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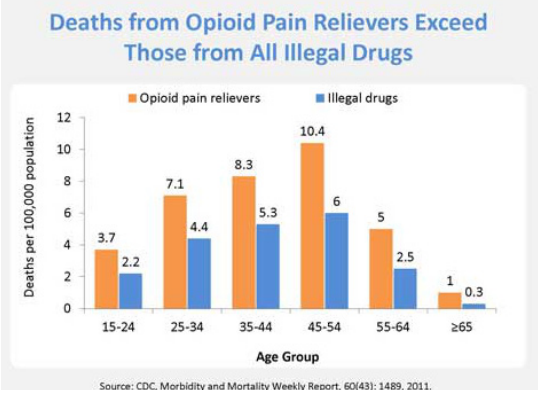
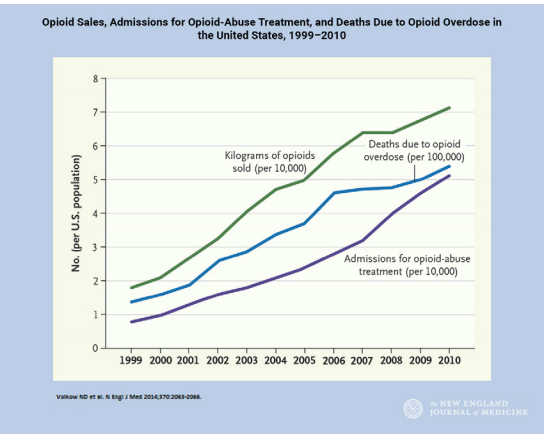
Opioid Addiction Treatment: Evidence-Based Medicine, Policy, and Practice

Opioid addiction is a national health crisis. According to the most recent data reported from the 2012 National Survey on Drug Use and Health, 2.5 million Americans are addicted to opioids. Of those addicted, 2.1 million Americans are addicted to opioid pain relievers and 467,000 Americans are addicted to heroin.[i] Nationally, prescription opioids were involved in 16,651 overdose deaths in 2010 and heroin was implicated in 3,036 deaths.[ii] Deaths from opioid abuse exceed those from all illegal drugs, and from 2000 to 2012 the rate of opioid overdose increased by 90% in the state of Massachusetts.[iii] These alarming trends led the U.S. Department of Health and Human Services (HHS) to declare an epidemic, prompting other states, including Massachusetts, to take local action. On March 27, 2014, then Massachusetts Governor Deval Patrick declared the state's opioid-addiction epidemic a public health emergency.[iv] In a recent publication, the Substance Abuse and Mental Health Services Administration (SAMHSA) reported that **four out of five heroin users started abusing prescription drugs first** (79.5%), but only 1% of prescription drug abusers had used heroin at any point in time.[v] In February, 2015, Governor Charlie Baker convened a task force to recommend immediate steps to alleviate the growing opioid addiction crisis.





Prescription Opioid Use Has Increased

Opioids are abused more than any other illicit drug in the United States.[vi] National Survey on Drug Use and Health data from 2010 and 2011 indicates that approximately **1 in 22 (4.6%)** people 12 or older nationwide used opioid pain relievers non-medically in the past year (SAMHSA, January 2013).[vii] According to the same data, 4.3% of people 12 or older in Massachusetts used opioid pain relievers non-medically in the past year.[viii] Experts cite a number of contributors to the exponential increase in the amount of patients treated with opioids, including providers' inappropriate prescribing or inadequate counseling and monitoring, patients' misuse or abuse of drugs, sharing of pain pills with relatives or friends, "doctor shopping" to obtain multiple prescriptions, and diversion of opioids leading to illicit sales and abuse.[ix]

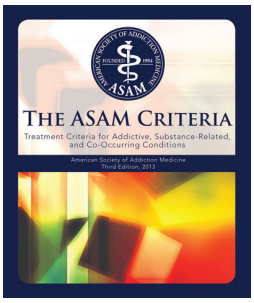
The medical use of opioids increased tenfold between 1990 and 2010.[x] According to the Centers for Disease Control and Prevention (CDC), inappropriate prescribing patterns have had a significant impact on the availability of opioids.[xi] The spike in opioid prescribing by medical personnel is often attributed to aggressive marketing techniques by pharmaceutical manufacturers, especially in the case of OxyContin, an extended-release form of oxycodone approved in 1995. This trend is also attributed to the liberalization of laws governing the prescribing of opioids by state medical boards and efforts to encourage clinicians to become more proactive in identifying and treating chronic pain.[xii] These practices brought the epidemic to rural communities and introduced "abusable" drugs into rural areas where no distribution network had previously existed for other illicit drugs, such as heroin or cocaine.[xiii] Prescription-tracking data demonstrates that more than 40% of all opioid prescriptions come from general or family practitioners, osteopaths, or internists.[xiv] According to a 2014 statement released by the CDC, most people who abuse prescription opioid drugs obtain them for free from a friend or relative.[xv] More specifically, data from a 2010 SAMHSA report shows that **more than half of those who abuse opioids obtain them from a friend or relative.**[xvi]

Prescription opioids impact the same brain systems as heroin and morphine. Over time, a person can develop physical dependence on opioids and may experience withdrawal symptoms if they do not use opioids regularly. This leads to compulsive escalating drug use to avoid withdrawal, and in the worst-case scenario it can lead to overdose. According to the National Institute on Drug Abuse, it is possible for a small number of people to become addicted even when they take opioids as prescribed, but the extent to which this happens is currently not known.

Treatment

Medical Guidelines and Best Practice

SAMHSA is the federal agency within the U.S. Department of Health and Human Services (HHS) charged with leading public health efforts to address substance abuse and mental illness within the United States. SAMHSA has produced a number of policy guidelines and treatment improvement protocols (TIPS) relating to opioid addiction. SAMHSA guidelines stress that patients should be treated in the least restrictive setting that is available.



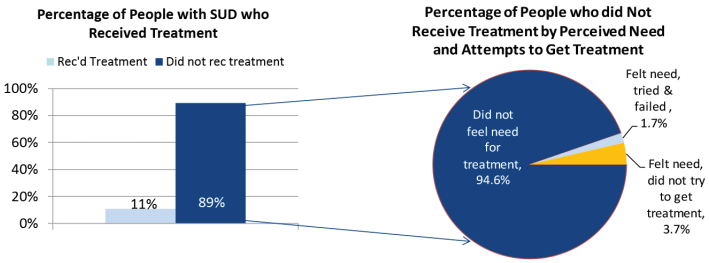
In addition to developing policy guidelines, SAMHSA leverages the knowledge of professional organizations for guidance surrounding policy and best practice. The most comprehensive set of guidelines for assessment, service planning, placement, continued stay, and discharge of patients with addictive disorders[xvii] is *The ASAM Criteria; Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions*, developed by the American Society of Addiction Medicine. Over 30 states, including Massachusetts, require state-funded providers to use ASAM for their standard patient placement criteria.[xviii] The ASAM criteria focus on providing a flexible continuum of care that allows for patients to begin individualized treatment at any level within the spectrum of services with flexible lengths of stay or treatment, cautioning against mandated lengths of stay. Both ASAM and SAMHSA state that care should be delineated based on the substance; therefore, the guidelines for the treatment of opioid addiction differ from the treatment of alcohol addiction.

Substance Abuse Treatment in Massachusetts

The Bureau of Substance Abuse Services (BSAS) at the Massachusetts Department of Public Health (DPH) is the single state authority for the prevention and treatment of substance use disorders in the Commonwealth[xix]. BSAS licenses a range of inpatient and outpatient services for substance use disorders. The first access point for someone seeking opioid addiction treatment while in crisis is generally **Acute Treatment Services (ATS)** or detoxification programs. ATS are often followed by "stepdown" treatment services within the BSAS system defined as **Clinical Stabilization Services (CSS), Transitional Support Services (TSS)**, residential rehabilitation treatment programs, and outpatient substance abuse treatment. For a full description of each type of service, please refer to Appendix I.

BSAS also licenses a number of Medication Assisted Treatment (MAT) services to treat opioid addiction called **Opioid Treatment Programs (OTP)**. The three medications that have received FDA approval for treating opioid use disorders are Methadone, Buprenorphine and Naltrexone. These medications work by interacting with some of the same receptors in the brain that are triggered by the abused drug without causing a high. Methadone and Buprenorphine are opiate replacement therapies, occupying the same receptors in the brain that are triggered by abused drugs but normalize functioning. Naltrexone is not a substitution medication but works by blocking the effects of opiates; if abused drugs are used, the user will not experience a high. There are different combinations of these medications available for treating opioid addiction (see Appendix II).

Treatment Statistics



Unfortunately, many of those suffering from opioid addiction do not access treatment. Awareness and readiness to seek treatment are enormous barriers to providing care. In a recent presentation by the Massachusetts Department of Public Health, SAMHSA data was used to demonstrate that 89% of patients presenting with substance abuse disorder did not receive treatment. Of the 89% of patients that did not receive treatment, an overwhelming majority (94.6 %) did not "feel the need for treatment."[xx]

MA BSAS Substance Abuse Treatment Statistics

The BSAS reported high utilization of acute inpatient services as compared with other treatment levels in 2012[xxi] and in 2014.[I] Acute Inpatient Treatment Services received the highest percentage of admissions with 37.1% (37,618) of all admissions in 2012 and 40.1% (43,476) of all admissions in 2014. This was followed by outpatient treatment services with 18.6% (18,848) in 2012 and 15.2% (16,488) in 2014. BSAS did not provide isolated statistics for all opioids, but according to the 2012 data, 42% (42,670) of those admitted reported injection drug use in the past year and 48.5% (52,628) reported injection drug use in 2014. Despite the high percentage of injection drug use, only 7.2% of admissions in 2012 (7,280) were admitted to Opioid Treatment Services (OTP)[xxi] and only 7.6% (8,109) were admitted to OTP in 2014.

The high utilization of inpatient care that BSAS has reported is similar to treatment patterns described in the clinical literature. The existing data does not indicate that inpatient treatment is more effective than other forms of treatment, but ASAM reports that more money is spent on the most intensive level of care.

The ASAM criteria notes that funding for opioid withdrawal management is generally limited to the most intensive and expensive levels of care [levels *3.7-4 or medically monitored inpatient care*], which results in treatment waiting lists and access issues. Contradictory to practice patterns, ASAM reports that the reality experienced by physicians in clinical practice demonstrates that many patients either do not need to begin withdrawal management in the most intensive level of care or could be moved earlier to less intensive levels of withdrawal management if a system allows for flexible care within a continuum of settings. ASAM also notes that medications can eliminate the severity of withdrawal symptoms, allowing patients to benefit from treatment at lower levels of care and fostering engagement in recovery services early in the course of treatment. This increases the potential for long-term engagement in treatment.

Table 1. Recidivism Rates for Selected Service Types, FY 2014

Service Type	# Clients Admitted	# Clients Admitted With Multiple Enrollments	Recidivism Rate
Methadone Treatment	6,631	465	7.01%
Office Based Opioid Treatment	1,032	21	2.03%
Acute Treatment Services	22,804	8,846	38.79%
Clinical Stabilization Services	5,725	1,069	18.67%
Transitional Support Services	3,434	567	16.51%
Residential Treatment	6,171	930	15.07%

BSAS data from FY 2014 indicates that those who enter ATS, CSS, or TSS treatment are more likely to need treatment again. Recidivism rates for ATS, CSS, and TSS are significantly higher than those for methadone treatment and Office Based Opioid treatment. See Table 1.[I]

Medication Assisted Treatment (MAT)

Treatment options for opioid addiction are very different than those for other addictions; there are currently no FDA-approved medications to treat addiction to cannabis, cocaine, or methamphetamine.[xxii] MAT is associated with increased treatment retention, decreased rates of overdose, lower rates of illicit drug use, fewer infectious disease transmissions, and reduced criminal activity.[xxiii] The psychosocial needs of every patient vary, and treatment must continue to be tailored for the individual, but clinical data demonstrates that MAT is clinically effective in treating opioid addiction. MAT helps reduce opioid craving, avert or reduce signs and symptoms of withdrawal, and prevent relapse, and it reestablishes normal physiological function, affording those who suffer from addiction the ability to resume functional lives.

A growing body of academic literature, including data from a comprehensive comparative effectiveness analysis conducted by the Institute for Clinical and Economic Review (ICER), demonstrates that those who receive Medication Assisted Treatment (MAT) for opioid addiction tend to have better long-term outcomes than those who went through detoxification as a primary treatment approach.[xxiv] The long-term provision of MAT, which is referred to as Maintenance Treatment, typically yields greater positive outcomes when compared with short-duration tapers and withdrawal.[xxv] According to an Office of National Drug Control Policy Healthcare brief, programs that provide medically assisted detoxification services, which involve weaning patients off addictive substances and managing withdrawal without providing continued medication maintenance treatment, have been found to be **closely associated with relapse.**[xxvi] The National Institute on Drug Abuse reports that MAT has been found to be cost-effective. A 2005 study that tracked methadone patients from age 18 to 60 and examined variables including heroin use, treatment for heroin use, criminal behavior, employment, and healthcare utilization found that **every dollar spent on methadone treatment yields $38 in related economic benefits** — seven times more than previously thought.[xxvii]

Due to a number of barriers, MAT is underutilized in the United States,[xxviii] and less than 10% of Americans addicted to opioids receive MAT.[xxix] According to a recent paper published by the *New England Journal of Medicine (NEJM)*, **less than half of the existing private-sector treatment programs in the United States offer MAT, and of those that do only 34.4% of patients receive MAT for opioid addiction.** [xxx] Many treatment programs in the Commonwealth treat opioid addiction without providing access to MAT. **BSAS-licensed facilities vary in their ability to provide MAT in Massachusetts.** Expanding access to MAT would require the widespread participation of physicians and pharmacies.

Barriers to Access and Availability of Opioid Treatment

There are a number of barriers that have contributed to the access and availability of opioid addiction services. These barriers impact treatment systems, practicing patterns, and availability of services.

Access

A 2010 Executive Office of Health and Human Services EOHHS needs assessment reported significant gaps in substance abuse services across the Commonwealth, as indicated by waiting lists, inadequate staff capacity, a lack of coordination among state agencies, and the locations of where services are targeted.[xxxi]

Program Design and Care Coordination

Clinical practices are often reluctant to take on patients with opioid addiction because they do not offer a full range of behavioral and psychosocial services necessary to meet the needs of individuals. Many existing treatment programs do not have coordinated care networks that allow for patients to receive services within a continuum of care. For example, those with co-occurring substance abuse and mental health disorders are constrained by the system, as some mental healthcare facilities do not accept patients who are currently receiving MAT,[xxxii] leaving patients to choose between MAT and entering the mental healthcare facility.

Lack of Providers

According to the New England Comparative Effectiveness Public Advisory Council, current provider capacity in New England is not sufficient to meet patient need for treatment for opioid dependence.[xxxiii] Several recent policy papers have identified barriers to provider and pharmacy participation, including limited training in addiction medicine and physician resistance to providing the therapy.

- Resistance to take on patients is often driven by the complexity of cases and the stigma attached to drug addiction. Providers have identified barriers to the use of office-based opioid treatment (OBOT) including coordinating logistics between providers, potential for Buprenorphine diversion, fear of being overwhelmed by referrals, fear of drug enforcement agency intrusion, and on-call demands.[xxxiv] This is the result of regularity constraints and pervasive suboptimal clinical practices.[xxxv]

Perception of Opioid Addiction and Treatment

While most people have been impacted by opioid addiction in some capacity, the disease and treatment are not widely understood by providers, patients, families, policymakers, and members of the public. Individuals and families in crisis cannot make informed decisions about treatment without education. In addition to changing perceptions surrounding readiness to seek treatment, there is a specific stigma associated with MAT and a misconception that medications used for treatment replace one substance with another. In order to improve treatment outcomes, patients and families must become familiar with evidence-based treatment options, including MAT.

Potential Policy Initiatives to Improve Patient Outcomes

Policymakers in the commonwealth are acutely aware of the increasing number of citizens impacted by opioid addiction and have been working toward developing solutions to the epidemic. Unfortunately to date, much of the proposed legislation and conversation surrounding substance abuse in the state has overlooked clear recommendations made by existing professional bodies and independent research organizations.

There are a number of barriers preventing individuals from accessing appropriate treatment for opioid addiction. Recent legislation has aimed to alleviate barriers to care by targeting specific access points and mandating coverage of inpatient services. These services are necessary for some patients seeking opioid addiction treatment, including those with complex psychosocial support needs or severe medical and/or behavioral health comorbidities. However, this level of care has been cited in clinical research and by professional organizations as costly and over-utilized. By narrowly focusing on one level of care, this legislation has the potential to create massive backlogs of patients unable to access care in these expensive settings. In order to avoid these scenarios, it is necessary to create an environment that fosters evidence-based treatment options that include care that can be provided in less restrictive settings with greater positive outcomes.

Recommendations

Rather than focus on length of stay in a specific setting, a comprehensive approach will address system capacity and treatment opportunities at all access points within the continuum of care. The following recommendations will help improve the existing delivery system and improve the treatment landscape for those addicted to opioids:

Treatment Standards, Care Coordination, and Integration

State-based accreditation standards for treatment facilities licensed by BSAS

The psychosocial needs of an individual vary, but the clinical efficacy of MAT remains the same. In order for opioid addiction treatment to be tailored at the individual level, all patients must have access to the full range of services. To ensure a robust treatment system within the commonwealth, BSAS programs licensed to treat opioid addiction must be required to provide access to all forms of MAT. Programs that do not offer the full range of MAT must be required to coordinate care with other facilities. This will ensure appropriate placement and transition through the spectrum of services.

Improve care coordination

Create a system that allows for coordinated care that effectively transitions patients along the continuum of care to ensure that individuals get the necessary care in the most clinically appropriate setting. Providers will develop treatment plans for those transitioning from one level of treatment to another along the continuum of care and will communicate treatment plans to providers in other settings on discharge. Chapter 258 of the Acts of 2014 (An Act to Increase Opportunities for Long-Term Substance Abuse Recovery) directed DHP to promulgate regulations to enhance care coordination and management across the continuum of care and requires a discharge plan for each patient leaving a licensed substance use disorder treatment facility. As noted in the comparative effectiveness analyses conducted by ICER and Governor Baker's comments during the opioid addiction press conference on February 19, 2015, Vermont has addressed opioid addiction through developing an innovative model for care delivery called the "Hub and Spoke" program. This treatment system creates an integrated care continuum for patients with opioid addiction; it may be useful for policymakers to build off of this approach.

Address integration of Behavioral Health and substance abuse treatment with primary care

In addition to developing integrated health IT systems, one of the inherent challenges to coordinated care is ensuring that members of a care team have access to necessary information regarding their patients' healthcare needs. Information relating to an individual's diagnoses, co-morbidities, medications, and treatment goals should be available to all members of the care team to ensure consistency in treatment.

It is necessary to develop a mechanism for primary care providers to work with substance abuse providers to obtain the consent to allow access to patient health information. The rules around information sharing are restrictive and have created a challenging regulatory environment for care coordination (see footnote for description[1]), but it is possible to develop care coordination strategies within the boundaries of the regulations. Any solution must balance patient privacy rights with the need for an individual's care team to have access to information regarding their care.

Improve access to treatment

Identify gaps in opioid addiction services across the Commonwealth and provide support to develop a robust treatment system within Massachusetts. The focus should be on ensuring that patients and families are educated about available treatment options as well as information about the effectiveness of each option. The planned BSAS Central Navigation System will help patients, families, and providers locate appropriate and available services. Additionally, DPH should convene providers, payers, and other stakeholders to develop evidence-based screening tools that can be used to help identify the most appropriate treatment for individuals.

Common set of guidelines

State agencies, private-sector associations, and professional organizations should require providers to adopt and utilize opioid addiction treatment guidelines that are evidence-based and nationally recognized. Currently, state-funded providers are required to use ASAM criteria, but increased oversight of licensed providers may help to ensure that clinicians are providing care in line with best practices. DPH, as part of its licensure authority, should strengthen its oversight of licensed providers to ensure that they are in conformance with up-to-date evidence-based best practices.

Data Collection and Best Practice

Measure treatment outcomes

Building off of Governor Baker's announcement for improved transparency, we feel that there is additional opportunity within the commonwealth for reporting opioid addiction data. BSAS-licensed treatment facilities operating within the commonwealth should be required to collect and report comprehensive quality assessment data, including treatment type, level of care, and outcomes in order to measure the system's success in treating opioid addiction. Each program should submit data specific to opioid addiction to the Center for Health Information and Analysis (CHIA) on an annual basis for review of services provided and treatment outcomes.

Utilize urine analysis for screening and to measure effectiveness

Laboratory measures, including urine analysis, can assist in assessing the severity of addiction, screening of all admissions prior to treatment, monitoring compliance with prescribed MAT regimens, and evaluating treatment program outcomes.[xxxvi] ASAM has endorsed the use of drug testing in clinical diagnostic settings, addiction treatment settings, and for monitoring, as it is a valuable tool to use as part of a comprehensive diagnostic evaluation and assists in developing appropriate treatment and monitoring treatment plans.[xxxvii]

Education and Support

Create education programs and support systems for providers

Train and support physicians in screening and treatment for opioid addiction, including primary care clinicians. This training should be grounded in medical best practices to ensure that the workforce is capable of providing treatment based on up-to-date clinical guidelines. Providers need education surrounding appropriate treatment modalities and regulations surrounding the use of these therapies, including MAT. This may require incentives to increase the number of willing providers within the system. Providers who believe only in abstinence-based treatment should let patients know about alternative treatments (such as MAT) as part of informed consent in treatment. Potential options include mandated addiction education in medical schools, along with increased financial incentives in the form of specific physician billing codes for providing MAT.

Education campaign to increase knowledge and improve public perception of opioid addiction treatment

There is a need to educate the public about effective treatment for opioid addiction in order to reduce stigma and alleviate barriers to access. Opioid addiction is different from other substance abuse disorders, and those assisting in making treatment decisions must understand best practice. It is necessary to shift public perception and generate understanding that opioid addiction is a chronic disease that can be treated and managed through medical care. This will help facilitate treatment processes that focus on the timing and appropriateness of treatment services, consistent with other chronic diseases such as diabetes.

Most of the recommendations in this paper are in reference to treatment; however, interventions designed to prevent opioid use are also of importance. In conjunction with creating a robust treatment system, it may be necessary to develop a mechanism for monitoring prescribing practices. Recently, policy conversations in the Commonwealth have touched upon strengthening the prescription drug-monitoring program by developing pharmacy lock-in programs. This is valuable as part of any discussion surrounding the opioid epidemic, but for the purpose of this paper we chose to focus specifically on the opioid addiction treatment landscape within the commonwealth in order to generate understanding of effective treatment strategy among policymakers, patients, families, and providers.

1. Footnote: The Health Insurance Portability and Accountability Act (HIPAA) together with numerous provisions of Massachusetts law provide broad protection of individually identifiable health information. In addition, the Federal Drug and Alcohol Confidentiality Law (42 CFR Part 2) provides additional protection relating to individuals with or who seek treatment for alcohol or other substance use problems. 42 CFR Part 2 applies broadly to any program that provides alcohol or drug abuse diagnosis, treatment, referral for treatment, or prevention and is "federally assisted" and requires specific written authorization by an individual to share information on substance use, diagnosis, and treatment at the point of each potential disclosure.

In relation to this discussion we would like to emphasize that a prescription drug monitoring program should be strengthened in concurrence with the development of a robust and coordinated screening and treatment system. Prescription drug monitoring programs reduce the number of prescription opioids available and act as a deterrent to new addicts, but should not be seen as a method of reducing addiction overall. A 2015 NEJM article describes data that indicates prescription monitoring and abuse deterrent drug formularies have helped to level off the rate of prescription opioid abuse but have contributed to an increase in reported heroin use. The National Survey on Drug Use and Health and data from the National Poison Data System both showed that changes in rates of prescription opioid abuse are associated with increasing heroin-related mortality.[xxxviii] As noted in earlier statistics, prescriptions drugs contribute to the lion's share of overdose deaths at this point; however, unless treatment is available, accessible, and widely understood, reducing the number of prescription opioids could lead to an increase in heroin-related deaths in the commonwealth.

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Appendix I

The Bureau of Substance Abuse Services (BSAS) at the Massachusetts Department of Public Health (MDPH) is the Single State Authority (SSA) for the prevention and treatment of substance use disorders in the Commonwealth. Levels of care licensed by BSAS include:

- **Acute Treatment Services** (ATS) or **detoxification programs:** Residential treatment programs that medically treat withdrawal symptoms in people dependent on opioids, alcohol, or other drugs for up to 30 days often followed by "step-down" treatment.

  Step-down services include:
  - Clinical Stabilization Services (CSS): Nursing, education, and counseling; usual length of inpatient stay is 10–14 days.
  - Transitional Support Services (TSS): Short-term residential intensive care management services for up to 30 days.
  - Residential rehabilitation treatment programs: A planned program of substance abuse treatment within a 24-hour residential setting designed to serve individuals for 6-12 months; youth programs are generally 3 months in duration.
  - Outpatient substance abuse treatment: Counseling, intensive day treatment, and educational services.

- **BSAS Opioid-Specific Treatment Services**
  BSAS licenses a number of Medication Assisted Treatment (MAT) services to treat opioid addiction. Three medications have received FDA approval for treating opioid use disorders: Methadone, Buprenorphine, and Naltrexone. Medications used to treat opioid addiction work by interacting with some of the same receptors in the brain that are triggered by the abused drug. These medications bind with receptors to reduce cravings and prevent withdrawal without causing a high.

- **Medication Assisted Treatment (MAT) services include**
  - Opioid Treatment Programs (OTP): Provide methadone dosing services in combination with an array of other services including counseling, drug screening, and case management services.
  - Office-Based Opioid Treatment (OBOT): Buprenorphine treatment prescribed to patients in physician offices by a physician who has obtained a waiver from the Drug Enforcement Agency.
  - Injectable naltrexone (Vivitrol): A third form of MAT that can be prescribed by any qualified health professional, including mid-level practitioners, and is given in the form of an injection on a monthly basis in the prescriber's office

Appendix II

FDA Approved Opioid Addiction Treatment Medications

- Buprenorphine (generic sublingual tablet)
- Suboxone (buprenorphine/naloxone sublingual film)
- Zubsolv (buprenorphine/naloxone sublingual tablet)
- Bunavail (buprenorphine/naloxone buccal film)
- Revia (naltrexone oral tablet)
- Vivitrol (naltrexone IM Injection)
- Methadone

Endnotes

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