Statement of Consensus on the
Proper Utilization of Urine Testing in
Identifying and Treating Substance Use Disorders

Final Report

October 2015

I. Executive Summary

In February 2014, a diverse group of experienced addiction treatment professionals, with support from the American Society of Addiction Medicine (ASAM) and the Center for Lawful Access and Abuse Deterrence (CLAAD), conducted a project to develop professional consensus on the proper utilization of urine drug testing in identifying and treating substance use disorders (SUDs). The consensus project was necessitated by a general lack of clinical knowledge, concerns related to unethical behaviors, and the emergence of ill-advised cost-saving measures, which have created confusion and imbalances in the utilization of urine drug testing services. Intended as a resource for clinicians in any health care practice area, this report documents the clinical consensus in an area of medicine in which no clinical consensus otherwise exists. Its purpose is to inform and enhance clinical practice and patient outcomes. While some attention is paid to cost, clinical care was the primary driving factor for the recommendations contained herein.

This report details the development of the project, its methods, results, and a statement of professional consensus on advisable clinical practices. The report is the product of extensive literature review; collaboration; a full-day facilitated, in-person expert panel meeting; several consensus group conference calls; and eighteen months of discussion among panelists.

II. Introduction

This report describes the project “Proper Utilization of Urine Testing in Identifying and Treating Substance Use Disorders.” The purpose of this project was to:

- Identify current issues and outstanding questions regarding the proper utilization of urine drug testing.
- Utilize a panel of experts to ascertain advisable urine drug testing practices, based on published research and clinical experience, for use by any clinician caring for people with SUDs.
- Present this consensus to practitioners, payers, and providers to optimize care and enhance the effectiveness of the clinical treatment system.

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1 The use of diagnostic testing in treating patients with SUDs is ultimately within the treating physician’s professional judgment.
III. Background

A. Summary of the Issue

The bounds of medical necessity of urine drug testing in addiction medicine and other clinical settings are currently being defined.\(^2\) When utilized and interpreted correctly, urine drug testing can provide objective data that health care practitioners may employ in the diagnosis, active treatment, and chronic care management phases of addiction treatment. Determining the proper test method and interpreting urine drug testing results are complicated endeavors, and mistakes can yield serious consequences for patients.

Until now, there has been no clinical consensus on urine drug testing to identify and address substance use. Lack of clinical knowledge, unethical ordering and billing practices, and ill-advised cost-saving measures have created confusion and imbalances in the utilization of urine drug testing services. To improve the utilization of these services, it is necessary for clinicians to increase their knowledge of best practices in urine drug testing emanating from the field of addiction medicine. Given that costs influence patients’ and practitioners’ decision making, third-party payers and policy makers in charge of coverage and reimbursement decisions must also better understand the purposes, proper utilization, and benefits of testing for substance use.

As used herein, the term “substance use” includes the consumption of an illicit substance or an analog thereof,\(^3\) nonmedical or non-prescribed use of prescription medication, and alcohol abuse.\(^4\)

B. Development of the Project

In January 2014, representatives of the addiction treatment industry agreed on the pressing need for clinical and policy leadership on this issue and resolved to share resources to develop consensus on advisable practices in testing for substance use. Alere Toxicology, Dominion Diagnostics, and Millennium Laboratories provided unrestricted educational grants to

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\(^2\) Owen GT, Burton AW, Schade CM, Passik S. Urine drug testing: current recommendations and best practices. *Pain Physician*. 2012; 15: ES119-ES133. In certain clinical situations beyond the scope of this paper in which urine testing is inappropriate, blood testing or testing of oral fluids may be suitable substitutes.

\(^3\) Analogs are psychoactive drugs developed by replicating or slightly modifying existing drugs of abuse. As used in this article, “analogs” include “synthetics” and “designer drugs.”

\(^4\) The term “substance use” here is synonymous with ASAM’s definition of “nonmedical drug use,” which includes the “use of an illicit drug or the use of a prescribed medicine for reasons other than the reasons intended by the prescriber, *e.g.*, to produce positive reward or negative reward. Nonmedical use of prescription drugs often includes use of a drug in higher doses than authorized by the prescriber or through a different route of administration than intended by the prescriber, as well as for a purpose other than the indication intended by the prescriber (for example, the use of methylphenidate prescribed for Attention Deficit Hyperactivity Disorder [ADHD] to produce euphoria rather than to reduce symptoms or dysfunction from ADHD).” Drug testing: a white paper of the American Society of Addiction Medicine (ASAM). American Society of Addiction Medicine (ASAM) Web site. Available at: http://www.asam.org/docs/default-source/publicy-policy-statements/drug-testing-a-white-paper-by-asam.pdf?sfvrsn=2. Published October 26, 2013. Accessed October 9, 2015.
support this endeavor. Andrea Barthwell, M.D., FASAM planned and executed the project as the executive secretary.

C. Purpose of the Consensus Statement

This report provides clinically relevant information that clinicians may use to familiarize themselves with urine drug testing to identify and treat SUDs. The information discussed herein is based on research and the collective views of various health care practitioners and academics, including licensed physicians, professors of clinical medicine and psychiatry, licensed pharmacists, physician assistants, nurse practitioners, and other professionals. The intended audiences for this report are health care practitioners, including substance use treatment providers, as well as public and private insurance providers and policy makers. Law enforcement officials, prosecutors, judges, and employers may also benefit from familiarity with principles for urine drug testing to identify and address substance use in the health care setting.

D. Methods

The consensus set forth herein was developed based on input from a diverse panel of independent, multidisciplinary experts who convened and reviewed research literature for the purpose of advancing the understanding of urine drug testing in addiction medicine. ASAM and CLAAD compiled a list of potential expert panel members. Dr. Barthwell then invited the experts to participate as advisors on the panel and offered honoraria for their support. The individuals who participated in the consensus panel are listed in Appendix 1.

Participants were provided with 17 resources to review in preparation for the consultative meeting. These documents are listed in Appendix 2. The expert panel meeting took place in West Palm Beach, FL on February 21, 2014 from 8:00 a.m. to 5:00 p.m. The meeting agenda may be found in Appendix 3.

The initial review of literature formed the basis of preliminary recommendations that the executive secretary presented to the panel of experts. Through moderated discussions, the expert panel developed a consensus around three common scenarios: 1) a clinician in any field of medicine using urine drug testing to identify and assess substance use; 2) a clinician in addiction medicine using urine drug testing to provide treatment to a person with an SUD; and 3) a clinician in addiction medicine using urine drug testing to provide chronic care management to a person with an SUD in remission.

Participants were afforded the opportunity to review and revise this document over the course of over eighteen months, from April 2014 through September 2015.

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5 These companies provided monetary support for the development and execution of this project, but did not contribute to or influence the recommendations of the panel, either through representation on the panel, or otherwise.
IV. Substance Use Tests

In the diagnosis and treatment of SUDs, urine tests are used to identify substance use early in disease progression, help assess etiology of unexplained symptoms, formulate and implement a care plan, evaluate the effectiveness of the treatment regimen, monitor for treatment compliance, and track the course of an SUD over time. All health care practitioners seeking to identify or treat substance use should familiarize themselves with the proper utilization of urine drug testing, including urine tests.

A. Methods of Testing

Urine tests for substance use are categorized in accordance with the science underlying them: immunoassay and chromatography-mass-spectrometry. Immunoassays are based on the ability of an antibody to bind with a specific analyte. These different technologies have varied specificity (i.e., the test’s ability to identify specific substances (parent drugs and metabolites) within a substance class and can detect the presence or absence of any specific substance, parent drug, or metabolite), sensitivity (i.e., the test’s ability to reliably detect the presence of a substance in low concentrations), and capabilities to detect controlled substances and metabolites. In order to select the test most suitable to the individual patient’s needs, clinicians must be aware of differences in test technology, complexity, accuracy, and speed of results. Clinician training is especially important given that inaccurate urine test results can potentially impart a false sense of security or a false sense that a patient has engaged in some wrongdoing.

1. Presumptive Tests

Immunoassay tests, referred to herein as presumptive tests, are based on the ability of an antibody to bind with a specific analyte or class of analytes. Presumptive tests are used to indicate the presence or absence of a class of substance, a few specific substances, or their metabolites based on a cut-off value. A positive test result is reported when the concentration of drug is present above the cutoff; a negative is reported when the concentration of drug is below the cut-off. Negative test results do not necessarily indicate the absence of a drug or substance in the urine specimen.

The clinicians should be aware of the limitations of presumptive tests and select the test based upon their clinical fact finding and the degree to which they can act on presumptive information. Presumptive tests have low specificity and low sensitivity. Given that presumptive

tests screen for drug classes rather than specific drugs, the practitioner may not be able to
determine whether a single drug or multiple drugs within the same class are causing the positive
result. Presumptive tests are unable to identify specific drugs within many drug classes,
particularly within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants, and
opiate/opioid drug classes. Additionally, presumptive tests may return false positives. False
positives occur when a substance is detected by the test, but is, in fact, absent.

Cross-reactivity with other compounds or inability to distinguish among drugs within a
class may lead to erroneous results. Another limitation is that not all prescription medications or
analog drugs are detectable or have assays available. A false negative result will occur when the
predetermined cut-off value is higher than the actual concentration of the substance in question.

Drugs such as buprenorphine, amphetamines, benzodiazepines, cocaine, and heroin often
yield false negative results when using presumptive test technology due to low cross-reactivity or
non-reactivity, and drugs such as fentanyl, carisoprodol, tramadol, tapentadol, and synthetic
designer drugs cannot be detected by presumptive tests. As such, a negative result does not rule
out the presence of an undetected analyte.

Any of these reasons could cause a practitioner to make a wrong assumption or clinical
decision. Therefore, it may be medically necessary for clinicians to utilize chromatography-
mass-spectrometry tests with lower cut-off levels when the presumptive tests for these drugs are
negative.

2. Definitive Tests

Chromatography-mass-spectrometry tests, referred to herein as “definitive tests,” identify
the presence of a specific drug, its metabolite, or illicit substance by measuring the quantity of
the analyte (molecule) in the specimen. Chromatography separates analytes by their valence or
other physical properties so that they can be independently identified, and mass-spectrometry
ionizes chemical compounds to generate charged molecules. Mass spectrometry techniques are
divided into two methods: gas chromatography-mass spectrometry (GC-MS) and liquid
chromatography-tandem mass spectrometry (LC-MS/MS). Identification is based on the drug’s
unique specific mass and breakdown in the same way that each person has a specific
fingerprint.

Definitive tests typically have high sensitivity and specificity. Given that definitive tests
are drug specific, accurate, and reliable, they are often used to validate results for presumptive

10 Kirsh KL, Heit HA, Huskey A Strickland J, et al., Trends in drug use from urine drug testing of addiction
11 Substance Abuse and Mental Health Services Administration. Substance abuse: clinical issues in intensive
outpatient treatment, A Treatment Improvement Protocol (TIP) 47.2006; 47:1-267.
12 Pesce A, West C, Egan-City K, Clarke W. Diagnostic Accuracy and Interpretation of Urine Drug Testing for Pain
13 Your laboratory can let you know the cut-off levels and related validation standards for each specific substance
requested.
Definitive testing can detect drugs with low cross-reactivity or non-reactivity that presumptive methods cannot detect, such as buprenorphine, amphetamines, benzodiazepines, and illicit substances, such as cocaine and heroin. Furthermore, definitive testing is useful for the detection of drugs such as fentanyl, carisoprodol, tramadol, tapentadol and synthetic designer drugs that are not detected by presumptive methods or for which no presumptive test is available.

Definitive testing is reasonable in the following circumstances:

- To identify specific drugs within a drug class;
- To identify a specific substance or metabolite that is not detected or is inadequately detected by a presumptive test, such as fentanyl, meperidine, synthetic cannabinoids, and other analog drugs;
- When a definitive concentration of a drug is needed to guide management (e.g., discontinuation of THC use according to a treatment plan);
- When a presumptive test result is inconsistent with a patient’s self-report, presentation, medical history, or current prescribed medication plan;
- To identify non-prescribed medication or illicit substance use for ongoing safe prescribing of controlled substances;
- Rule out an error as the cause of a presumptive UDT result; and
- For use in a differential assessment of medication efficacy, side effects, or drug-drug interactions.\textsuperscript{15}

The clinician must decide which technology and method to use depending upon the information she needs and the goal she is trying to achieve clinically. Definitive testing may be reasonable and necessary based on patient-specific indications, including historical use, medication response, and clinical assessment, when accurate results are necessary to make clinical decisions. The clinician’s rationale for the definitive test and the analytes ordered must be documented in the patient’s medical record.

\textbf{B. Terminology}

Confusion exists among clinicians, payers, policy makers, and patients as to the terminology used to describe the distinct methods of urine drug testing. The table below presents some of the terms commonly used to refer to presumptive and definitive testing.


### Presumptive vs. Definitive

<table>
<thead>
<tr>
<th>Presumptive</th>
<th>Definitive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary</td>
<td>Confirmatory</td>
</tr>
<tr>
<td>Imunoassay</td>
<td>Chromatography– Mass Spectrometry</td>
</tr>
<tr>
<td>Qualitative</td>
<td>Quantitative</td>
</tr>
<tr>
<td>Point-of-care / in-office / lab-based Screen</td>
<td>In-office / lab-based Confirmation</td>
</tr>
<tr>
<td>Semi-quantitative / quasi-quantitative Simple test (cup / strip / dip / cassette)</td>
<td>Absolute level, creatinine corrected Complex test</td>
</tr>
<tr>
<td>Class of or specific drug identification</td>
<td>Specific drug identification</td>
</tr>
</tbody>
</table>

### C. Timing

The length of time it takes to obtain test results varies based on whether the sample is sent to the laboratory. Whether the test is presumptive or definitive, if done in a reference laboratory, it may take 24 to 72 hours to obtain the reported results.

Presumptive tests done during the patient encounter may be used for immediate results, which can be incorporated into therapeutic interventions.\(^\text{16}\) Results may be available within minutes;\(^\text{17}\) however, the benefit of faster results can be outweighed by detriments to care if treatment decisions are based on rapid but incomplete, less accurate information obtained from presumptive testing.\(^\text{17}\)

### D. Sample Integrity Checks

Sample integrity checks, also referred to as specimen validity tests, are used to determine whether a urine specimen is consistent with normal human urine or if it has been adulterated by dilution or other chemical methods, or substituted to obtain a particular result. In SUD diagnosis and treatment, sample integrity checks may be medically necessary when a provider suspects that a patient may have tampered with a urine sample,\(^\text{18}\) or may want to hide substance use, and may be viewed as a behavioral indicator reflective of the patient’s intent to deceive the clinician.

Presumptive tests can be altered through adulteration to obtain a result that would hide drug use. Definitive tests can detect analytes present in diluted specimens. Therefore, if a sample integrity check is performed concurrently with a definitive test, the clinician will be informed not only of whether the sample has been diluted or adulterated, but whether the analyte of interest is present.

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E. Substances Selected for Testing

Clinicians select the particular analytes to be tested based upon medical necessity. A test menu is a list of substances or classes of substances, including tobacco, alcohol, prescription medications, and illicit substances, that a clinician may choose and test for in a urine specimen.\(^\text{19}\) A test selection is a set of substances that a clinician chooses from a test menu and tests for in a urine specimen.

F. Method Selection and Need for Accuracy

Testing for substance use has the ability to change the course of a patient’s disease and recovery. It is imperative to be able to accurately detect use in order to assure an objective therapeutic relationship, and modify the treatment plan to reflect the patient’s unique needs. Testing is a part of the patient evaluation and should not be considered as the sole determinant for treatment.

False positive results can substantially harm patients who are not using substances by subjecting them to unjust suspicion and accusations, alterations to the treatment plan, and the deterioration of the provider-patient relationship.\(^\text{20}\) False negative results may give a clinician misplaced confidence that substance use is not occurring, cause misdiagnosis or diagnostic delay, and reinforce aberrant drug-related patient behaviors, which, in turn, may lead to inadequate treatment outcomes, overdoses, or death.\(^\text{20}\) False negatives may also lead to inappropriate or unsafe prescribing, increased potential for drug interactions, and untrue allegations of medication diversion.

Some Presumptive tests are only 50 to 70 percent as accurate as definitive tests.\(^\text{10}\) Presumptive testing for opiates has been documented to inaccurately report some 30 percent of positive results and 22 percent of negative results.\(^\text{10}\) False positive rates for presumptive tests can range from a low of 11 percent for benzodiazepines to a high of 100 percent for PCP.\(^\text{10}\) False negative rates for presumptive tests can range from a low of 0 percent for PCP to a high of 50 percent for MDMA (3, 4-methylenedioxy-methamphetamine).\(^\text{10}\)

While this document sets forth consensus recommendations, the clinician must ultimately select the method—presumptive or definitive—based upon the medical goals and intended use of the test. Clinicians should ascertain the specific information they want to obtain from testing based on the patients’ needs and should choose the test that can provide information on the particular drugs, metabolites, and illicit substances they want to detect or quantify. The clinician should be familiar with the capabilities and limitations of the different test methods, type of results each method provides, and cost of the test before making the final decision.

V. Testing Stratified by Stages of SUD Care

With greater information on urine drug testing, clinicians can learn to make a proper determination of the appropriate urine testing methods to employ throughout the diagnosis, active treatment, and chronic care management stages of care.

A. Diagnosis of SUDs

Routine clinical screening is a preventative service in which a practitioner uses standardized tools to indicate whether the patient is likely using substances or prescribed medications. Urine drug testing can be used as part of the routine clinical screening process to evaluate whether a patient is at risk for or has already manifested substance use, and to assess what type of intervention or treatment, if any, is appropriate.

B. Active Treatment of SUDs

Urine drug testing in the management of those with SUDs is often an integral part of the treatment plan and can act as an external locus of behavioral control until a patient can establish his internal locus. It allows the ordering clinician to monitor the course of the disease over time as well as the patient’s adherence to and progress on his prescribed treatment regimen.

C. Chronic Care Management of SUDs

A practitioner may use urine drug testing to continue to monitor the patient after active treatment has ended to determine whether the patient is at risk for or has relapsed, and to alert the practitioner that he should encourage the patient to recommit to recovery. Urine drug testing continues to act as an external locus of control.

VI. Consensus

The points that follow emerged as the consensus from the experts’ deliberations during the consultative meeting. They constitute suggestions for the clinical utilization of urine drug testing in various medical settings and treatment stages based on the panel’s collective opinions. They may serve as a reasonable starting point for the appropriate use of urine drug testing in identifying and treating SUDs, but should not be regarded as guidelines.

The experts’ areas of consensus are organized into categories:

- General;
- Diagnosis of SUDs in All Settings;
- Active Treatment for SUDs;

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22 Comprehensive information on the principles and practice of addiction medicine may be found in the publications of the American Society of Addiction Medicine, such as Principles of Addiction Medicine, available at www.asam.org/publications.
• Chronic Care Management of SUDs; and
• Test Selection.

A. General

• Urine is the specimen of choice when testing for substance use (with the exception of alcohol) because it is easy to collect, requires no pre-analytical preparation, is relatively affordable, and provides timely results. Alcohol testing is not available by presumptive tests, but can be detected in urine with definitive tests of metabolites EtG and EtS. Definitive urine drug testing for alcohol metabolites is sometimes advisable, but to rapidly detect alcohol use at the time of a patient encounter, breath tests are preferred. A definitive test of alcohol metabolites EtG and EtS can detect use for days after ingestion.

• A clinician interested in detecting every incidence of a patient’s substance use should look to tests’ detection capabilities and windows of detection to determine the frequency of testing and test methods to assure detection of specific substances.

• Clinicians should use the urine drug test method likely to detect the analytes to be tested.

• Cutoff concentrations and error rates should be low, so that any substance may be detected.

• Substance use test selections should be individualized to the patient based on the patient’s history, prescribed medications, substances of common use in the patient’s peer group, and circumstantial considerations, such as the introduction of a substance into a treatment setting.

• All ordering clinicians performing urine drug testing should obtain proper training and education on how to select, administer, and interpret substance use tests. If this is not possible, clinicians should collaborate with their lab toxicologists or the results should receive an expert medical review or consultation with the laboratory toxicologists.

• Sample integrity checks are medically necessary to identify deceptive patient

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24 Urine testing for alcohol provides a greater window of detection than breath tests, which are only reliable for approximately four to six hours after alcohol use. Ethyl glucuronide (EtG) and ethyl sulfate (EtS) are the most commonly used urine tests to detect alcohol use. EtG is sensitive to incidental alcohol exposure and is synthesized by bacteria in vivo. Therefore, it requires clinical review of exposures and correlation to the patient’s historical performance in treatment. Both tests provide a window of detection for approximately two to three days but can last up to six days depending upon the amount that was consumed. Helander A, Böttcher M, Fehr C, Dahmen N, Beck O. Detection times for urinary ethyl glucuronide and ethyl sulfate in heavy drinkers during alcohol detoxification. Alcohol and Alcoholism. 2009 Jan-Feb; 44(1): 55-61. EtG alcohol test – urine. Forensic DNA & Drug Testing Services Web site. http://www.forensicdrugtesting.net/alcohol-tests.html Accessed January 30, 2014.
behaviors and should be conducted as necessary when the clinician is assessing for or suspects the patient is concealing substance use.

- If a practitioner does not take steps to properly diagnosis or monitor his or her patient’s conditions, he may be found civilly or criminally liable. Urine drug testing at appropriate frequency reduces risk to the patient. A patient’s overdose or even death could be avoided by conducting a substance use test, which would indicate the need to assess whether addiction treatment or a change in the course of treatment is necessary.

B. Diagnosis of SUDs in All Settings

1. Principles to Aid in the Diagnosis of an SUD in General (unknown history or risk)

- Although evidence of substance use alone is insufficient to substantiate that an SUD is present, urine drug testing can be a key component of the initial assessment process when evaluating for a possible diagnosis of an SUD.

- Universal and routine clinical screening eliminates racial and socioeconomic profiling and stigma associated with screening for substance use and is consistent with federal policy, which recommends Screenings, Brief Interventions, and Referrals to Treatment (SBIRT) for early substance use identification, intervention, and treatment engagement.

- Universal and routine clinical screening for substance use, including a consideration of urine drug testing, should be conducted in various health care settings, including primary and urgent care, pain, addiction, psychiatry, obstetrics, and peri-operative. It should be treated like any other routine aspect of a physical exam, reflective of the fact that anyone could develop an SUD at any time, regardless of apparent risk.

- Patients should be reviewed for substance use upon their first consultation with a practitioner and periodically thereafter depending on their indicators of risk and clinical findings, including test results.

- For individuals with one or more indicators of risk for substance use, presumptive tests that deliver results during the patient encounter should only be used when it is necessary to obtain more immediate, albeit less accurate, results due to specific


clinical indications. Otherwise, for individuals with one or more indicators of risk for substance use, the more reliable definitive tests should be employed. Indicators of risk are defined as characteristics of individuals or their environments that, when present, increase the likelihood that individuals will develop a substance use disorder. Indicators may include such factors as a personal or family history of substance use, and the legitimate prescription of a controlled substance or other central nervous system drug. It should be noted that a prior diagnosis of an active SUD is more than an indicator of risk given that an SUD is a life-long disorder and is managed according to the stage of care.

• If a patient exhibits no indicators of risk for substance use, the practitioner should take the following steps:
  o Consider conducting a presumptive test as part of the first consultation.
    ▪ If results indicate abstinence, consider testing again based upon the frequency of clinical contact, but no more than once annually, unless a change in patient presentation or risk indicates a possible SUD.
    ▪ If results indicate use, conduct a definitive test.
      ♦ If results confirm use, intervene and establish a treatment plan, as necessary.
      ♦ If the results suggest abstinence, speak with the patient, and if it is possible to rule out a diagnosis of substance use, test the patient again based upon the frequency of consultations but no more than once per year.
      ♦ If the results suggest abstinence but, after speaking with the patient, it is not possible to rule out a diagnosis of substance use, assess the patient’s indicators of risk to determine how best to proceed.

• If the patient exhibits one or more indicators of risk for substance use, the practitioner should take the following steps:
  o Conduct a definitive test.
    ▪ If test results indicate abstinence, test the patient again within 12 months.
    ▪ If within 12 months there is a change in patient presentation or additional risk indicates a possible SUD, test again.
  o If test results indicate use, intervene and establish a treatment plan, if necessary.

2. Principles for Diagnosis in Women Who Are or Could Be Pregnant

• Care should be used to avoid further stigmatization of women with SUDs who are, or could be pregnant, emphasizing the routine nature of clinical screening and

that testing is for therapeutic purposes rather than for punitive purposes. By universally testing all patients, practitioners avoid profiling women who are or could be pregnant, in particular.

- Treatment during pregnancy can reduce fetal harm caused by drug exposure, whereas failing to obtain treatment generally leads to the mother continuing to use the substance of abuse and, unfortunately, may result fetal risk for Neonatal Opioid Withdrawal Syndrome, loss of custody, or termination of parental rights in many states.\(^{28}\) **Practitioners should obtain consent from women who are or could be pregnant, should explain the reasons for and consequences of urine drug testing before conducting a test, and should take care to keep test results confidential to the extent permitted by law.**

- Practitioners must make certain that their patients who are or could be pregnant abstain from using non-prescribed substances in order to avoid harm to the fetus.\(^ {29}\)

- Women who are using substances of abuse or non-prescribed medications may not realize they are pregnant.\(^ {30}\) At times, women may mistakenly associate early signs of pregnancy as symptoms related to use or withdrawal from certain substances.\(^ {30}\) Some of the most negative effects of substance use on the developing embryo can occur in the first weeks of pregnancy.\(^ {30}\) Timely identification of substance use and initiation of treatment is, therefore, crucial among women who could be pregnant.

- A clinician interested in detecting every incidence of a patient’s substance use should look to tests’ capabilities and windows of detection to determine the frequency of testing and test method to assure detection of specific substances.

- Practitioners caring for women who are or could be pregnant must test for any substance – at any concentration level – that may threaten the health of a newborn, using definitive tests.

- If the patient is a woman who could be pregnant, the practitioner should take the following diagnostic steps:

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\(^{29}\) Maternal substance use during pregnancy can threaten the health and life of a newborn. For example, neonatal opioid withdrawal syndrome (NOWS) can occur in a newborn exposed to opioids while in the mother’s womb. NOWS may be life-threatening. FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. Food and Drug Administration Web site. Available at: [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm). Published September 10, 2013. Accessed March 7, 2014.

Conduct a definitive test as part of the first consultation.

- If the results indicate abstinence, test again based upon the frequency of clinical contact, up to two times annually.
- If the test results indicate use, intervene and establish an active treatment plan.

If the patient is a woman who is pregnant, the practitioner should take the following steps during the diagnosis phase of treatment:

- Conduct a definitive test as part of the first prenatal consultation.
  - If the results indicate abstinence, test again according to obstetrics practice guidelines.
  - If the definitive test results confirm use, intervene and establish an active treatment plan.

C. Active SUD Treatment

- When a patient is in active SUD treatment, testing should be conducted on a regular basis and at random intervals. The process of collection, to the extent possible, should aim to reduce the likelihood that the patient could successfully plan to undermine the test results.

- A clinician interested in detecting every incidence of a patient’s substance use should look to test method’s capabilities and windows of detection for medications and substances being assessed to determine the frequency of testing and test method to assure detection of specific substances.

- In any stage of treatment, if the recommended testing frequency is reached and a patient presents with unexpected symptoms or substance use is suspected, the clinician may consider additional testing. She should always document the rational underpinning her testing decisions.

- Monitoring patients with urine drug testing during treatment fosters honesty and trust between the patient and provider, encourages patients to follow the prescribed course of treatment, and assists practitioners in determining whether the course of treatment should be modified. As with all patients, in order to avoid stigmatization of the patient, the practitioner must educate the patient on the purpose of urine drug testing and emphasize that such practice is intended for therapeutic purposes rather than punitive purposes. Test results should be kept confidential to the extent permitted by law.

- Definitive test should be utilized to detect specific drugs and substances, as needed.

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• If the patient is in the first 30 days of treatment or if the clinical records and test results suggest that the patient has abstained from substance use for 30 days or less, the clinician should perform, based upon clinical judgment, test method capabilities, and knowledge of the windows of detection, presumptive or definitive tests one to three times per week, taking into consideration the following:
  o If the clinician has chosen a presumptive test and the test results indicate use, follow up with a definitive test, if indicated.
  o When using presumptive testing, one in every three tests should be a definitive test.

• If the clinical record and prior test results suggest that the patient has abstained from substance use for 31 to 90 days, the clinician should perform, based upon clinical judgment, test method capabilities, and knowledge of the windows of detection, presumptive or definitive tests one time per week, taking into consideration the following:
  o If the clinician has chosen a presumptive test and the test results indicate use, follow up with a definitive test, and
  o When using presumptive testing, one in every three tests should be definitive.

• If the clinical record and prior test results suggest that the patient has abstained from substance use for 91 days to two years, the clinician should perform, based upon clinical judgment, test method capabilities, and knowledge of the windows of detection, presumptive or definitive testing one to three times per month, taking into consideration the following:
  o If the clinician has chosen a presumptive test and the test results indicate use, follow up with a definitive test, and
  o When using presumptive testing, one in every three tests should be definitive.

• If tests indicate return to use after a period of abstinence, the clinician should resume the testing schedule recommended for abstinence of 30 days or less, and treatment may need to be adjusted or intensified to meet the clinical requirements of the patient. Even though durability of abstinence is thought to be related to length of abstinence, the clinician may make the decision not to revert to a higher frequency of testing for substance use based upon clinical judgment. The clinician’s judgment can be influenced by knowledge of the patient gained over time, highest level of stability, substances used, duration of use, response to using episode, current functioning, social stressors, etc.

D. Chronic Care Management for SUDs

• Patients who enter the chronic care management phase of treatment, having

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32 The clinician may set up a schedule of decreasing frequency the longer the patient is from his or her last use.
accumulated over two (2) years of abstinence from substance use, are often self-directed in their activities that support recovery. Consultation with the professional is less prescriptive, may be periodic, and is often driven by the individual’s self-identified need. Urine drug testing should be conducted, to the extent possible, on a regular basis and at random intervals to reduce the likelihood that the patient could successfully plan to undermine the test results. The random nature of the test is hard to accomplish with a reduced frequency of visits. Often patients in stable mature recovery, when advised of the value of random testing, will agree to or encourage their practitioner to work out a random schedule of appointments for testing that are not necessarily connected to office visits.

- If more than two years but less than five years have passed since the patient’s last substance use, perform a definitive test at a frequency of no less than once annually.

- If five years or more have passed since the patient’s last substance use, perform a definitive test based on clinical judgment.

E. Test Selections

- Substance use tests should be customized for individual patients based on the patient’s prior use, prescribed medications, suspected current use, substances of common use in the patient’s peer group and locale in which the specimen is collected, and circumstantial considerations, such as the introduction of a substance into a treatment setting.

- With new variations of substances continually becoming available, clinicians should update their test selections to reflect current trends of prescription and non-prescription substances used in their communities and patient populations. Test selection should, however, be primarily based on the clinical evaluation of the patient.

- Clinicians should use the overall medical and psychosocial assessment of the patient to narrow the test selection to that which is relevant and would impact the treatment plan.

- The practitioner should collaborate with the laboratory when determining the preferred test selections to obtain information about local and demographic trends in substance use.

- Reflex testing should not be ordered. Definitive testing should be targeted, be specific, and have clinical ramification in the treatment plan prior to any request for the order.

Clinicians should document in the medical records the bases upon which they personalize test selections\(^{34}\) and how the test results were used in patient care.

VII. Conclusion

Urine drug testing can be a useful tool in the diagnosis, treatment of, and recovery from SUDs when properly utilized in addiction treatment. Yet, no clinical consensus previously existed for urine drug testing in addiction medicine, and a lack of knowledge, unethical behavior, and ill-advised cost-saving measures have resulted in confusion and imbalances in utilization of such services. In response to these issues, a panel of experts convened to create this consensus statement. It is the hope of the panel members that this consensus statement will improve the utilization of urine drug testing by providing health care practitioners in various areas of practice with recommendations on test selection, analysis, and appropriate responses to test results in SUD diagnosis, addiction practitioners’ active treatment, and chronic care management.

\(^{34}\) For example, a practitioner may choose a comprehensive opioid menu for an individual taking an opioid medication to make sure the patient is taking the prescribed medication and no other diverted medications or illicit substances. Medication-assisted treatment for opioid addiction in opioid treatment programs, A Treatment Improvement Protocol (TIP) 43. Substance Abuse and Mental Health Services Administration Web site. Available at: [http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf](http://www.ncbi.nlm.nih.gov/books/NBK64164/pdf/TOC.pdf), Published 2012. Accessed October 14, 2015.
Appendix 1

Expert Panel

The expert panel developed the findings, conclusions, and recommendations found this report. Members of the panel included:

- Louis E. Baxter, Sr., M.D., F.A.S.A.M., Immediate Past President, ASAM
- Adrienne M. Brown, M.S.W., L.M.S.W., Consumer Advocate
- Ernest Joseph Dole, Pharm.D, Clinician Pharmacist, University of New Mexico Hospitals, Pain Consultation and Treatment Center
- Tracey Fremd, N.P., Principal, Tracey Fremd Consulting, Inc.
- Jeff Fudin, R.Ph, B.S., Pharm.D, D.A.A.P.M., F.C.C.P., Director, PGY2 Pharmacy Pain Residency & Clinical Pharmacy Specialist, Pain Management, Samuel Stratton Department of Veteran Affairs Medical Center
- Chris Kottenstette, P.A.-C, Physician Assistant, USA Pain Professionals
- Mark Krause, M.D., F.A.S.A.M., Assistant Clinical Professor of Medicine, Yale School of Medicine; Chief Medical Officer, Connecticut Counseling Centers; General Internist, Westside Medical Group; Diplomat, American Board of Addiction Medicine
- Terry Rustin, M.D., F.A.S.A.M., Medical Director of the Addiction Treatment Program, Harris County Psychiatric Center

Other consultative meeting participants included:

- Michael C. Barnes, Esq., Executive Director, CLAAD
- Andrea G. Barthwell, M.D., F.A.S.A.M., Director, Two Dreams; Medical Director, Encounter Medical Group; Former President, ASAM
- Penny Mills, Executive Vice President and Chief Executive Officer, ASAM
- Stacey Sklaver, Esq., Associate Attorney, DCBA Law & Policy
- Michael Walsh, M.S., C.A.P., Berkley Research Impact Institute, President and Chief Executive Officer, National Association of Addiction Treatment Providers
Appendix 2

Preparatory Resources Provided to Panel Members


## Appendix 3

Agenda for Consultative Meeting on Proper Utilization of Urine Testing in Identifying and Treating Substance Use Disorders

February 21, 2014
9 a.m. to 5 p.m. eastern

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Title</th>
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<tbody>
<tr>
<td>8 a.m.</td>
<td>Networking Breakfast</td>
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<tr>
<td>9 a.m.</td>
<td>Welcome and Meeting Goals</td>
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<tr>
<td>9:15 a.m.</td>
<td>Introductions</td>
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<tr>
<td>9:30 a.m.</td>
<td>Need for Clinical Guidelines</td>
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<tr>
<td>10 a.m.</td>
<td>Participants’ Perspectives and Priorities</td>
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<tr>
<td>10:45 a.m.</td>
<td>Break</td>
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<tr>
<td>11 a.m.</td>
<td>Terminology</td>
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<tr>
<td>11:15 a.m.</td>
<td>Overview of Draft Guidelines</td>
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<tr>
<td>11:45 a.m.</td>
<td>Discussion</td>
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<tr>
<td>12:15 p.m.</td>
<td>Break</td>
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<tr>
<td>12:30 p.m.</td>
<td>Lunch and Discussion of Test Reliability and the Need for Accuracy</td>
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<tr>
<td>1 p.m.</td>
<td>Break</td>
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<tr>
<td>1:15 p.m.</td>
<td>Principles for Testing to Identify Use and Diagnose Disorders</td>
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<tr>
<td>1:45 p.m.</td>
<td>Discussion</td>
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<tr>
<td>2:15 p.m.</td>
<td>Principles for Testing in the Active Treatment Stage of Care</td>
</tr>
<tr>
<td>3 p.m.</td>
<td>Break</td>
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<tr>
<td>3:15 p.m.</td>
<td>Discussion</td>
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<tr>
<td>3:45 p.m.</td>
<td>Principles for Testing as Part of Recovery Support</td>
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<tr>
<td>4 p.m.</td>
<td>Discussion</td>
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<tr>
<td>4:30 p.m.</td>
<td>Next Steps</td>
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<tr>
<td>5 p.m.</td>
<td>Meeting Conclusion</td>
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<tr>
<td>6 p.m.</td>
<td>Meet in the Hotel Lobby for Dinner</td>
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