

# Management of Patients with Opioid Dependence: A Review of Clinical, Delivery System, and Policy Options



The New England Comparative Effectiveness Public Advisory Council  
**An Action Guide for Management of Opioid  
Dependence: Next Steps for Payers and Policymakers**  
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Completed by:  
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# Introduction

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## About this Guide

Evidence from clinical effectiveness reviews is critical to judgments that patients, clinicians, and health insurers must make about treatment choices and coverage policies. Yet that evidence is often not translated in a way that is helpful to inform health care decisions. This document is a companion policy guide designed to help health insurers and policymakers make use of the results from a recent evidence review and meeting results, titled [“Management of Patients with Opioid Dependence: A Review of Clinical, Delivery System, and Policy Options”](#). This report formed the basis for the deliberations and votes of the New England Comparative Effectiveness Public Advisory Council (CEPAC) – an independent body composed of physicians, methodologists, and patient/public members that meets in a public, transparent forum to provide objective guidance on how information from evidence reviews can be used by regional decision-makers to improve the quality and value of health care services. The report pulls together the best available evidence on the effectiveness and value of management strategies for the treatment of opioid dependence from the published literature, findings from interviews with expert stakeholders, new survey results benchmarking the status of treatment in New England, and public testimony.

CEPAC held its meeting on management options for opioid dependence on June 20, 2014 in Burlington, VT. During the meeting, CEPAC voted on the comparative clinical effectiveness and value of different treatment approaches, and explored how best to apply the evidence to practice and policy with a distinguished Policy Expert Roundtable of patient advocates, clinical experts, and policy leaders from across New England.

The information contained in this guide is designed to help decision makers benchmark best practices for expanding access to treatment and improving the quality of care delivery for individuals with opioid dependence based on the published literature and expert opinion. The content provided here is for informational purposes only, and it is not designed to replace professional medical advice.

## About ICER and CEPAC

*The Institute for Clinical and Economic Review (ICER) is an independent non-profit health care research organization dedicated to improving the interpretation and application of evidence in the health care system. The New England Comparative Effectiveness Advisory Council (CEPAC) is one of ICER’s two core programs. It is a regional body whose goal is to provide objective, independent guidance on the application of medical evidence to clinical practice and payer policy decisions across New England. Backed from a consortium of New England state health policy leaders, CEPAC holds public meetings to consider evidence reviews of a range of topics, including clinical interventions and models for care delivery, and provides judgments regarding how the evidence can best be used across New England to improve the quality and value of health care services. ICER manages the day-to-day operations of CEPAC as one of its core programs designed to translate and implement evidence reviews to improve their usefulness for patients, clinicians, payers, and policymakers. For more information about CEPAC, please visit [cepac.icer-review.org](http://cepac.icer-review.org).*

# Expanding Access to Opioid Dependence Treatment

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In spite of strong evidence demonstrating the effectiveness of medication-assisted treatment (MAT) in the management of opioid dependence, access to this service is insufficient to meet patient need in New England and nationally. The availability of MAT is limited by a multitude of factors. Federal law restricts the dispensing of methadone to federal- and state-approved opioid treatment programs (OTPs). Medication must be taken under observation at methadone clinics, unless take-home privileges are granted. This highly regulated environment can make OTPs an unattractive option for many patients and physicians, and long waiting lists are common at most facilities. To dispense or prescribe buprenorphine-containing medications like Suboxone<sup>®</sup>, physicians must obtain a special waiver (DATA 2000) proving that they are adequately licensed and trained in the field of addiction medicine. Physicians with a waiver may not treat more than 30 patients with Suboxone<sup>®</sup> or buprenorphine concurrently, but after one year can apply for a second waiver to treat up to 100 patients at one time.

Even with excess demand for treatment, many DATA 2000 waived physicians are not prescribing to capacity or at all. Approximately one-third of licensed physicians have obtained a waiver to move from a patient cap of 30 – 100 patients. Some practices abstain from treating more patients with addiction due to insufficient resources to address the full scope of behavioral and psychosocial needs associated with substance abuse disorders where others fear risk of diversion and potential abuse of medications. Primary care providers in particular often feel undertrained or unsupported to take on new patients with addiction. Coordinated efforts are therefore needed across New England to improve access to opioid dependence treatment for the large numbers of individuals who lack adequate access to high quality care options.

Action steps that health insurers and policymakers should consider for expanding access to treatment include:

1. Change regulations that isolate methadone treatment from the rest of clinical care, and consider pilot programs allowing the extension of methadone treatment to office-based settings.

Primary care-based methadone treatment may improve access to care and avoid some of the negative aspects of OTPs, such as interactions between patients who continue to use illicit drugs. Expanding access to methadone in office-based settings would also serve to reduce the stigma associated with this intervention, which serves as a deterrent for many patients and physicians. Allowing patients to receive methadone at their primary care provider may also support greater patient retention in treatment, since substance abuse services and other medical care can be accessed in one location.

Several pilot studies have investigated the use of methadone in an office-based environment with take-home dosing provided for up to one month, in contrast to the federally-mandated approach of daily observed dosing in a clinic setting. Studies included in the CEPAC report suggest that office-based methadone programs result in high treatment retention (79-98% at 12-60 months), and low illicit drug use (0.4-2.3%) among all patient groups (Harris, 2006; King, 2006). A sample pilot program from Connecticut for an office-based methadone treatment is described below for policymakers and payers interest in developing similar programs.

**The Connecticut Methadone Medical Maintenance Pilot Project (1997):**

*Medical model:* Patients received a weekly dose of methadone from their physician's office; one dose was taken under observation, and six bottles were provided for take-home use. In addition, patients met in-person with their physician on a monthly basis to address general concerns and to discuss goals and other components of treatment. Patients provided monthly random urine tests throughout the six-month pilot.

*Recruitment:* Patients recruited for the pilot provided names of their primary care physicians in order to provide a set of physicians interested in providing long-term care for patients receiving methadone. Each enrolled physician had to receive special dispensation from the FDA as well as a special registration from the DEA in order to provide methadone. Physicians also received approval from the Connecticut state government, and underwent in-person interviews with physicians from a local OTP. Patients selected for the pilot came from a local OTP who had been active in treatment for over a year, had stable living environments, and had no positive urine samples within the prior 12 month period.

*Training:* Physicians received two 1/2 day training sessions (Fiellin, et.al, available at [www.caas.brown.edu/ATTC](http://www.caas.brown.edu/ATTC)). Manuals outlining standard procedures and clinical protocols were provided to each practice. In order to fully prepare office-staff, nurses and office personnel at each physician office received training regarding opioid dependence, management approaches, and the rationale for opioid agonist maintenance and its expansion to office-based settings.

For complete information on the pilot, and study results: <http://www.dpt.samhsa.gov/pdf/Final040901.pdf>

Additional information regarding office-based methadone programs:

Office-based Methadone Program Resources	
American Society of Addiction Medicine (2004): Public policy statement on office-based opioid agonist treatment	<a href="http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2011/12/15/office-based-opioid-agonist-treatment-(obot)">http://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2011/12/15/office-based-opioid-agonist-treatment-(obot)</a>
Treating Opioid Addiction in an Office-Based Practice Knowledge Asset (2007): by Joseph Merrill, MD, MPH, University of Washington <u>Knowledge Assets</u> is a web site created by the Robert Wood Johnson Foundation's Substance Abuse Policy Research Program	<a href="http://saprp.org/knowledgeassets/knowledge_detail.cfm?KAID=7">http://saprp.org/knowledgeassets/knowledge_detail.cfm?KAID=7</a>

2. Relax limits on the number of patients that can be treated with buprenorphine-containing medications by qualified clinical teams in appropriate organizational settings. Broaden the scope of DATA 2000 to allow qualified nurse practitioners to prescribe buprenorphine and Suboxone®.

To expand access to Suboxone® and buprenorphine, policymakers could relax the limits on the number of patients that can be treated by qualified clinical teams in appropriate clinical settings. If clinical practices are allowed to increase the volume of patients receiving buprenorphine medications, measures should also be taken to ensure that these practices are part of well-organized group settings that can provide adequate structure and support for physicians and other clinicians.

Both of these recommendations have been recently included in federal legislation proposed by Senator Edward J. Markey (D-Mass.) and co-sponsored by Senators Diane Feinstein (D-Calif.), John D. Rockefeller (D-W.V.), Sherrod Brown (D-Ohio) and Mazie Hirono (D-Hawaii) designed to expand access to opioid dependence treatment:

[http://www.markey.senate.gov/imo/media/doc/2014-07-23\\_TREATAct\\_text.pdf](http://www.markey.senate.gov/imo/media/doc/2014-07-23_TREATAct_text.pdf)

POLICY AND PRACTICE INNOVATIONS TO INCREASE TREATMENT CAPACITY AND EXPAND ACCESS TO CARE

***Policy/Practice Option: Utilizing physician assistants and nurse practitioners to increase physician-prescribing capacity***

In Massachusetts, a network of office-based addiction treatment programs called [Clean Slate Centers](#) has attempted to increase the number of DATA 2000 waived physicians prescribing at capacity. According to this model, licensed prescribers work as part-time physicians who treat patients with Vivitrol® or Suboxone®. In addition to prescribing treatment, these physicians review patient charts, conduct group medical visits, and answer questions from staff regarding patient management. The model also utilizes full-time clinical and supportive staff to manage all other aspects of care, allowing physicians to increase their prescribing capacity beyond their main clinic. The goal of this approach is to “remove treatment from busy, over-stretched primary care settings, and provide the infrastructure necessary for primary care physicians and psychiatrists to collaborate with behavioral health providers and experienced full-time clinicians so that patients are able to receive the comprehensive care necessary to achieve recovery” ([Substance Abuse and Mental Health Services Administration](#), 2012).

***Policy/Practice Option: Use of technology and telemedicine to expand access to treatment***

Researchers in Vermont have recently received National Institutes of Health (NIH) funding to make use of a new computerized device called the [Med-O-Wheel](#) to help patients on treatment waiting lists access some level of medication-assisted treatment. The device is for take-home use and dispenses a single dose of buprenorphine for a limited three-hour window each day, making it difficult for patients to abuse medication. The transparent back to the device also allows physicians to monitor diversion. Patients receiving buprenorphine through the Med-O-Wheel will also receive telephone-based monitoring and support that provides daily check-ins, documents patient cravings, and refers patients to other needed resources. The goal of this model is to expand patient access by offering an alternative safe delivery option for medication, thereby increasing the willingness of physicians with concerns for diversion to provide treatment.

# Connecting individuals in the criminal justice system to treatment

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MAT is unavailable in most correctional facilities, with approximately only 10% of individuals whom require opioid replacement therapy receiving it as part of their criminal justice supervision (Substance Abuse and Mental Health Services Administration (SAMHSA), 2013). Many individuals leaving the correction systems are wait-listed for treatment at OTPs and unable to find primary care physicians to provide substance abuse services, increasing the risk for recidivism. Solutions to addiction cannot be achieved in penal institutions alone, and therefore stronger integration between the criminal justice system and clinical systems is required. Innovative strategies that better link individuals in the criminal justice system to long-term treatment for their addiction should be explored by policymakers across the health care spectrum.

Action steps for health insurers and policymakers to consider include:

### 3. Create jail diversion programs in which non-violent offenders are assessed for addiction and referred to appropriate treatment in lieu of incarceration.

Jail diversion programs are designed to connect individuals with serious mental health disorders to community-based treatment and support as an alternative to incarceration. There are different types of jail diversion programs. **Pre-booking refers to** the identification and assessment of individuals for treatment at the point of contact with law enforcement, before formal charges are pursued (SAMHSA). **Post-booking** diversion, more common in the United States, diverts individuals after arrest, at different stages in the criminal justice process. Mental health and other specialty courts are increasingly utilized as part of post-booking diversion programs to help link individuals to long-term community-based treatment and support for their addiction.

Examples of different jail diversion programs:

- **Crisis Intervention Team Programs:** Started in 1988 in Memphis, Tennessee, this model trains police officers in crisis intervention, the recognition of mental illness and psychopharmacology. These specially-trained officers provide first response services to cases involving mental illness to ensure an appropriate and measured response. The model involves collaboration with local mental health providers and mental health consumers, and has been implemented nationally. For more information, visit: <http://www.memphistn.gov/Government/PoliceServices/CrisisInterventionTeam.aspx>.

- **The LEAD Model – Washington State:** The LEAD Model is a pilot program in the Seattle area that diverts low-level drug offenders whom meet certain thresholds into community-based support services and treatment programs. The LEAD model establishes diversion at the pre-booking stage to avoid the legal costs associated with court trials, etc. Individuals participating in the program are connected with case management and counseling services immediately. Addiction services for LEAD participants are provided through a formal contract with a community-based organization that specializes in outreach services to chronically homeless and dependent adults. The LEAD program is the result of multi-stakeholder collaborative between representatives from the criminal justice system, the legal system, local and state governments, and community organizations. The pilot is fully funded through foundation and grant support and the model for the pilot is based on similar programs in the United Kingdom that have been employed broadly throughout the country. For more information: <http://leadkingcounty.org/about/>.
- **Connecticut Department of Mental Health and Addiction Services:** Connecticut utilizes diversion team composed of one to three clinicians who attend court weekly to assist in the arraignments of individuals with mental illness. Clinicians are employees of local mental health centers, and receive daily arraignment lists to crosscheck for individuals who are recent or current clients of the clinic. The clinician conducts an assessment of individuals to establish medical history, symptoms, and current treatment needs. Individuals are then assessed for diversion by the judge, based on guidance from the diversion team and the seriousness of the charge. The clinician also prepares a treatment plan that is presented to the court on the day of the arraignment. Clinicians typically have to attest the individual's compliance and participation in treatment for them to remain part of the program. For more information: <http://www.ct.gov/dmhas/LIB/dmhas/publications/jaildiversion.pdf>.

The table on the following page provides resources for policymakers or organizations interested in establishing new programs or benchmarking best practices.

Guidance for Diversion Programs and Benchmarking Best Practices	
<b>SAMHSA GAIN’s Center for Behavioral Health and Justice Transformation:</b> Provides overview of jail diversion programs and references for implementing new programs	<a href="http://gainscenter.samhsa.gov/topical_resources/jail.asp">http://gainscenter.samhsa.gov/topical_resources/jail.asp</a>
<b>A Guide to Implementing Police-Based Diversion Programs for People with Mental Illness (2004):</b> by Melissa Reuland, published by the TAPA Center for Jail Diversion. This document describes in detail CIT programs and other models for pre-booking diversion programs.	<a href="http://gainscenter.samhsa.gov/pdfs/jail_diversion/PERF.pdf">http://gainscenter.samhsa.gov/pdfs/jail_diversion/PERF.pdf</a>
<b>Council of State Governments Justice Center – Mental Health Courts:</b> Provides training and resources for policymakers on developing and improving mental health court systems.	<a href="http://csgjusticecenter.org/mental-health-court-project/">http://csgjusticecenter.org/mental-health-court-project/</a>
<b>Massachusetts Department of Mental Health Pre-Arrest Law Enforcement Based Jail Diversion Programs Fact Sheet (2013):</b> Brief on Massachusetts’ experience implementing jail diversion programs.	<a href="http://www.mass.gov/eohhs/docs/dmh/forensic/idp-fact-sheet.pdf">http://www.mass.gov/eohhs/docs/dmh/forensic/idp-fact-sheet.pdf</a>

4. Expand treatment to incarcerated individuals by providing Suboxone® to individuals who will be in prison for more than a short period and making medication-assisted treatment (MAT) available to individuals who are waiting for sentencing.

The vast majority of prisons in the United States do not offer methadone or Suboxone® to drug abusing offenders experiencing addiction or dependence, despite the evidence of cost-effectiveness for these therapies and the risks for recidivism or overdose for individuals who go without treatment.

The following resources and guidelines are available for policymakers interested in establishing evidence-based opioid dependence treatment for criminal justice populations:

- The National Institute on Drug Abuse (NIDA): Principles of Drug Abuse Treatment for Criminal Justice Populations – a Research-Based Guide  
<http://www.drugabuse.gov/publications/principles-drug-abuse-treatment-criminal-justice-populations/principles>

- SAMHSA: Substance Abuse Treatment for Adults in the Criminal Justice System (Treatment Improvement Protocol 44): <http://store.samhsa.gov/product/TIP-44-Substance-Abuse-Treatment-for-Adults-in-the-Criminal-Justice-System/SMA13-4056>
- The KEEP Program at Rikers Island, New York: <http://www.wmich.edu/evalctr/wp-content/uploads/2012/08/KEEP-Methadone.pdf>

## 5. Avoid indiscriminate use of naltrexone in individuals exiting the corrections system.

Although naltrexone has been recognized as an opportunity to support opioid-dependent individuals at risk for relapse who are exiting the controlled environment of the corrections system, it should not be used indiscriminately in this population. Many individuals who are believed to be opiate-free are not, and some individuals that exit incarceration with Vivitrol<sup>®</sup>, injectable naltrexone, are likely to never return to treatment and will be at higher risk for overdose.

Guidance on the appropriate use of naltrexone, including Vivitrol<sup>®</sup>:

Appropriate Use of Naltrexone	
<b>American Psychiatric Association (2010)</b> <a href="http://psychiatryonline.org/pdfaccess.ashx?ResourceID=243188&amp;PDFSource=6">http://psychiatryonline.org/pdfaccess.ashx?ResourceID=243188&amp;PDFSource=6</a>	The APA clinical guidelines recommend naltrexone as a maintenance agent as it is highly effective in blocking heroin and other short-acting opioids. Retention in treatment is generally poor and has a high risk of relapse. As such, the APA states that though naltrexone is typically underutilized, the treatment option has higher efficacy with motivated patients who are participating in ancillary substance abuse services such as counseling. Voucher incentives appear to improve adherence to naltrexone treatment.
<b>National Institute on Drug Abuse (2012)</b> <a href="http://www.drugabuse.gov/sites/default/files/podat_1.pdf">http://www.drugabuse.gov/sites/default/files/podat_1.pdf</a>	NIDA considers naltrexone typically to be associated with poor patient compliance, and therefore has limited effectiveness in the treatment of opioid dependency. However, the guidelines suggest that Vivitrol <sup>®</sup> appears to be an effective alternative for those unable to or undecided on whether to use agonist treatment.
<b>Substance Abuse and Mental Health Services Administration</b> <a href="http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf">http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf</a> (2004) <a href="http://adaiclearinghouse.org/downloads/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs-51.pdf">http://adaiclearinghouse.org/downloads/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs-51.pdf</a> (2006)	Patients must be fully withdrawn for up to two weeks before beginning naltrexone maintenance treatment. Naltrexone is particularly effective among subgroups with strong psychosocial supports, including health care professionals, business executives, younger patients, and patients involved in the criminal justice system.

# Care Coordination and Efficient Allocation of Resources

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Policymakers and treatment centers in New England are considering ways to allocate resources more effectively to manage the growing numbers of opioid-dependent patients. Coordinated care systems are needed that triage patients entering treatment to the level of care most appropriate for their individual needs in order to support patient-centered treatment and allow for more capacity in the system.

## 6. Develop coordinated care networks in which patients receive short-term intensive outpatient care until stabilized, and then are referred to other outpatient practices for supportive services and MAT in primary care settings or community-based practices.

Policymakers, provider organizations, and health insurers each have an important role to play in establishing coordinated care networks that connect patients to the appropriate level of care based on each individual patient's unique circumstances and treatment needs. As ACOs and global payment systems become more prominent, payers should ensure funding that adequately supports addiction services. Consideration should be given to innovative payment models and coordination of care to integrate addiction services. Vermont is one of the states implementing this model on a state-wide basis, as described below.

### ***Policy/Practice Option: Vermont "Hub and Spoke" Model***

Vermont is employing a coordinated system-wide model for triaging patients with opioid dependence to appropriate levels of care. The goal for this model is to support patient-centered treatment while more effectively distributing resources to allow for greater capacity in the system. Called the "Hub and Spoke" model, this system makes use of specialty treatment centers ("hubs"), as well as federally-qualified health centers, patient-centered medical homes, and other practices with physicians licensed to prescribe Suboxone® ("spokes"). Patients begin treatment for opioid dependence centrally at the "hub," where they receive a period of intense treatment composed of comprehensive assessment, MAT, and other supportive services for an initial stabilization period. Once stabilized, patients are referred outward to a "spoke" for ongoing care and maintenance with Suboxone®. Clinically complex patients may continue to receive care at the "hub," or are referred elsewhere for inpatient or rehabilitation services if more intensive care is deemed appropriate. Stable patients receive ongoing care at the "spoke," which typically involves a prescribing physician, nurse, case manager, and counselor-led care team that monitors treatment adherence, provides counseling, supports contingency management, and coordinates patient access to other recovery supports as needed. Alternatively, if patients become "unstable" at a "spoke," they can be referred to a "hub" for stabilization. This prevents patients from losing treatment by being dropped by the "spoke" physician for illicit drug use. The "hub" can stabilize patients so they can maintain MAT and if warranted transition back to the "spoke." This model is being implemented in stages and additional improvements are needed, as the average spoke maintains a small number of patients and not all licensed physicians are prescribing to capacity.

For more information: <http://www.healthvermont.gov/adap/documents/HUBSPOKEBriefingDocV122112.pdf>

# Medical Policy

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Insurance coverage policies for the management of opioid dependence that support efficient, effective clinical practice and provide enough flexibility to help clinicians appropriately support the care needs of a diverse group of patients are critical.

Action steps to consider include:

## 7. Reconsider medical policies that require treatment plans to provide counseling in order for patients to receive MAT.

State and health insurer medical policy often require that treatment plans meet certain criteria for counseling in order for patients to receive MAT. Though social supportive services are critical for many patients, the decision for counseling should be individual rather than a blanket requirement. Moreover, since there are not enough counselors to serve every patient with addiction, these policies may potentially “bottleneck treatment” and serve as an additional barrier to care.

## 8. Institute efficient prior authorization processes for Suboxone® and Vivitrol® to achieve intended policy goals while minimizing the burden to patients, clinicians, and pharmacists.

Strict prior authorization criteria establish an additional layer of regulation that many stakeholders feel create another barrier to treatment. At present, some payers require prescribing physicians to call in patient information and answer a series of questions that some clinicians interviewed feel could easily be addressed through fax. Though prior authorization requirements have validity to ensure quality prescribing, they often ultimately serve as another obstacle to providing high quality treatment. Many patients wait until they are down to one or two pills before refilling their prescription, and prior authorization requirements mean that some patients are unable to receive their medication when needed. Payers may consider providing “fast-track” prior authorization processes for reliable prescribers. Doing so would allow those with a history of high quality prescribing to treat patients as efficiently as possible, while keeping in place safeguards for prescribers with less experience. Examples of regional private payers who do not require prior authorization for Suboxone® include Blue Cross Blue Shield of Vermont, ConnectiCare, and Harvard Pilgrim Health Care.

## 9. Individualize medical policy for dosing and tapering to the extent possible.

Insurers and providers share the burden of balancing concerns for diversion with the desire to provide a dose high enough to ensure a patient does not experience withdrawal and drop out of treatment. No standardized approach for dosing (or tapering) will work for all patients, and therefore the level at which patients receive medication must be individualized. Mechanisms to facilitate rapid consideration of requests for dosing beyond established dosing limits should be instituted.

## 10. Exempt certain patients from meeting specific coverage criteria for MAT, such as patients with long histories of successful maintenance therapy.

Some coverage criteria, such as regular urine testing for patients with long histories of successful maintenance therapy, may serve as deterrents to care. Strict protocols and regular testing are important in the initial phases of treatment, but they reinforce the stigmatization of opioid-dependent patients by requiring ongoing monthly testing of individuals who have been stable on treatment for many years. Payers should therefore consider exemptions for some patients from specific coverage criteria.

Given concerns for patient safety when taking MAT, many clinicians support policies for compliance monitoring and random “call backs” to prevent abuse and diversion. (“Call backs” refers to the practice of randomly selecting patients with take-home medication privileges to return to clinic and present the medication dose in its original bottle.) Mechanisms that allow exempting some patients demonstrating long-term adherence to treatment may support long-term treatment success.