Medication Assisted Treatment

An evidence-based pathway to recovery in West Virginia.

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Medication Assisted Treatment (MAT)

Medication Assisted Treatment (MAT) combines psychosocial therapy (at a minimum, psychosocial needs assessment, supportive counseling, links to existing family supports, and referrals to community services)[i] with medication, typically in an out-patient setting. The purpose of MAT:

- Prevent relapse and overdose death
- Prevent euphoric effects of opioids
- Prevent cravings
- Decrease withdrawal symptoms
- Retain people in treatment
- Foster recovery: improve people's health and social function, in their families, communities, workplaces, and state.[ii, iii]

MAT AS STANDARD OF CARE:

According to entities including the American Society of Addiction Medicine (ASAM) and the Pew Charitable Trusts, when it comes to opioid use disorders, and treatment, recovery, and withdrawal management that involves medication, "The strongest evidence supports use of MAT."[iv]

> "The research is unassailable: Staying in recovery and avoiding relapse for at least a year is more than twice as likely with medications as without them. Medications also lower the risk of a fatal overdose. …[Individuals in an] abstinence-based program are at a high risk of fatally overdosing if they relapse. Within days, the abstinent body's tolerance for opioids plummets and even a small dose of the drugs can shut down the lungs….And yet as the country's opioid epidemic worsens — every day, more than 70 Americans die from overdoses, and the numbers are climbing — only about a fifth of the people who would benefit from the medications are getting them, according to a new study by the Johns Hopkins Bloomberg School of Public Health." [v]

MEDICATIONS AND THERAPY FOR MAT:

There are currently three types of FDA-approved medications that can be used as part of treatment protocol for opioid use disorder: *methadone*, *buprenorphine* (e.g., Suboxone and Subutex), and *naltrexone* (e.g., Vivitrol), and there are three medications approved for alcohol use disorder: *Disulfiram*; *naltrexone*; and *Acamprosate*.[vi] Naltrexone is not appropriate for use in detoxification, but it can be used to treat opioid addiction in certain individuals who are abstinent from opioids. The accompanying psychosocial therapy includes, at a minimum, psychosocial needs assessment, supportive counseling, links to existing family supports, and referrals to community services, according to the American Society of Addiction Medicine.[vii] Psychosocial interventions can be delivered in different treatment modalities (e.g., inpatient, outpatient) and in a variety of formats, such as cognitive behavioral therapy or family therapy.

WHO PROVIDES MAT AND WHERE:

To prescribe or dispense buprenorphine, physicians, and, as of the passage of the national Comprehensive Addiction and Recovery Act of 2016, nurse practitioners and physician assistants, must qualify and apply for a waiver under the Drug Addiction Treatment Act of 2000, and are federally required to undergo specific addiction and pharmacology training prior to obtaining a special DEA number that is necessary for all prescriptions for buprenorphine. State regulations further restrict buprenorphine in an office-based setting.

As a result of West Virginia's 2017 Legislative Rule 69 CSR-12, Office-Based Medication Assisted Treatment, 2016's WV Senate Bill 454, and 2018's WV Senate Bill 273, West Virginia offices providing Office-Based Medication Assisted Treatment treating more than 30 patients with MAT are subject to the West Virginia Office of Health Facility Licensure & Certification oversight and a registration application, with additional organizational, programmatic, and clinical requirements, on top of federal requirements.

To prescribe and provide methadone as part of treatment for opioid use disorder, the physician, nurse practitioner, or physician assistant prescriber must be located at an Opioid Treatment Program (OTP) (a methadone clinic), subject to federal regulations, and which, under the State's moratorium, is limited to 9 locations; under West Virginia's SUD 1115 Waiver (2017), West Virginia Department of Health and Human Resources, Bureau for Medical Services (state Medicaid) regulations are in effect for OTP locations that bill Medicaid.

Naltrexone (unlike either methadone or buprenorphine) can be prescribed by any licensed physician or other medical professionals with prescribing authority.

Nationally, the Substance Abuse and Mental Health Services Administration (SAMHSA) "strongly encourages" states to require treatment facilities to have MAT capacity and for states to require "the use of MAT for substance use disorders for opioid use, alcohol use, and tobacco use disorders where clinically appropriate."[viii]

According to the American Society of Addiction Medicine:

> "The choice of available treatment options for addiction involving opioid use should be a shared decision between clinician and patient. Clinicians should consider the patient's preferences, past treatment history, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone in the treatment of addiction involving opioid use. The treatment setting described as level 1 treatment in the ASAM Criteria may be a general outpatient location such as a clinician's practice site. The setting as described as level 2 in the ASAM Criteria may be an intensive outpatient treatment or partial hospitalization program housed in a specialty addiction treatment facility, a community mental health center, or another setting. The ASAM Criteria describes level 3 or level 4 treatment, respectively, as a residential addiction treatment facility or hospital."

LENGTH OF TREATMENT, WITHDRAWAL MANAGEMENT, AND OTHER PROTOCOL:

Research shows that a minimum of 12 months of Medication Assisted Treatment must be provided to be associated with effectiveness.[ix] Withdrawal management also has medication-related recommendations from ASAM.

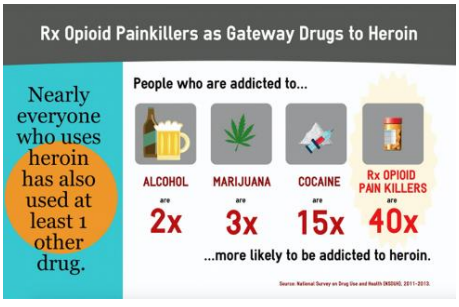
> "Using medications for opioid withdrawal management is recommended over abrupt cessation of opioids. Abrupt cessation of opioids may lead to strong cravings, which can lead to continued use. Opioid-dependent patients should wait until they are experiencing mild to moderate opioid withdrawal before taking the first dose of buprenorphine to reduce the risk of precipitated withdrawal."[x]

ASAM also notes: "Further research is needed to identify the comparative advantages of specific psychosocial treatments. Further study is needed to evaluate the effectiveness of psychosocial treatment in combination with specific pharmacotherapies."[xi] "There is no recommended length of treatment with medications taken by patients as part of medication-assisted treatment. Duration depends on clinical judgment and the patient's individual circumstances."

MAT AND THE ROOT CAUSES OF ADDICTION:

The American Society of Addiction Medicine defines addiction as ''a primary, chronic disease of brain reward, motivation, memory, and related circuitry,'' with a ''dysfunction in these circuits'' being reflected in ''an individual pathologically pursuing reward and/or relief by substance use and other behaviors.''[xii] In order to address the root causes, brain dysfunction must be addressed in order that psychosocial therapies can address the effects of addiction at an individual level.

ACEs (Adverse Childhood Experiences) are "stressful or traumatic events, including abuse and neglect…[and m]ay also include household dysfunction" are strongly related to prevalence of substance use disorders (SUDs). Seventy percent (70%) of individuals receiving addiction treatment have a history of trauma exposure.[xiii] Half of West Virginians have at least 1 of the 10 individual Adverse Childhood Experiences (and the most common ACE in WV is growing up with a parent with a substance use disorder, followed by divorce/separation of parents).[xiv] The average ACE score in West Virginia is higher than the national average of 46%. [xv] ACEs are viewed more fully in the context of Adverse Community Events (also ACEs, or community ACEs) including poverty, community disruption, and lack of opportunity, economic mobility, and social capital; presumably these ACEs are high for many West Virginians.[xvi]



Co-occurring disorders are very common: over half of individuals with a substance use disorder also have a mental illness; more than half of individuals with a mental illness have a drug addiction.[xvii] In 2014–2015, West Virginia's annual average percentage of past year serious mental illness (SMI) among adults aged 18 or older was higher than the corresponding national annual average percentage [5.4% vs. 4.1%]….From 2011 to 2015, West Virginia's annual average of past year mental health service use among adults aged 18 or older with any mental illness (AMI) [48.6%] was higher than the corresponding national annual average percentage (42.9%).[xviii]

POLYSUBSTANCE USE AND MAT:

On September 20, 2017, the Food and Drug Administration (FDA) issued the following FDA Advisory on Opioid Addiction Medications in Patients Taking *Benzodiazepines* or CNS Depressants:

Based on additional review, FDA is advising that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care professionals can reduce these risks.[xix]

In 2016, preliminary data indicated that heroin-related and fentanyl-related overdose deaths increased dramatically since 2014 (WV Health Statistics Center, Vital Statistics System). *Stimulant* overdoses are also on the rise: amphetamine or methamphetamine-related, as well as cocaine-related overdose deaths increased significantly between 2004 and 2016.

> "The data…support CDC recommendation [sic] that drug testing occurs before and periodically throughout opioid use and suggests that this testing should be extended to benzodiazepine prescribing as well. Expansion of electronic Prescription Drug Monitoring programs in many states has greatly improved clinicians' ability to identify all prescription information for their patients in real time. Unfortunately, these programs cannot capture non-prescribed drug use. Clinicians should be aware of potentially dangerous drug interactions beyond the prescription level, and our data demonstrate these interactions are happening with alarming frequency. Insights gained through drug testing can inform health care providers, affect treatment strategies, and save lives."[xx]

The focus on opioids does not in any way diminish the need to address other substance use disorders or mental health disorders nationally or in West Virginia. Prevalence of alcohol use disorders (AUDs) has increased dramatically over the last decade in multiple populations subgroups: Women (83.7% increase); African Americans (92.8%); age 45-64 (81.5%) and age 65+ (106.7%); only high school education (57.8% increase); individuals with incomes less than $20,000 (65.9% increase). [xxi] More than 1 in 4 (26.3%) of WV women reported smoking during pregnancy, double the national rate of 13%, and 60% of births in WV are to mothers receiving Medicaid. More than 4,000 births in WV are to mothers with substance use disorders. Cannabis is the most commonly used drug among pregnant women, at 11.63% of pregnant mothers, and leads to 2.3 times greater risk of still birth as well as poor cognitive functioning. [xxii]

NALOXONE AND ITS ROLE IN MAT:

Naloxone is an FDA-approved medication used in medication-assisted treatment (MAT) to counter opioid overdose, reversing the toxic effects of the overdose.

> "Naloxone is also added to buprenorphine to decrease the likelihood of diversion and misuse of the combination drug product. A doctor can prescribe naloxone to patients who are in medication-assisted treatment (MAT), especially if the patient is taking medications used in MAT or considered a risk for opioid overdose. Naloxone is effective if opioids are misused in combination with other sedatives

> or stimulants. It is not effective in treating overdoses of benzodiazepines or stimulant overdoses involving cocaine and amphetamines. Use of naloxone may cause symptoms of opioid withdrawal. Opioid overdose is life-threatening and requires immediate emergency attention."[xxiii]

SAMHSA's 2014 Opioid Overdose Prevention Toolkit provides material to develop policies and practices to help prevent opioid-related overdoses and deaths.

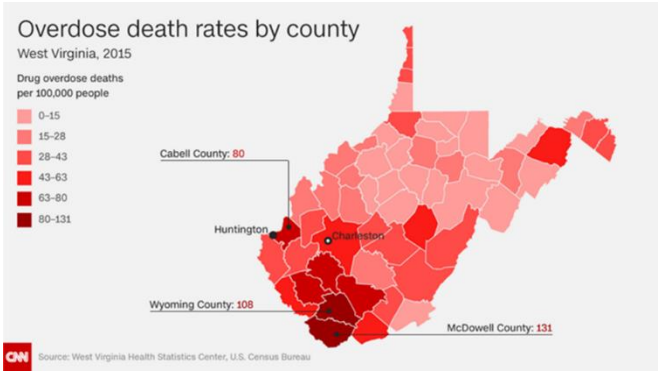
ACCESS TO MAT:

Recognizing the need to match health professions in West Virginia to meet the state's health needs is critical. "Only 10 percent of physicians serve rural populations, and the number of specialists per capita is a third of the number that practice in urban areas. The Centers for Medicare and Medicaid Services (CMS) considers the per capita physician shortage to be an important health care access problem."[xxiv] Growing the behavioral health workforce continues to be an important priority for West Virginia. In addition, the Health Resources Services Administration (HRSA) has determined that there are 49 Mental Health Professional Shortage Area designation areas within West Virginia.

Not only does West Virginia have shortages in primary care providers and behavioral health specialists, there are further shortages in practitioners who can and do prescribe medication as part of treatment for individuals with opioid use disorders. "Approximately 90% of physicians with waivers were in metropolitan areas and only 1.3 percent were in small and remote rural counties…; a third of providers have a single patient and almost half treat five or fewer patients"; "[o]nly 28% of waivered physicians reported actively prescribing buprenorphine and …less than half of those listed their name on the SAMHSA Physician and Treatment Locator site."[xxv] (IMIRPC:ES)

Working in behavioral health can be both extremely hard work, which can lead to burnout, and very rewarding. Dedication and passion are often higher than the salaries. As is consistent with West Virginia's general population, the behavioral health workforce in West Virginia is growing older and many in the workforce are getting closer to retirement. With issues like the opioid epidemic, the need is growing, and the training required for the workforce, both initially and ongoing, is significant.

DHHR continues to pursue strategies to strengthen the behavioral health workforce, including building the pipeline of new workforce, supporting continuing education, pursuing creative incentives, and developing and evolving telehealth solutions in West Virginia to improve access to quality behavioral health care.



Inadequate access to MAT arguably is associated with the high overdose death rates that WV has as compared to national rates, and within West Virginia, that some counties have in comparison with state rates.

To increase access to MAT, West Virginia is using multiple national best practice models in multiple locations, for example, ECHO (New Mexico) and Hub and Spoke (Vermont). Recommendations by the National Rural Health Association to address MAT access issues include: identifying and targeting "MAT deserts;" eliminating barriers so that MAT may continue during detoxification of other substances and is coordinated with outpatient treatment prior to discharge; allowing patients to be induced on buprenorphine while in inpatient settings to improve inpatient and outpatient treatment continuity, reduced side effects and treatment dropout.

SPECIAL POPULATIONS AND MAT:

Individuals who have been incarcerated are at high risk of overdose and therefore MAT is of significant interest for this population.

> "An RCT [randomized controlled trial] comparing buprenorphine and methadone among male heroin users who were newly admitted to prison showed that treatment completion rates were similar, but that buprenorphine patients were significantly more likely to enter community-based treatment after release. In a more recent trial, buprenorphine initiated in prison was also associated with a greater likelihood of entering community treatment. However, buprenorphine was diverted in some cases. Although promising, more research needs to be done to establish the effectiveness of in prison treatment with buprenorphine."[xxvi]

ASAM also makes recommendations specific to protocols for *pregnant women* with opioid use disorders, recommending that they

> "receive treatment …[other] than withdrawal management or abstinence. Treatment with methadone or buprenorphine should be initiated as early as possible during pregnancy. Hospitalization during initiation of methadone or buprenorphine may be advisable due to the potential for adverse events, especially in the third trimester."[xxvii]

ASAM RECOMMENDATIONS:

On April 24, 2013, the American Society of Addiction Medicine Board of Directors adopted the following recommendations, including the first and primary recommendation for thorough, multidimensional evaluation of primary and co-occurring conditions by skilled physicians with initiation of and ongoing engagement in individualized treatment. Other recommendations include:

"Pharmacological therapy can be a part of effective professional treatment for opioid use disorder and should be delivered by physicians appropriately trained and qualified in the treatment of opioid withdrawal and opioid addiction.

Furthermore, pharmacological therapy is best accompanied by and provided in conjunction with evidence-based psychosocial treatments and recovery support interventions as described in the ASAM Patient Placement Criteria.

Decisions about the appropriate type, modality and duration of treatment should remain the purview of the treatment provider and the patient, working in collaboration to achieve shared treatment goals.

Arbitrary limitations on the duration of treatment, medication dosage or on levels of care, that are not supported by medical evidence, are not appropriate [sic] can be specifically detrimental to the wellbeing of the patient and his/her community. Thus, such arbitrary treatment limitations should not be imposed by law, regulation, or health insurance practices.

Arbitrary limits on the number of patients who can be treated by a physician or the number and variety of pharmacologic and/or psychosocial therapies that may be used for treatment should not be imposed by law, regulation, or health insurance practices.

Prior authorization requirements, medical necessity criteria tests, patient copays or in/out-of-network provider requirements for opioid use disorder treatment should be on par with similar requirements for other chronic medical illnesses.

Pharmacological therapy guidelines for use by treatment providers in the care of patients with opioid use disorder should be developed by addiction physician specialists, in partnership with the U.S. Department of Health and Human Services and other federal, state and local public-private partnerships.

Long-term prospective studies aimed toward defining best practices should be developed and funded." [xxviii]

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[i] "American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use" https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24

[ii] "For OUD specifically, MAT utilizes medications to prevent the euphoric effects of opioids, assuage cravings for opioids, and/or decrease withdrawal symptoms by acting as opioid agonists, partial agonists, or antagonists…..Research has demonstrated that MAT can be a highly effective treatment option in terms of retaining people in treatment and reducing opioid abuse and overdose death." "…[P]atients who receive MAT…[have a l]ikelihood of relapse decreases significantly for those who are in treatment for at least 3 years." (*Implementing MAT in Rural Primary Care: Environmental Scan, 2017. https://integrationacademy.ahrq.gov/sites/default/files/MAT_for_OUD_Environmental_Scan_Volume_1_1.pdf*)"

[iii] Results of the systematic reviews (American Society of Addiction Medicine, 2013) have provided unequivocal evidence that, when used as indicated, these medications are both cost effective and clinically effective in reducing opioid use, opioid-related withdrawal and craving, and public health and safety problems related to opioid use (eg, infectious diseases, overdose death, crime).

[iv] Johns Hopkins Bloomberg School of Public Health Report 2015.

[v] http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/01/11/in-drug-epidemic-resistance-to-medication-costs-lives

[vi] https://store.samhsa.gov/shin/content//SMA15-4907POCKETGUID/SMA15-4907POCKETGUID.pdf

[vii] "The goal of psychosocial treatment is to help patients control urges to use drugs and remain abstinent, while also serving to assist patients in coping with the emotional strife that often accompanies addiction (Dutra et al., 2008). Psychosocial interventions can be delivered in different treatment modalities (eg, inpatient, outpatient) and in a variety of formats (eg, social skills training, individual, group and couples counseling, cognitive-behavioral therapy [CBT], contingency management (CM), 12-step facilitation therapy, motivational interviewing (MI), family therapy, and others (Carroll and Onken, 2005)]. Although each type of therapy may differ in its structure and theoretical underpinnings, many utilize common therapeutic elements in an aim to (a) modify the underlying processes that serve to maintain addictive behavior, (b) encourage engagement with pharmacotherapy, or (c) treat psychiatric comorbidity that either complicates the addictive disorder or acts as a trigger for relapse.""A

Systematic Review on the Use of Psychosocial Interventions in Conjunction With Medications for the Treatment of Opioid Addiction," J Addict Med, Volume 10, Number 2, March/April 2016. Karen Dugosh, PhD, Amanda Abraham, PhD, Brittany Seymour, BA, Keli McLoyd, JD, Mady Chalk, PhD, and David Festinger, PhD.

[viii] https://www.samhsa.gov/sites/default/files/grants/fy18-19-block-grant-application.pdf

[ix] https://www.drugabuse.gov/publications/principles-drug-addiction-treatment-research-based-guide-third-edition/frequently-asked-questions/how-long-does-drug-addiction-treatment

[x] https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-jam-article.pdf?sfvrsn=70ee6fc2_0 "American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use"

[xi] https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-jam-article.pdf?sfvrsn=70ee6fc2_0 "American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use"

[xii] https://www.asam.org/resources/definition-of-addiction

[xiii] Funk, McDermeit, Godley, Adams, 2003. https://www.samhsa.gov/capt/practicing-effective-prevention/prevention-behavioral-health/adverse-childhood-experiences

[xiv] "The ACE reported most often by West Virginia adults was household substance abuse (28.8%) which could include alcohol and/or drug abuse. More than one-fourth (26.6%) of West Virginia adults reported that their parents were separated or divorced during their childhood. Approximately 21.5% or 301,114 West Virginia adults would be considered high risk for developing health problems based on having three or more ACE. West Virginia adults reported an average of 1.4 ACE during their childhood, and almost half report zero ACE." http://www.wvdhhr.org/bph/hsc/pubs/briefs/030/Brief30_Adverse_Childhood_Experiences.pdf

[xv] http://wvpublic.org/post/report-west-virginia-childhood-adversity-tops-us-average

[xvi] Ellis W., Dietz W. BCR Framework Academic Pediatrics (2017).

[xvii] SAMHSA's 2014 National Survey on Drug Use and Health.

[xviii] https://store.samhsa.gov/shin/content//SMA17-BAROUS-16/SMA17-BAROUS-16-WV.pdf

[xix] https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm576755.htm

[xx] McClure FL, Niles JK, Kaufman HW, Gudin J. Concurrent Use of Opioids and Benzodiazepines: Evaluation of Prescription Drug Monitoring by a United States Laboratory. *Journal of Addiction Medicine*. 2017;11(6):420-426. doi:10.1097/ADM.0000000000000354. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5680991/

[xxi] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2647075

[xxii] Marc. A. Schuckit, MD editorial in JAMA Psychiatry in August 9, 2017.

[xxiii] https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone

[xxiv] http://www.healthaffairs.org/do/10.1377/hblog20171022.713615/full/?utm_source=Telehealth+Enthusiasts&utm_campaign=c79f5b2585-EMAIL_CAMPAIGN_2017_10_31&utm_medium=email&utm_term=0_ae00b0e89a-c79f5b2585-353219337

[xxv] Implementing MAT in Rural Primary Care: Environmental Scan, 2017.

[xxvi] https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf

[xxvii] https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-jam-article.pdf?sfvrsn=70ee6fc2_0 "American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use"

[xxviii] https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2013/04/25/pharmacological-therapies-for-opioid-use-disorders