/institute_for_health_policy_and_practice/pdfs/sud_privacy_part_2_idn_workbook_unh_1017.pdf).

The heightened confidentiality obligations in Part 2 apply to the records created by a Part 2 program, or records received from a Part 2 program.

A Part 2 program* can be any of the following:

- A medical personnel or staff member who:
 - Holds themselves out as providing and does provide SUD treatment, diagnosis, or referral for treatment; or
 - Whose primary function is SUD treatment, diagnosis, or referral for treatment and is identified as such, and practices in a general medical facility; or
 - Is a NH Licensed Alcohol and Drug Counselor (LADC) providing SUD services; or
- An entity (other than a general medical facility) that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment; or
- A unit within a general medical facility that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment.

MAT providers are not automatically defined as a Part 2 program unless the providers “holds themselves out as providing” or identifies SUD treatment, diagnosis, or referral to treatment as their primary function.

*A Part 2 program is one that meets the definition and is federally assisted, which means it receives federal financial assistance of any kind, is authorized by the federal government or is tax exempt through the IRS.

Instances Not Requiring Written Consent:

- a patient is in imminent danger of harming himself/herself or others
- crimes on agency/program property
- child abuse or neglect abuse, neglect, exploitation, or self neglect of incapacitated adults
- medical emergency
- research
- audit by CMS
- court order
- internal communication
- de-identified information
- qualified service organization agreement

³⁵ Technical Assistance regarding 42 CFR Part 2 provided by Lucy Hodder, Director of Health Law and Policy Programs, UNH School of Law/Institute for Health Policy and Practice.

Part 2 requires the following five components, as applicable.

1. **Patient Records Security Policies** – Specific policies and procedures are required to protect patient information. Refer to page 25 of the SUD privacy workbook for more details.
2. **Notice of Privacy Rights** – Patients must receive a notice of the federal confidentiality requirements in writing immediately. Refer to page 26 and form A of the SUD privacy workbook for more details.
3. **Patient Consent Forms** – Refer to pages 27-29 and form B (pages 43-48) of the SUD privacy workbook for detailed consent instructions. Please refer to Appendix VI for a sample consent without instructions.

The consent form must include the following elements:

1. Name of Patient
2. Name of Provider
3. Type and Amount of Information to be Disclosed
4. “To Whom” the Disclosure is to be Made: Including the name of the entity if a treating provider, or the name of the individual if a non-treating provider.
5. Purpose of Disclosure
6. Date When Consent is Signed
7. Signature of Patient
8. Signature of Parent or Guardian (if applicable)
9. Signature of Individual Authorized to Sign in Lieu of the Patient (if applicable)
10. Language Regarding the Right to Revoke the Consent (“This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it.”)
11. Date Consent Expires

4. **Non Re-Disclosure Notices** – Any information disclosed by a Part 2 program pursuant to a written consent must be accompanied by the following disclosure language. Refer to page 30 and form C of the SUD privacy workbook.

“This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosure of this information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at Sections 2.12(c)(5) and 2.65.”

5. **Qualified Service Organization (QSO) Agreements** – Part 2 providers can share SUD information with certain third parties who provide specific services to the organization pursuant to a QSO Agreement. Refer to pages 22-24 and form D of the SUD privacy workbook for more details on what type of organization can be a QSO.

V.

B. Communications

B. Communications

Effective and timely communication among the prescriber and other providers and the patient is critical. The communication must be well documented, and confidential, consistent with SAMHSA confidentiality regulation *Title 42, Part 2 of the Code of Federal Regulations* (42 CFR Part 2). It is recommended that policies and practices be established for each level of communication to ensure that care is well coordinated and aligned with patient needs.

The chart below highlights several communication factors to consider.

Patient Communication	Intra-office Communication	External Communication
- Establish and review program guidelines, and expectations and medication plan - Discuss frequency of visits with prescriber and other treatment expectations - Review how to communicate with prescriber and the office outside of scheduled visits	- Identify care coordinator and the responsibilities of the position (e.g. nurse, addiction clinician, other office staff) - Document care plan in electronic record - Document office visits and drug test results - Establish routine meeting times for MAT team to discuss patient progress, challenges and administrative issues	- Establish protocol for written and oral communication between prescriber and primary care provider and clinician (if not located in practice) and incorporate into electronic medical record - Determine responsibility for monitoring adherence to program, need for change in treatment plan, etc. - Collaborate with other health care providers who are managing concurrent health problems that are complicated by the patient's MAT (e.g., pregnancy, surgical procedures requiring pain control)

V.

C. Stigma

C. Stigma

Addiction is highly stigmatized on many fronts. Similarly, MAT can be a controversial issue. Some professionals in the field, as well as individuals in recovery, do not support the use of medication and consider methadone, buprenorphine and naltrexone as “replacing one drug for another”. It is important for all staff to recognize that:

1. addiction is a chronic, relapsing disease;
2. on-going support will be needed to help a person reach their recovery goals;
3. treatment may require the use of medications, low- or high-intensity SUD treatment and/or recovery support services;
4. the use of medication in conjunction with treatment and recovery supports is reinforced by literature in reducing the risk of relapse, overdose and death and is superior in efficacy to not being on a prescription; and
5. people are at a higher risk of addiction because of their genes, temperament, or personal situation.³⁶

People who have an addiction are often extremely sensitive to the stigma attached to this disease and may also self-stigmatize due to feelings of guilt and shame. This stigma may be reinforced by past treatment they have received from medical providers, thus making them cautious about trust and open communication. Providers need to recognize this reluctance and train all staff to avoid stigmatizing language and behavior. Using person first language, e.g. person with a substance use disorder or opioid use disorder, and appropriate medical terminology, e.g. “unexpected” results related to drug testing rather than “dirty” results, is important. Stronger than the language that you use is the attitude that you convey through your interactions. It is necessary to:

- Be recovery-oriented rather than disease-oriented.
- Treat each patient with respect.
- Recognize and celebrate all levels of progress.

If patients express concerns about stigma, reassure them that they have a disease in the same way that others may have diabetes, hypertension or other chronic conditions. In each of these cases, a treatment plan is developed which may include the use of medications. Commend efforts to seek help and participate in the necessary treatment to reach recovery goals.

Remember: You are not just providing medical treatment for an OUD. You are also dispensing hope and a belief that recovery is possible for this particular patient.

³⁶ Substance Abuse and Mental Health Services Administration. Medication-Assisted Treatment for Opioid Addiction: Facts for Families and Friends.

APPENDICES

Appendix I: MAT Quality Planning Tool

Appendix II: Objective Opiate Withdrawal Scale (OOWS)

Appendix III: Subjective Opiate Withdrawal Scale (SOWS)

Appendix IV: Clinical Opiate Withdrawal Scale (COWS)

Appendix V: Sample Treatment Agreement

Appendix VI: Consent Form

APPENDIX I: MAT Quality Planning Tool

To download a fillable form, visit:

http://1viuw040k2mx3a7mwz1lwva5.wpengine.netdna-cdn.com/wp-content/uploads/2018/04/FINAL_MAT_Quality_Planning_Tool_3-30-18.pdf

I. PROGRAM DEVELOPMENT								
STAFFING								
Best Practice Recommendations	Measures	Implementation Status					Comments	Page #
		Not Developed	In Development	Developed	Developed & Regularly Implementing	Not Applicable		
1. Establish a core team to deliver MAT (to include at least one prescriber, behavioral health clinician, care coordinator, administrative support)	# of Prescribers	☐	☐	☐	☐	☐		17 - 21
	# of Non-Prescribing Healthcare Providers	☐	☐	☐	☐	☐		
	# of BH Clinicians	☐	☐	☐	☐	☐		
	# of Care Coordinators	☐	☐	☐	☐	☐		
2. Develop clearly defined, written roles and responsibilities for each member of the MAT team	Written Protocol (e.g. workflow, job descriptions)	☐	☐	☐	☐	☐		17 - 21
3. Ensure prescribers become waived to prescribe buprenorphine	Total # of Waivered Prescribers	☐	☐	☐	☐	☐		19
	# of MDs/Dos	☐	☐	☐	☐	☐		
	# of NPs	☐	☐	☐	☐	☐		
	# of PAs	☐	☐	☐	☐	☐		
4. Provide training to each prescriber on FDA approved opioid and alcohol use disorder medications (e.g. pharmacotherapy, contraindications)	# and Types of Trainings	☐	☐	☐	☐	☐		23 - 25
	% of Providers in Attendance by Provider Type	☐	☐	☐	☐	☐		
5. Provide initial training and resources related to substance use disorders and MAT to all staff, including administrative staff	# and Types of Trainings	☐	☐	☐	☐	☐		23 - 25
	% of Staff in Attendance	☐	☐	☐	☐	☐		

APPENDIX I: MAT Quality Planning Tool

I. PROGRAM DEVELOPMENT								
POLICY AND PROCEDURES								
Best Practice Recommendations	Measures	Implementation Status					Comments	Page #
		Not Developed	In Development	Developed	Developed & Regularly Implementing	Not Applicable		
6. Develop procedures to evaluate patients for eligibility onto MAT (e.g. screening, assessment, physical exam)	Documentation of Procedures	☐	☐	☐	☐	☐		30 - 34
	Assessment Instrument Identified							
	Screening Tool Identified							
7. Establish a process to routinely review and share PDMP data with prescriber (e.g. frequency, person responsible for checking PDMP)	Written Procedure	☐	☐	☐	☐	☐		32 - 33
	Documentation of Checklist of Items to Review in PDMP							
	Role Identified for Checking and Sharing Data							
8. Develop drug testing policies and procedures (e.g. frequency, testing type, responding to expected and unexpected test results, method of collection)	Documentation of Drug Testing Policy	☐	☐	☐	☐	☐		48 & 49
9. Develop written induction procedures	Documentation of Induction Procedures	☐	☐	☐	☐	☐		40 & 41
10. Establish billing policies and procedures	Documentation of Billing Policy	☐	☐	☐	☐	☐		27 & 28
11. Establish policies and procedures specific to communicating with team, external providers, and patients (e.g. confidentiality, documentation)	Documentation of Communication Policies	☐	☐	☐	☐	☐		55
12. Develop diversion control policies and procedures	Documentation of Diversion Policy	☐	☐	☐	☐	☐		24
13. Create patient consent form that is compliant with 42 C.F.R., part 2 requirements	Consent Form	☐	☐	☐	☐	☐		52 & 53
14. Create patient treatment agreement	Treatment Agreement	☐	☐	☐	☐	☐		37
15. Establish continued patient practice participation guidelines (including for non-adherent patients, voluntary discharge, treatment completion)	Documentation of Continued Patient Practice Participation Guidelines	☐	☐	☐	☐	☐		36 - 38

APPENDIX I: MAT Quality Planning Tool

I. PROGRAM DEVELOPMENT								
OTHER INFRASTRUCTURE NEEDS								
Best Practice Recommendations	Measures	Implementation Status					Comments	Page #
		Not Developed	In Development	Developed	Developed & Regularly Implementing	Not Applicable		
16. Make modifications to electronic health record to collect, track, and measure patient outcomes	Description of New Fields Added Successful retrieval of data (e.g. data reports)	☐	☐	☐	☐	☐		program specific
17. Establish agreements with external behavioral health providers	Written Agreement(s)	☐	☐	☐	☐	☐		43 - 46
18. Establish agreements with external peer recovery support service providers	Written Agreement(s)	☐	☐	☐	☐	☐		43 - 46
19. Establish collaborative relationships with ancillary service providers (e.g. transportation, childcare)	Written Agreement(s)	☐	☐	☐	☐	☐		43 - 46
20. Identify process for determining treatment and recovery support and social service resources	Resources Identified	☐	☐	☐	☐	☐		43 - 46
21. Determine mechanism for referring patients to higher levels of care and other supports, as needed	Role Identified for Managing Referrals	☐	☐	☐	☐	☐		43 - 46

APPENDIX I: MAT Quality Planning Tool

II. PROGRAM IMPLEMENTATION

STAFFING

Best Practice Recommendations	Measures	Implementation Status					Comments	Page #
		Not Developed	In Development	Developed	Developed & Regularly Implementing	Not Applicable		
22. Establish team meetings at least once a week	Regular Meeting Time	☐	☐	☐	☐	☐		55
	# of Meetings Held	☐	☐	☐	☐	☐		

II. PROGRAM IMPLEMENTATION

TRAINING

Best Practice Recommendations	Measures	Implementation Status					Comments	Page #
		No Staff Trained/ Informed	Some Staff Trained/ Informed	Most Staff Trained/ Informed	All Staff Trained/ Informed	Not Applicable		
23. Provide ongoing training and resources related to substance use disorders and MAT to all staff, including administrative staff	# and Types of Trainings	☐	☐	☐	☐	☐		23 - 25
	% of Staff in Attendance	☐	☐	☐	☐	☐		
24. Assess patients using ASAM dimensions	Assessment Instruments Used	☐	☐	☐	☐	☐		30 & 31
25. Screen patients routinely for co-occurring disorders	Screening Tool(s) Used	☐	☐	☐	☐	☐		36 - 38
	Documentation of Screening Results	☐	☐	☐	☐	☐		
26. Conduct physical exam, at a minimum identifying for Intoxication, impairment or withdrawal	Documentation of Physical Exam	☐	☐	☐	☐	☐		31
	Documentation of Withdrawal Risk Assessment(s)	☐	☐	☐	☐	☐		
27. Draw labs to include testing for infectious disease, pregnancy, liver function and blood counts	Documentation of Lab Results	☐	☐	☐	☐	☐		32
28. Conduct drug tests	Documentation of Test Results	☐	☐	☐	☐	☐		48 & 49
29. Determine diagnosis of opioid use disorder	Documentation of Diagnosis	☐	☐	☐	☐	☐		30 - 34
30. Query PDMP	Documentation of PDMP Review (e.g. field in EHR, administrative note)	☐	☐	☐	☐	☐		32 & 33
31. Inform patients about MAT medications available and recommended as most appropriate	Documentation of Discussion	☐	☐	☐	☐	☐		36

APPENDIX I: MAT Quality Planning Tool

II. PROGRAM IMPLEMENTATION

TREATMENT DELIVERY

Best Practice Recommendations	Measures	Implementation Status					Comments	Page #
		None of the Time	Some of the Time	Most of the Time	All of the Time	Not Applicable		
32. Develop written individualized treatment plan with each patient	Documentation of Treatment Plan	☐	☐	☐	☐	☐		36 - 38
33. Obtain signed treatment agreement from all patients	Signed Agreement	☐	☐	☐	☐	☐		37
34. Obtain signed 42 CFR Part 2 compliant consent forms from all patients to allow for communication with external providers	Signed Consent Forms	☐	☐	☐	☐	☐		52 & 53
35. Start patient on medication assisted treatment (induct as needed)	Documentation of Induction	☐	☐	☐	☐	☐		40 & 41
36. Schedule patients with routine prescriber visits based on treatment progress/recovery status and other factors	Progress Notes	☐	☐	☐	☐	☐		36 - 38
37. Query the PDMP each time a prescription is written	Documentation of PDMP Check	☐	☐	☐	☐	☐		32 & 33
38. Conduct drug tests	Documentation of Test Results	☐	☐	☐	☐	☐		48 & 49
39. Conduct random drug tests	Documentation of Test Results	☐	☐	☐	☐	☐		48 & 49
40. Conduct random pill/film counts	Documentation of Random Check	☐	☐	☐	☐	☐		36 - 38
41. Review treatment plan at every visit for each patient	Documentation of Review	☐	☐	☐	☐	☐		36 - 38
42. Update treatment plan as needed for each patient	Documentation of Updated Treatment Plan	☐	☐	☐	☐	☐		36 - 38
43. Actively refer patients to SUD treatment services as needed	Documentation of Treatment Services #/% of Patients Referred to Treatment Services #/% of Referrals By Level of Care	☐	☐	☐	☐	☐		43 - 46
44. Actively refer patient to peer recovery support services as needed	Documentation of Recovery Support Services #/% of Patients Referred to Recovery Support Services	☐	☐	☐	☐	☐		43 - 46

APPENDIX I: MAT Quality Planning Tool

II. PROGRAM IMPLEMENTATION								
TREATMENT DELIVERY (CONTINUED)								
Best Practice Recommendations	Measures	Implementation Status					Comments	Page #
		None of the Time	Some of the Time	Most of the Time	All of the Time	Not Applicable		
45. Provide care coordination to patients for other needs (e.g. mental health provider, primary care services)	Documentation of Care Coordination	☐	☐	☐	☐	☐		20 & 21
	#/% of Patients Referred to Other Services							
	#/% of Referrals By Service Type							
46. Communicate regularly with external provider(s)	Documentation of Communication with External Provider(s)	☐	☐	☐	☐	☐		55
47. Provide routine support to patients outside of office visits (e.g. phone check-ins)	Documentation of Communication	☐	☐	☐	☐	☐		36 - 38

APPENDIX II: Objective Opiate Withdrawal Scale (OOWS)

Observe the patient during a 5 minute observation period then indicate a score for each of the opioid withdrawal signs listed below (items 1-13).
Add the scores for each item to obtain the total score

DATE							
TIME							
1	Yawning 0 = no yawns 1 = ≥ 1 yawn						
2	Rhinorrhoea 0 = < 3 sniffs 1 = ≥ 3 sniffs						
3	Piloerection (observe arm) 0 = absent 1 = present						
4	Perspiration 0 = absent 1 = present						
5	Lacrimation 0 = absent 1 = present						
6	Tremor (hands) 0 = absent 1 = present						
7	Mydriasis 0 = absent 1 = ≥ 3 mm						
8	Hot and cold flushes 0 = absent 1 = shivering / huddling for warmth						
9	Restlessness 0 = absent 1 = frequent shifts of position						
10	Vomiting 0 = absent 1 = present						
11	Muscle twitches 0 = absent 1 = present						
12	Abdominal cramps 0 = absent 1 = Holding stomach						
13	Anxiety 0 = absent 1 = mild - severe						
	TOTAL SCORE						

Source: Handelsman et. al, 1987

APPENDIX III: Subjective Opiate Withdrawal Scale (SOWS)

Please indicate if you are having any of the following withdrawal symptoms by rating its severity.						How long AFTER your last dose did you begin to feel this symptom?	
	Symptom	Not at all	A Little	Moderate	Quite a bit	Extremely	Onset (hrs)
1	Anxious/Nervous	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
2	Body Aches & Pains	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
3	Constipation	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
4	Diarrhea	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
5	Drug Hunger/Craving	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
6	Goosebumps	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
7	Hot/Cold Flashes	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
8	Muscle Twitching	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
9	Nausea	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
10	Restlessness	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
11	Runny Nose	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
12	Sedation/Sleepiness	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
13	Shaking	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
14	Stomach Cramps	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
15	Sweating	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
16	Teary Eyes	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
17	Vomiting	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
18	Yawning	0	1	2	3	4	☐ 3-4 ☐ 8 ☐ 16 ☐ 24
Total							

Mild withdrawal is considered to be a score of 1-10.

Moderate withdrawal is considered to be a score of 11-20.

Severe withdrawal is considered to be 21-30.

Adapted from: Handelsman, L., Cochrane, K.J., Aronson, M.J. et al. (1987) Two New Rating Scales for Opiate Withdrawal, American Journal of Alcohol Abuse, 13, 293-308

APPENDIX IV: Clinical Opiate Withdrawal Scale (COWS)

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Clinical Opiate Withdrawal Scale (COWS)

Flowsheet for measuring symptoms over a period of time during buprenorphine induction.

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example: If heart rate is increased because the patient was jogging just prior to assessment, the increased pulse rate would not add to the score.

Patient Name: _____		Date: _____			
Buprenorphine Induction: _____					
Enter scores at time zero, 30 minutes after first dose, 2 hours after first dose, etc.		Times of Observation:			
Resting Pulse Rate: Record Beats per Minute					
Measured after patient is sitting or lying for one minute					
0 = pulse rate 80 or below					
1 = pulse rate 81-100					
2 = pulse rate 101-120					
3 = pulse rate greater than 120					
Sweating: Over Past 1/2 Hour not Accounted for by Room Temperature or Patient Activity					
0 = no report of chills or flushing					
1 = subjective report of chills or flushing					
2 = flushed or observable moistness on face					
3 = beads of sweat on brow or face					
4 = sweat streaming off face					
Restlessness Observation During Assessment					
0 = able to sit still					
1 = reports difficulty sitting still, but is able to do so					
3 = frequent shifting or extraneous movements of legs/arms					
5 = Unable to sit still for more than a few seconds					
Pupil Size					
0 = pupils pinned or normal size for room light					
1 = pupils possibly larger than normal for room light					
2 = pupils moderately dilated					
3 = pupils so dilated that only the rim of the iris is visible					
Bone or Joint Aches if Patient was Having Pain Previously, only the Additional Component Attributed to Opiate Withdrawal is Scored					
0 = not present					
1 = mild diffuse discomfort					
2 = patient reports severe diffuse aching of joints/muscles					
4 = patient is rubbing joints or muscles and is unable to sit still because of discomfort					
Runny Nose or Tearing Not Accounted for by Cold Symptoms or Allergies					
0 = not present					
1 = nasal stuffiness or unusually moist eyes					
2 = nose running or tearing					
4 = nose constantly running or tears streaming down cheeks					
GI Upset: Over Last 1/2 Hour					
0 = no GI symptoms					
1 = stomach cramps					
2 = nausea or loose stool					
3 = vomiting or diarrhea					
5 = multiple episodes of diarrhea or vomiting					
Tremor Observation of Outstretched Hands					
0 = no tremor					
1 = tremor can be felt, but not observed					
2 = slight tremor observable					
4 = gross tremor or muscle twitching					
Yawning Observation During Assessment					
0 = no yawning					
1 = yawning once or twice during assessment					
2 = yawning three or more times during assessment					
4 = yawning several times/minute					
Anxiety or Irritability					
0 = none					
1 = patient reports increasing irritability or anxiousness					
2 = patient obviously irritable/anxious					
4 = patient so irritable or anxious that participation in the assessment is difficult					
Gooseflesh Skin					
0 = skin is smooth					
3 = piloerection of skin can be felt or hairs standing up on arms					
5 = prominent piloerection					
Score: 5-12 = Mild		Total score			
13-24 = Moderate		Observer's initials			
25-36 = Moderately Severe					
More than 36 = Severe Withdrawal					



The National Alliance of Advocates for Buprenorphine Treatment
PO Box 333 • Farmington, CT 06034 • MakeContact@naabt.org
naabt.org

*Source: Wesson et al. 1999.

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APPENDIX IV: Clinical Opiate Withdrawal Scale (COWS)



naabt.org

The National Alliance of Advocates for Buprenorphine Treatment
Precipitated Withdrawal. What it is. How to avoid it.

What Is Precipitated Withdrawal?

It is a **rapid and intense onset** of withdrawal symptoms initiated by a medication. In the case of Buprenorphine, because it has a higher binding strength at the opioid receptor, it competes for the receptor, “kicks off” and replaces existing opioids. If a significant amount of opioids are expelled from the receptors and replaced, the opioid physically dependent patient will feel the rapid loss of the opioid effect, initiating withdrawal symptoms.

More precisely, precipitated withdrawal can occur when an antagonist (or partial agonist, such as Buprenorphine) is administered to a patient who is physically dependent on full agonist opioids. Due to the high *affinity* but low *intrinsic activity*



Full Agonist Opioid.
Perfect receptor fit. Maximum
intrinsic activity (opiate effect).



Partial Agonist Opioid
(Buprenorphine). Imperfect Fit.
Less intrinsic activity (opiate effect).

insignificant and has virtually no effect. (Except in rare cases of an allergic reaction or naloxone hypersensitivity.)

of Buprenorphine at the μ -receptor, the partial agonist displaces full agonist opioids from the μ -receptors, but activates the receptor to a *lesser* degree than full agonists which results in a net *decrease* in agonist effect, thereby precipitating withdrawal.¹

A common misconception is that the naloxone in the buprenorphine/naloxone combination medication initiates precipitated withdrawal. Naloxone may only initiate withdrawal if *injected* into a person physically dependent on opioids. Taken sublingually, as directed, naloxone is clinically

Avoiding Precipitated Withdrawal

Patient education and developing realistic expectations are essential before beginning treatment.

To **avoid** precipitated withdrawal, physically dependent patients must no longer be experiencing the agonist effects of an opioid. One way to gauge this is to observe objective symptoms of withdrawal sufficient to score a minimum of 5 to 6 on the COWS (Clinical Opioid Withdrawal Scale). Scores of >10 are preferable. Due to patient individuality, required abstinence times may vary considerably from patient to patient. Only use the time since last use as an estimate to anticipate the onset of withdrawal symptoms.⁴

The **induction begins** by assessing last use of all opioids, short and long acting, objective and subjective symptoms and a COWS score calculation. If not in sufficient withdrawal (mild to moderate: COWS of 5 to 24), it is in the patient's best interest to wait. Long-acting opioids will require a longer period of abstinence, than short-acting opioids.

Short-acting Opioids

(Heroin, Crushed OxyContin®, Percocet®, Vicodin®, Oxycodone and others)

Prior to induction, patients must abstain from all short-acting opioids for 12 to 24 hours **and/or** have objective withdrawal symptoms sufficient to produce a score of 5 to 24 on the COWS.¹

Long-acting Opioids

OxyContin® (Taken Orally)

Discontinue use for at least 24 hours prior to induction. A minimal score of at least 5 on the COWS is recommended, although some physicians prefer scores of 15 or higher.⁵

Methadone

It is recommended that patients transitioning from methadone to Buprenorphine slowly taper to 30 mg./day of methadone, for at least one week. Last dose must be no less than 36 hours prior to induction, and may be 96 hours or more. A minimal score of at least 5 on the COWS is recommended, although some physicians prefer scores of 15 or higher.⁵

Patients transferring from methadone or another long-acting opioid to Buprenorphine may experience discomfort for several days and dysphoria for up to 2 weeks.³

The **goal of induction** is to safely suppress opioid withdrawal as rapidly as possible with adequate doses of Buprenorphine. Failure to do so may cause patients to use opioids or other medications to alleviate opioid withdrawal symptoms or may lead to early treatment dropout.³ To achieve this, some physicians have found they may need to dose as high as 32 mgs. the first day with some methadone to Buprenorphine transfers.⁵

¹Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40*. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004. http://naabt.org/links/TIP_40_PDF.pdf

²FDA. Full Prescribing Information on Subutex® (buprenorphine)/Suboxone® (buprenorphine/naloxone). www.fda.gov/cder/foi/label/2002/20732bl.pdf

³Dosing Guide Maintenance therapy for Opioid Dependence. Suboxone®/Subutex® www.suboxone.com/pdfs/DosingGuides.pdf

⁴Practical Considerations for the use of Buprenorphine. Hendrie E. Jones, Ph.D., Johns Hopkins University School of Medicine, Baltimore, MD

⁵Physician Clinical Support System: www.pcssmentor.org/TransferFromMethadoneToBuprenorphine, Paul P. Casadonte, MD, PCSS guidance paper. 8/9/2006 http://www.pcssmentor.org/pdfs/documents/PCSS_MethadoneBuprenorphineTransfer.pdf

APPENDIX V: Sample Treatment Agreement

Sample Treatment Agreement

Treatment agreements are often employed in the treatment of addiction to make explicit the expectations regarding patient cooperation and involvement in the treatment process. Below is a sample addiction treatment agreement that may be a useful tool in working with patients in an office-based setting.

As a patient receiving opioid use disorder treatment with [medication name], I freely and voluntarily agree to accept this treatment agreement, as follows:

- ☐ I agree to keep, and be on time to, all my scheduled appointments with the prescriber and other providers.
- ☐ I agree to conduct myself in a courteous manner in the office.
- ☐ I agree not to arrive at the office intoxicated or under the influence of substances. If I do, the provider will not prescribe any medication until my next scheduled appointment.
- ☐ I agree not to sell, share, or give any of my medication to another individual. I understand that such mishandling of my medication is a serious violation of this agreement and would result in my treatment being terminated without recourse for appeal.
- ☐ I agree not to deal, steal, or conduct any other illegal or disruptive activities in the office.
- ☐ I agree that my medication (or prescriptions) can be given to me only at my regular office visits. Any missed office visits will result in my not being able to get medication until the next scheduled visit.
- ☐ I agree that the medication I receive is my responsibility and that I will keep it in a safe, secure place. I agree that lost medication will not be replaced regardless of the reasons for such loss.
- ☐ I agree not to obtain medications from any prescribers, pharmacies, or other sources without informing my treating prescriber. I understand that mixing buprenorphine with other medications, especially benzodiazepines such as valium and other drugs, can be dangerous. I also understand that a number of deaths have been reported among individuals mixing buprenorphine with benzodiazepines.
- ☐ I agree to take my medication as instructed and not to alter the way I take my medication without first consulting my prescriber.
- ☐ I understand that medication alone is not sufficient treatment for my disease, and I agree to participate in psychosocial treatment and recovery support services to support my recovery.

Patient Name: _____

Patient Signature: _____ Date: _____

APPENDIX VI: Consent Form

Draft 2017- For Reference Purposes Only

For Use and Review by IDNs Participating in UNH Privacy Bootcamp

SAMHSA has promised but has not yet published sub-regulatory guidance or draft Forms consistent with the 42 CFR Part 2 regulations published January 2017. Any Form should be reviewed with and revised by your provider's leadership/compliance team and counsel as necessary.



**School of Law / Institute for
Health Policy & Practice**
Health Law & Policy

SUBSTANCE USE DISORDER SERVICES:

AUTHORIZATION AND CONSENT TO DISCLOSE PROTECTED HEALTH INFORMATION

DRAFT Form B

Name: _____ Date of Birth: _____

Medical Record # (if known): _____

I understand my care providers at **[Name of SUD/Part 2 ENTITY making disclosure]** *[If part of hospital system, include affiliated entities if necessary, i.e., "I am a patient of Mount Ida Primary care, Mount Ida Capital partners and affiliated entities"]* will be providing and helping to coordinate aspects of my care and treatment and will therefore need to share certain private health information about my referral, diagnosis and/or treatment for substance use disorder [and mental health] with my treatment team, with other treating providers, with other individuals or entities involved in my care and/or recovery, with entities responsible for payment and with others listed below as authorized by me or by law.

I authorize [my Part 2 Program treatment team] to access, use, disclose and communicate both verbally and in writing, private substance use disorder and mental health information *[which is maintained as part of my integrated electronic health record]*, including:
[Check all the apply]

- ☐ My health care record
- ☐ Intake, progress and discharge reports and notes
- ☐ Evaluations and assessments by my providers
- ☐ Test, lab and radiology results
- ☐ Referrals for treatment
- ☐ Medications
- ☐ Case management and treatment plans (including addendums)
- ☐ Other:(specify) _____
- ☐ Other:(specify) _____

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I understand disclosures and re-disclosures both verbally and in writing may be made to and from my past, current and/or future treating providers for the purpose of *my ongoing treatment and recovery and helping me manage my care*, including but not limited to:
[Check all that apply]

- ☐ My Care Coordinator(s) at: _____
- ☐ [IDN Treating Provider Entity 1]
- ☐ [IDN Treating Provider Entity 2]
- ☐ [IDN Treatment Provider Entity 3]
- ☐ [IDN Treatment Provider Entity 4]
- ☐ [IDN Treatment Provider Entity 5]
- ☐ [IDN Treatment Provider Entity 6]
- ☐ [IDN Treatment Provider Entity 7]
- ☐ Other: (specify) _____
- ☐ Other:(specify) _____

I also authorize [my treatment team] to access, use, disclose and communicate both verbally and in writing the following private substance use disorder and mental health information [which is maintained as part of my integrated electronic health record], including:
[check all that apply]

- ☐ My medical events, care management plan and medication list
- ☐ My attendance at my recovery program
- ☐ Information confirming my compliance with my care and recovery plan
- ☐ Other: _____
- ☐ Other: _____

To and from the following individuals involved in my well-being and recovery:

- ☐ [My treating providers through the [Health Information Exchange]]: (Name/Title of Supervisor of HIE) _____
- ☐ Agency: (Title/Name of Individual/Tel #) _____
- ☐ Agency: (Title/Name of Individual/Tel #) _____
- ☐ Agency: (Title/Name of Individual/Tel #) _____
- ☐ Agency: (Title/Name of Individual/Tel #) _____
- ☐ Other: _____
- ☐ Other: _____

For the purpose of: [check all that apply]

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**School of Law / Institute for
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Health Law & Policy

- ☐ Monitoring and supporting my ongoing recovery
- ☐ Assessing/evaluating my readiness/ability to participate in housing/employment/vocational training
- ☐ Confirming compliance with court ordered treatment, probation or parole
- ☐ For the purpose of the care and treatment of my children
- ☐ Other: _____
- ☐ Other: _____

I authorize [my treatment team] to use, disclose and communicate both verbally and in writing any and all information about my care and treatment to and from my health insurance company or other entity responsible for my medical bills for the purpose of eligibility and payment. *[Either insert the name of the payer or refer to your program's policy regarding notification of payment]:*

Authorization to Discuss Health Status with Family, Friends or Advocates Members

If I am not present or available, I authorize [ENTITY] affiliated treating providers and staff to discuss my relevant health information, including my substance use disorder [and mental health] treatment, with the family members, friends and/or advocates named below.

Authorized individuals (please provide full names):

Name: _____	Tel # _____
Name: _____	Tel# _____
Name: _____	Tel # _____
Name: _____	Tel# _____
Name: _____	Tel # _____
Name: _____	Tel# _____

Acknowledgement of Rights

I understand that my substance use disorder treatment records are protected under the federal regulations governing Confidentiality and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the

APPENDIX VI: Consent Form

Draft 2017- For Reference Purposes Only

For Use and Review by IDNs Participating in UNH Privacy Bootcamp

SAMHSA has promised but has not yet published sub-regulatory guidance or draft Forms consistent with the 42 CFR Part 2 regulations published January 2017. Any Form should be reviewed with and revised by your provider's leadership/compliance team and counsel as necessary.



Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. pts 160 & 164, and cannot be disclosed without my written consent unless otherwise provided for by the regulations. I understand that if my treating providers disclose my substance use disorder treatment records pursuant to this consent, the recipient will be provided a notice of non-disclosure.

I also understand that I may revoke this consent, orally or in writing by contacting [APPROPRIATE ENTITY INFORMATION MANAGEMENT OFFICE _____] at [PHONE NUMBER _____] at any time except to the extent that action has been taken in reliance on it. We are unable to take back any disclosures we have already made with your consent and we are required to retain as records of the care we provide to you.

If not already revoked, this consent will expire on _____ [Example: One year/specified date/upon my death.]

Upon request, I can inspect or obtain a copy of the information I am authorizing to be released.

[I understand that I may be denied services if I refuse to consent to a disclosure for purposes of my treatment [or payment]. I will not be denied services if I refuse to consent to a disclosure for other purposes.]¹

If I have any questions about disclosure of my private health information, I can contact _____ at [PHONE NUMBER].

I understand I can ask for a copy of this authorization and consent form.

Signature of Patient or legal representative or guardian

Date and Time

Authority/Relationship of representative to patient
(Attach copy of documentation of authority)

¹ This provision is not necessary and may be different depending upon the type of provider offering services.

