



# Considerations When Implementing Medication-Assisted Treatment for Opioid Dependent Patients

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## The Opioid Problem

Our communities across the nation are flooded with opioid prescriptions, with the Centers for Disease Control and prevention reporting that over 214 million opioids were prescribed in 2016 (Figure 1).<sup>1</sup> This excess of prescriptions has resulted in the current opioid crisis, where it is estimated that, in 2016, at least 2.1 million people were living with an opioid dependency,<sup>2</sup> while only 374,000 individuals sought treatment.<sup>3</sup> Current laws aim to reduce opioid prescriptions, but do not address treatment solutions. Recent expansion of Suboxone®/buprenorphine waived physician capacity limits, as well as state laws encouraging medication-assisted treatment (MAT), are shifting treatment into clinical settings, but a shortage of providers continues to limit patients' access to recovery services.

## Financial Impact of the Opioid Crisis

It is estimated that in 2016, the annual potential economic benefit of eliminating the opioid crisis added up to \$95.3 billion (Figure 2).<sup>7</sup> Taking action by investing in addiction treatment programs will provide both economic and social benefits. For example, it is estimated that every dollar invested in addiction treatment programs can produce economic savings of \$4 to \$7 in reduced drug-related crime, criminal justice costs, and theft.<sup>8</sup> Total savings can top costs by a ratio of 12 to 1 when health care related savings are included.<sup>8</sup>

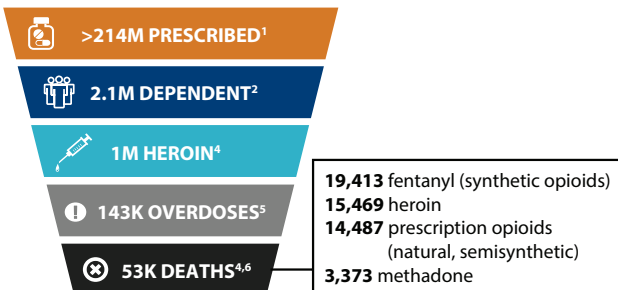
## The Importance of Expanding Medication-assisted Treatment

With the current shortage of providers qualified to administer MAT, it is critical to focus on ways to encourage physicians to apply for Suboxone®/buprenorphine waivers, and provide solutions that can help physicians expand patient care in their local communities. In 2016, there were almost 1 million active licensed physicians in the US,<sup>9</sup> but only 50,000 providers are currently approved to provide MAT.<sup>10</sup>

In order to maintain a Suboxone®/buprenorphine waiver, physicians must meet Substance Abuse and Mental Health Services Administration (SAMHSA) requirements including review of the state controlled substance database,<sup>13</sup> randomized urine drug testing,<sup>13</sup> and the capability to refer patients to counseling.<sup>14</sup>

Figure 1<sup>1</sup>

### OPIOID CRISIS ANNUAL STATISTICS\*



\*Statistics from available 2016-2017 data

Figure 2<sup>7</sup>

### 2016 Annual Economic Impact: \$95.3 Billion

Productivity - Fatal	\$43.2 Billion
Productivity - Nonfatal	\$12.4 Billion
Health Care - Overdoses	\$12.2 Billion
Health Care - Indirect	\$9.2 Billion
Criminal Justice	\$7.8 Billion
Child & Family Assistance	\$6.1 Billion
Education	\$4.4 Billion

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**Figure 3**

**To qualify for a Suboxone®/buprenorphine waiver, physician offices are required to:**

1. Currently registered with the Drug Enforcement Administration (DEA) to dispense controlled substances<sup>11</sup>
2. Register for a Buprenorphine Waiver<sup>11</sup> on the SAMHSA website, (<https://www.samhsa.gov>)
3. Complete Buprenorphine training (8 hours online or in-person)<sup>12</sup>
4. Establish Office Procedures for opioid use disorder treatment<sup>12</sup>
5. Assess a patient who has an opioid dependency<sup>12</sup> including relevant baseline laboratory testing
6. Develop a treatment plan based on the patient diagnosis<sup>12</sup>

**Policy Driven Guidelines For Drug Testing**

With the growing national concern regarding prescription drug dependency, some physicians may consider utilizing a screen-only (presumptive) drug test to evaluate patient drug use at the time of the office visit. When deciding upon laboratory testing, it is important to consider the individualized patient risk, payer policy coverage indications, and methodology-specific testing limitations as it relates to the individual patient situation. The decision to test must be based on medical necessity documented by the clinician, with test results used by the clinician to manage prescribing for the patient. Elements of medical necessity to be identified during clinical assessment and documented in the medical record should include the following:

- Patient history, physician exam and previous lab findings;
- Current treatment plan;
- Prescribed medication(s);
- Risk assessment plan.

**Comparing Point Of Care Testing vs Commercial Laboratory Performed Testing**

When deciding between different testing options, it is important to evaluate the method’s performance characteristics and implications for patient care. For example, point of care testing can provide immediate results during a patient visit, versus commercial laboratory performed testing. However, point of care testing often requires manual and subjective visual interpretation performed by physician staff, while commercial laboratory testing includes instrumented analysis and interpretation with the option to reflex to confirmation (definitive) testing based upon a physician’s request (Table 1). It is also important to consider that most point of care testing does not detect some drugs of abuse, including synthetic opioids such as fentanyl and fentanyl derivatives, synthetic cannabinoids (K2/Spice), cathinones (“bath salts”), kratom, and other drugs or analogues. These additional drugs of abuse may be detected using commercial laboratory performed testing based upon availability at the performing laboratory.

**Table 1**  
**Comparing Point Of Care Testing and Commercial Laboratory Performed Testing**

	Point of Care Testing	Commercial Laboratory Performed Testing
Test method	Screen (presumptive) immunoassays and enzymatic assays; typically visual read. Examples: point of care devices – cups, strips	Screen (presumptive) immunoassays and enzymatic assays, using spectrophotometric detection, with option to perform confirmation (definitive) mass spectrometry with chromatographic analysis including gas-chromatography mass spectrometry (GC/MS) and liquid chromatography tandem mass spectrometry (LC/MS/MS).
Typical results	Presumptive only, indicating presence (“positive”) or absence (“negative”) of a drug or drug class	Presumptive (presence or absence of a drug or drug class) and/or definitive, providing identification and/or quantitation of individual drugs and/or metabolites within the drug class
Features of Each Testing Methodology	Point of Care Testing	Commercial Laboratory Performed Testing
Option for results at point of care	Yes	No
Quantitative or qualitative results determined by analyzer instruments	No, typically manual visual interpretation performed by physician staff	Yes, with option to reflex to confirmation (definitive) testing based upon physician order request
Includes quality control measures to facilitate consistent assay performance	Internal device control for device performance; quality control for drug tests must be purchased separately	Yes, external quality control required for CLIA is standard with high quality commercial testing labs (including SAMHSA certified labs)
Access to technical laboratory experts to discuss result interpretation	No, physician staff is required to interpret results	Yes, when available through the commercial laboratory
Capability to transmit results via electronic health record	No, physician staff is required to record and enter results into EMR/EHR	Yes, when available through the commercial laboratory
Detects drugs/drug classes not available with point of care devices	No, requires sending additional testing to a commercial laboratory	Yes, when available through the commercial laboratory

**Table 2**  
**Considerations for Confirmation (Definitive) Testing Based On Screen (Presumptive) Test Results**

Drug/Drug Class	Overall performance of screen testing for MAT	Drugs within the class with potential of false negative	Other drugs outside of the class with potential of false positive*
<b>Amphetamines Methamphetamines MDMA</b>	Potential for false positives due to cross-reactivity with non-amphetamine compounds	Methylphenidate <sup>15</sup> (Concerta®, Ritalin®)	Bupropion <sup>15</sup> (Wellbutrin®), Ephedrine, <sup>15</sup> Pseudoephedrine, <sup>16</sup> Trazodone <sup>16</sup> (Desyrel®), Phentermine <sup>15</sup>
<b>Barbiturates</b>	Reliable, low frequency of non-prescribed use		
<b>Benzodiazepines</b>	Potential for false negatives with lorazepam and clonazepam	Lorazepam <sup>17</sup> (Ativan®), Clonazepam <sup>18</sup> (Klonopin®)	Sertraline <sup>16</sup> (Zoloft®)
<b>Buprenorphine</b>	Reliable for sublingual/ buccal formulations; thresholds are inadequate to detect transdermal formulations. When monitoring prescribed medications, unable to detect “pill scraping”		
<b>Cocaine</b>	Reliable, low potential for false positives		
<b>Methadone</b>	Moderate potential for false positives; when monitoring prescribed medications, unable to detect “pill scraping”		Tapentadol <sup>17</sup> (NuCynta®), Tramadol <sup>18</sup> (Ultram®)
<b>Opiates</b>	Reliably detects codeine, morphine, hydrocodone and hydromorphone; when monitoring prescribed medications, unable to identify a specific drug within the class and unable to detect “pill scraping”		Oxycodone – an opiate drug that has poor to little cross-reactivity with opiate drug class immunoassays. However, large amounts of oxycodone may result in positive results for some opiate class immunoassays.
<b>Oxycodone</b>	Reliably detects both oxycodone and oxymorphone; when monitoring prescribed medications, unable to detect “pill scraping”		Hydrocodone <sup>15</sup> – has been noted as a cross-reactant in some oxycodone class immunoassays.
<b>Phencyclidine</b>	Potential for false positives due to cross-reactivity with non-phencyclidine compounds		Dextromethorphan, <sup>16</sup> Diphenhydramine <sup>16</sup> , Venlafaxine <sup>16</sup> (Effexor®), Ketamine <sup>16</sup>
<b>Propoxyphene</b>	Reliable, low potential for false positives, low prevalence in the general population		
<b>THC</b>	Reliable, low potential for false positives	Synthetic cannabinoids (K2/Spice) <sup>15</sup>	
<b>Tricyclic Antidepressants</b>	Potential for false positives due to cross-reactivity with non-tricyclic antidepressant compounds	Non-Tricyclic Antidepressants <sup>15</sup>	Antihistamines, <sup>21</sup> Cyclobenzaprine <sup>15</sup> (Flexeril®)

\*Note: Drugs that cause false positive results vary by device and/or assay. Examples of drug brand names are indicated in parentheses next to the generic formulations. Drug names listed herein are registered trademarks of their respective owners.

When interpreting point of care test results or screen (presumptive) immunoassay results, it is important to understand the overall performance and limitations of the screen (presumptive) testing and whether it might be medically necessary to request confirmation (definitive) testing. There are several screening test performance measures that may be considered for a specific drug or drug class (Table 2).

For example, cocaine screen testing is very reliable with low potential of false positives, and unexpected positive results may not require confirmation (definitive) testing depending on corroborating factors. In contrast, buprenorphine screen testing is very reliable but cannot identify patients engaged in “pill

scraping” behavior, so positive screens may require confirmation (definitive) testing to identify presence and amount of the norbuprenorphine metabolite.

Physicians are responsible for evaluating test results compared to the prescribed medications and reported patient history, identifying if additional confirmation (definitive) testing may be warranted, and determining whether the lab results in conjunction with patient assessment may indicate a change in patient care and/or prescription status. It is important to consider the overall performance and limitations of point of care testing compared to laboratory-based analysis with associated expertise and capabilities in drug testing.

## Digital Solutions – Bringing Compliance To Recovery

Leveraging technological solutions can help physicians to adhere to SAMHSA requirements in order to continue prescribing Suboxone®/ buprenorphine as part of MAT for opioid use disorder (OUD) patients.

The Recovery Platform, available through LabCorp, is a digital electronic health record plug-in designed to monitor the progress of OUD recovery through a patient compliance dashboard and integrated digital capabilities. LabCorp is the exclusive national laboratory integrated within The Recovery Platform. The Recovery Platform allows physicians to

- Review details of a patient’s medical history
- Efficiently review patient progress over time utilizing centralized compliance data



## Physician Experience With The Recovery Platform

The Recovery Platform can allow physicians to increase productivity and improve overall patient care. Results from a 3-month pilot study<sup>22</sup> using The Recovery Platform showed a 59% decrease in average staff time per patient, which can result in more efficient workflow and increased productivity (Figure 4).

The study also found that 87% of patients were still in the practice care program. This indicates that The Recovery Platform could improve overall patient care by providing needed support and ease of use that enables patients with their recovery.

## Facilitating Collaborative Patient Care To Address The Opioid Crisis

Combining software designed to monitor a patient’s progress with appropriate laboratory testing can support compliance with MAT, and help patients with their recovery. Use of a digital solution such as The Recovery Platform can facilitate collaborative

Figure 4<sup>22</sup>

Standard workflow (before The Recovery Platform)	1.5 hours, including 1-on-1 counseling
Workflow using The Recovery Platform	0.6 hours, including 1-on-1 counseling
Time savings & productivity per patient visit	0.9 hours (59% decrease)

patient care by connecting each part of the care team ecosystem, including the physician, psychiatric consultants, counselors, laboratories, pharmacies, and state prescription drug monitoring program databases. Successful collaborative patient care can help benefit local communities and positively impact patient’s lives by addressing the opioid crisis.

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