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Guidance on Toxicology Testing in OASAS Certified Programs

Introduction:

The purpose of this document is to provide guidance for providers working in OASAS-certified programs who utilize toxicology testing during the course of a patient's treatment. This guidance should be used collaboratively with other OASAS guidance documents including Person-Centered Care Guidance, Standards for OASAS Certified Programs, and Standards for Person-Centered Medication Treatment at OASAS Certified Programs.

Toxicology testing can be a valuable part of treatment for substance use disorders. When used effectively and in a person-centered framework, it has been shown to be an important tool in providing patient care.[1] Toxicology testing is one tool among many available and should not be used as the sole source of information to guide treatment decisions. Toxicology testing should be used as a clinical tool rather than a surveillance mechanism. The results should be used to inform the treatment plan and for ongoing re-assessments in treatment. Results should be discussed with the patient from a supportive, clinical perspective, as opposed to a punitive one. Additionally, program staff should be trained to understand toxicology results including, but not limited to, the difference between a presumptive (i.e., screening, qualitative) and a definitive (i.e., confirmatory, quantitative) test and the importance of consulting with medical staff when toxicology test results are not consistent with a patient's self-reported substance use or other relevant patient information such as current medications. Policies pertaining to toxicology testing should include the reasons for testing, how toxicology test results will be used to inform treatment, and general plans for ongoing testing including testing frequency, circumstances for ordering definitive testing, how the testing schedule will be determined, and how providers determine which substances will be included in testing. When utilizing toxicology testing within an OASAS-certified setting, the following principles should be integrated into treatment practices and used as guidance in developing policies and procedures:

Program Competency:

- Medical Directors at programs/agencies should be involved in creating, reviewing, and approving toxicology testing policies and procedures. Medical Directors or other medical staff should be consulted when toxicology test results are not consistent with a patient's self-reported substance use or other relevant clinical information such as the patient's current medications.
- Programs should have detailed toxicology testing policies and procedures that are person-centered, culturally responsive, trauma-informed, non-judgmental, and non-punitive.
- Toxicology testing is not used as an alternative to a therapeutic relationship (e.g., performing toxicology testing and not asking patients about current substance use with the view that the toxicology test results are all that matter).
- Toxicology results provide another source of information to complement self-report, collateral report, and provider assessment.

- Procedures should be developed for orienting patients to toxicology testing, including why toxicology testing is done, where, when, and how samples for toxicology testing are collected, and what the patient's role and rights are in this process. Furthermore, patients should be educated on the therapeutic uses of toxicology testing so they understand the role of testing in their treatment. Patients should be engaged in informed and shared decision-making about toxicology testing.
- Programs should educate patients about changes to their current toxicology testing policies and procedures as a result of implementing this guidance.

Rationale for Testing:

A person-centered, culturally responsive, trauma-informed approach should be used when determining if toxicology testing will be part of a patient's initial assessment or ongoing treatment plan. When toxicology testing is performed it can be used for the following:

- To determine, when clinically indicated, if substances have been used recently as part of a program's initial assessment. The results of the initial assessment and toxicology testing, if testing was determined to be indicated clinically, should guide clinical decisions thereafter about what type(s) of toxicology testing should be utilized and what substances should be included.
- To assist providers in determining placement in a level of care (i.e., crisis stabilization, inpatient rehabilitation, outpatient, etc.) by clarifying the potential for substance withdrawal due to the types and combinations of substances used recently.
- To monitor progress in treatment, like medical or medication monitoring for another health condition, as clinically indicated.
- To facilitate discussions about reducing the harms from or preventing future substance use (e.g., drawing a relationship between toxicology test results and changes in the patient's health or functionality).
- To help determine whether a symptom is related to substance use or another medical or mental health condition (e.g., substance-induced psychosis vs. schizophrenia).
- To provide documentation about whether substances are being used currently when such documentation is needed (e.g., employment, benefits-related, or criminal justice mandates).

When to Test:

This is unique to the setting and population needs. Considerations for when to test include:

- At intake/admission when clinically indicated.
- As requested by the patient.
- At predetermined and intermittent intervals during treatment with less frequent testing as treatment progresses. It should be noted that increasing the frequency of toxicology testing is not correlated with a decrease in substance use.[2]
- As clinically indicated during treatment (e.g., based on behavioral changes, reports from significant others, a return to the program after an absence from treatment).
- Windows of detection for specific substances should be considered when determining frequency of toxicology testing. For example, if a patient reports regular fentanyl use, weekly testing would not be indicated clinically. Fentanyl clearance may take several weeks for persons with opioid use disorder

(OUD) who are using fentanyl regularly. Treatment providers should be aware that fentanyl and its metabolite norfentanyl are cleared more slowly from the body. This reduced rate of clearance can cause serious complications during initial treatment of OUD with buprenorphine or naltrexone because of the possibility of precipitated opioid withdrawal. Innovative treatment initiation strategies for persons with OUD should account for the unique pharmacokinetics of fentanyl in persons who use fentanyl regularly.[3]

- **Toxicology Testing for Drug Court Participants**: For participants in NYS Drug Courts, twice weekly toxicology testing may be required, and providers and the courts should share responsibility for conducting the toxicology testing as well as the cost. If a court mandates two or more toxicology tests per week, the responsibility for those extra toxicology tests should be borne by the court. Some courts may ask providers to order/conduct tests (e.g., EtG tests) that do not conform to NYS Limited Laboratory Certification requirements. In such instances, the provider should inform the court that they cannot perform the toxicology test, but that the court can conduct the toxicology test on their own. For the provider, conducting more than one toxicology test and confirmatory test per week would be based on medical necessity only. The medical necessity must be documented and may be subject to review to determine if it was justified.

- **Toxicology Testing in Opioid Treatment Programs:** For patients in Opioid Treatment Programs (OTPs), NYS OASAS regulations Part 822.7(f {i}) and federal regulations 42 CFR 8.12(f)(6) indicate that programs must provide adequate toxicology testing or analysis for "commonly used and misused substances." Treatment providers should use qualitative indicators of treatment progress, such as how the patient is functioning in their personal and/or professional life, to determine patient stability for more flexible take-home dosing. Toxicology test results are just one factor in determining patient stability.

Toxicology Testing Procedures

- Toxicology testing matrices include urine, blood, breath, oral fluid, sweat, and hair. Urine is the most common and validated matrix, but some programs may use other matrices for specific reasons in select patients.

- If a patient is unable to provide a specific specimen, programs should consider collecting the specimen through an alternative method/matrix.

- It is important for staff involved in testing to have knowledge of all testing techniques used and when a specific technique is more appropriate than another (e.g., when to do a urine test and when to do a breath test for alcohol use).

- Providers should understand what constitutes a positive or inconclusive toxicology test result. For example, they should understand how test results may be affected by a substance's metabolism and removal from the body and that prescribed and over-the-counter medications, herbal supplements, and certain foods may affect the test results.

- Providers should be aware that certain substances may not be detected by toxicology tests for the class of substances that the substance belongs to. For example, buprenorphine, fentanyl, and methadone are not among the substances detected by urine toxicology tests for opiates and alprazolam, lorazepam, and clonazepam may not be detected reliably by urine toxicology tests for benzodiazepines.

- Prior to toxicology testing, the patient should be asked to self-report any substance use that may result in a positive toxicology test result. This should be queried in a non-judgmental, person-centered way. Patients are more likely to disclose any interim use once trust has been established and if the discussion is conducted in a nonjudgmental, respectful manner.

- All samples should be collected using an infection control protocol that reduces health and safety risks to all persons handling the sample.
- Toxicology testing samples should be obtained in a person-centered, respectful, culturally responsive, and trauma-informed manner that minimizes the risk of adulteration, substitution, or dilution (e.g., a private area with minimal or no means to alter the sample; dye in the toilet water; non-flushing toilet; etc.). Staff should be trained in collection techniques that protect the integrity of the toxicology test results.[4]
- When there are clinical reasons to question the integrity of samples provided (e.g., negative toxicology results for prescribed medications that should be present in the sample; clinical evidence of substance use but negative toxicology test results; evidence of sample adulteration or tampering; etc.), programs should work with laboratory providers to develop toxicology protocols to test the integrity of samples, such as temperature measurement and analyses for urine specific gravity, creatinine, etc. All samples should not be subjected routinely to such tests, but rather, they should be reserved for when there is reason to suspect problems with sample integrity.
- Use of a different testing matrix (e.g., blood, oral fluid) also can be considered when urine sample integrity is in question. However, this approach should be reserved for when there is a specific clinical reason to do so.
- ***Direct observation of urine sample collection for toxicology testing can be considered but should be used as a last resort in rare instances*** when the above sample integrity confirmation techniques have been ineffective in resolving suspected problems with submitted urine samples. An example may include a patient who specifically requests direct observation when their urine sample is collected so they can feel more confident about the sample's integrity. In these cases, programs should have policies and procedures to observe urine sample collection for toxicology testing in a person-centered, respectful, culturally responsive, and trauma-informed manner, and should train staff in said policies and procedures. Another way to honor the patient's request for direct observation is to refer them to a community-based laboratory that provides direct observation of urine sample collection. ***Direct observation of urine sample collection for toxicology testing should not be part of usual clinical practice.***
- Staff who review toxicology test results should consult with the Medical Director or other medical staff when the toxicology test results are not consistent with a patient's self-reported substance use or other relevant clinical information such as current medications.
- Staff also should consult with the program's medical staff when they have specific questions about which substances, environmental exposures, or testing procedures may or may not cause false-positive or false-negative test results. Additionally, the program's medical staff should know when and how to consult with laboratory personnel, including the Medical Review Officer, where the testing was conducted or with a toxicologist.
- Please see the guidance from the Center for Medicare and Medicaid Services (CMS) and the guidance from the New York State Department of Health (NYS DOH) for information about proper billing for toxicology testing.

Substances to Include in Toxicology Tests and Interpretation of Toxicology Test Results

- Toxicology testing is designed to identify whether a substance was taken within a specific time period. It should be used in conjunction with self-report and clinical assessment to obtain a full clinical picture.

- When choosing tests for initial presumptive toxicology panels, programs should consider including the most common substances used in the local community, any substances of particular public health concern (e.g., fentanyl), any substances of particular clinical concern for a given patient, as well as confirming the presence of therapeutic medications (e.g., methadone, buprenorphine, benzodiazepines).

- For ongoing presumptive toxicology testing, as feasible, panels should be individualized to patients, and should, to the greatest extent that is practical, only include substances relevant to a specific patient's care. For instance, programs should not test arbitrarily for a wide range of substances on a routine basis. It is potentially wasteful to test for multiple substances routinely when a patient has a history of only using one or two substances. With the legalization of adult-use cannabis in NYS, testing for the metabolite of THC routinely is not recommended unless the patient has identified a reduction in, or cessation of cannabis use as part of their treatment goals. However, recognizing that there may be pragmatic limits to individualizing completely all follow-up toxicology testing, programs should work with laboratory providers to create limited follow-up toxicology panels that suit the most common needs of the population they serve.

- Substances should be included only if the toxicology tests have a reasonable degree of sensitivity and specificity and therefore can inform clinical care usefully beyond self-report, collateral report, and clinical evaluation. For instance, while presumptive toxicology testing for fentanyl and its analogues is reliable, and potentially could enhance clinical care in multiple ways, testing for synthetic cannabinoids adds little value beyond asking about synthetic cannabinoid use, given the poor sensitivity of the test due to the wide array of potential synthetic cannabinoid compounds, and the characteristic clinical signs of synthetic cannabinoid use/intoxication.

- Alcohol and THC metabolites should not be included in routine toxicology panels unless a clinician determines that alcohol or cannabis is a concern and toxicology testing would be appropriate clinically.

- Programs should use definitive (confirmatory) toxicology testing to verify positive presumptive test results that are not verified through patient self-report and that may have implications for patient care (e.g., transition to an alternate level of care or impact on legal status). Positive presumptive results can be confirmed through patient self-report and do not always need to be sent for definitive (confirmatory) toxicology testing.

- Positive presumptive results that are not confirmed by self-report should be considered preliminary until positive definitive (confirmatory) results are received. Therefore, revisions in the treatment plan or reporting to third parties should not occur prior to receiving confirmation by patient self-report or definitive/confirmatory toxicology testing.

- Negative presumptive test results do not need to be sent for definitive (confirmatory) toxicology testing unless there are specific clinical reasons such as suspicion of a return to use (e.g., behavioral or physical signs of substance use).

- Obtaining quantitative substance levels through definitive toxicology testing is almost never clinically meaningful or helpful and should be avoided generally. However, there are exceptions, such as testing for norbuprenorphine, a buprenorphine metabolite, if confirmation that a patient is taking prescribed buprenorphine versus adulterating a sample is needed.

On-Site and/or Off-Site Laboratory Testing Registration Requirements

- A laboratory is defined as any provider, practitioner, or other person that collects and performs testing on human specimens for the diagnosis, prevention, or treatment of any disease.

- Providers who wish to perform on-site and/or off-site laboratory testing must obtain approval from the Department of Health's Clinical Laboratory Evaluation Program (CLEP).
- Providers interested in performing on-site and/or off-site laboratory testing must register as a Limited Services Laboratory (LSL) or a New York State (NYS) Clinical Laboratory depending on the testing performed, and the device used to perform the testing.
    - LSLs perform tests by using devices categorized as CLIA Waived by the Food and Drug Administration (FDA).
        - Applications for an LSL Registration certificate can be found at https://www.wadsworth.org/regulatory/clep/limited-service-lab-certs
    - NYS Clinical Laboratories perform laboratory tests by using devices categorized as CLIA Non-Waived by the FDA.
        - Applications for a NYS Clinical Laboratory Permit can be found at https://www.wadsworth.org/regulatory/clep/clinical-labs/obtain-permit
- Providers can determine if a testing device they are interested in using is FDA CLIA approved by searching the FDA database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm
- Providers who already have testing devices can determine if the device is FDA CLIA approved by:
    - Reading the package insert for the device to see if it says "CLIA Waived"
        - If the package insert does not say this, contact the 800-number provided by the manufacturer.
    - Contacting the distributor where the test device was purchased.
- A testing device that is not categorized as "CLIA Waived" cannot be used with an LSL Registration and an application for a NYS Clinical Laboratory permit must be submitted.
- Staff administering waived tests must perform the test as directed by the manufacturer and in accordance with established policies and procedures.
- Staff administering waived tests must be assessed for competency at least once per year.
- Information about NYS OASAS on-site laboratory Testing can be found at Service Laboratory Registration | Office of Addiction Services and Supports (ny.gov)

Clinical Use of Toxicology Results

- Policies and procedures should specify clearly what the toxicology test results will be used for (e.g., discussing progress towards treatment goals) and what they should not be used for (e.g., surveillance and punishment).
- The use of toxicology testing should be normalized as a therapeutic tool used to support a patient's treatment goals.
- Programs should ensure that all toxicology test results are discussed with patients and documented in the patient's record.
- Clinical staff should discuss both positive and negative toxicology test results with patients. Patients should have the opportunity to discuss their reaction to the test results and how the test results will inform their treatment going forward. Discussing discrepancies in self-reported versus laboratory

reported substance use is critical as well. For example, a patient may report use of what they believed to be heroin, only, but unknowingly used heroin that had fentanyl and amphetamines mixed in. Their urine sample may be positive for opioids, fentanyl, and amphetamines even though they reported use of only heroin.

- All toxicology test results should be utilized in a non-punitive and non-confrontational manner that helps provide motivation for the patient (e.g., to provide objective feedback to a patient, and help reinforce a patient's treatment goals rather than constituting a reason for program discharge or an administrative taper of medication for addiction treatment). Additionally, the pattern of toxicology test results can assist in modifying their treatment plan when needed. For example, ongoing opioid use as evidenced by frequent opioid positive urine toxicology test results and confirmed by patient self-report may indicate that a patient's current methadone or buprenorphine dose is not adequate to modulate opioid cravings and the dose should be increased with the patient's assent. It is important to note that the results of a single toxicology test result should not be used to modify a patient's treatment plan.
- It is important for programs and providers to use non-stigmatizing and clinically appropriate terms; for example, "positive" or "unexpected" or "unanticipated" toxicology test result rather than "dirty urine."
- A patient's refusal to participate in toxicology testing should be viewed as a clinical issue to be addressed in the treatment plan rather than an administrative issue.
- Negative toxicology test results can provide positive reinforcement and motivation for patients who are meeting their treatment goals. They can provide the patient and treatment provider with useful information to develop new therapeutic interventions to assist in treatment planning and in meeting the patient's goals and objectives.
- Definitive toxicology test results that are negative for a medication that should be present in a patient's urine sample, such as methadone negative toxicology test results when a patient is being treated with methadone, should not be grounds for program discharge due to concerns of methadone diversion. Instead, clinical staff should have a non-punitive, non-judgmental conversation with the patient to address the methadone negative toxicology test results.

Reporting to Third Parties

The legal, ethical, and regulatory requirements of reporting to third parties are outside the scope of this guidance. However, when navigating these relationships, focus should be placed specifically on the patient's treatment goals and needs, which include the following considerations:

- In general, mandates apply to the patients, not to the providers. Providers should help patients understand the details and potential consequences of their mandates around toxicology testing and assist patients in making informed decisions. However, whether toxicology results are reported to a third party is the patient's decision and informed consent must be obtained. See additional information about 42 CFR Part 2 and a 42 CFR Part 2 Consent Form. Versions of these forms in different languages can be found on the OASAS website.
- If a patient requests that their toxicology test results be shared with outside parties on their behalf, the parameters of that relationship should be established at the start of the therapeutic relationship, including all necessary releases. For more information, see SAMHSA's Disclosure of Substance Use Disorder Patient Records
- Patients retain the right to rescind their permission to release their toxicology test results at any time (other than certain criminal justice consents). A Consent to Release Information Concerning Substance Abuse Treatment for Criminal Justice Clients is available on the OASAS website.

- When collaborating with criminal justice entities, a Memorandum of Understanding (MOU) should be developed specifically for toxicology testing protocols, which are consistent with this guidance and NYS OASAS regulations.
- Prior to sharing toxicology test results with outside entities, positive presumptive results must be verified with a definitive (confirmatory) toxicology test unless the patient confirms substance use by self-report.[5]
- Be aware of the dual role when dealing with mandating agencies (i.e., toxicology testing as a monitoring tool rather than a treatment tool) and attempt to work with patients openly around this potential risk to the provider-patient relationship. See OASAS Local Services Bulletin No. 2014-02 for more information

Special Populations:

Transgender or Gender Non-conforming Persons:

- In those rare circumstances when direct observation of urine sample collection is indicated, programs should ask transgender or gender non-conforming patients which gender they prefer for staff monitoring. If the program does not have a staff member who identifies as the patient's preferred gender, an appointment with a community-based laboratory that can provide direct observation by a staff member of the preferred gender should be arranged or an alternative testing matrix should be utilized.

Pregnant and Parenting Persons:

- The American College of Obstetricians and Gynecologists (ACOG) recommends ***universal (not risk-based) verbal screening*****,** with a validated screening tool for substance use during pregnancy. **ACOG *does not recommend* routine toxicology testing during pregnancy and delivery, or for the newborn**. Toxicology testing should be performed only when medically indicated as part of the work up for the pregnant person and infant to determine any appropriate medical treatment.[5] **Suspicion of substance use, which can be influenced by implicit and explicit bias, is not a medical basis for toxicology testing.**[6,7] Pregnant and parenting persons with substance use and/or substance use disorder face profound stigma within the healthcare system as well as in the media. Fear of stigmatization can prevent pregnant persons from accessing care, including prenatal care and substance use disorder treatment, which worsens both parental and neonatal outcomes.
- Providers should understand that there may be heightened social and legal consequences for positive toxicology test results among pregnant persons, persons planning to conceive, and parenting persons. Therefore, providers should take extra care to engage this group of patients in shared and informed decision-making before screening for substance use, and before performing any clinically indicated toxicology testing. Fully informed consent includes a clear discussion and confirmed patient understanding of the potential harms, consequences, and benefits of screening, including, but not limited to, a confirmation of confidentiality of medical information, a description of any legal requirements for healthcare providers when toxicology results are positive (e.g., reporting requirements when a newborn is affected by substance exposure; a discussion of federal and/or NYS reporting requirements is beyond the scope of this guidance*), and a discussion of the patient's ability to refuse toxicology testing unless it is mandated by an outside entity such as a court. **Substance use and/or substance use disorder, in and of itself, whether disclosed by self-report, verbal screening, toxicology test results, or newborn symptoms, is not evidence of child neglect, child maltreatment, or child abuse.**

The NYS DOH guidance on the implementation of federal CAPTA/CARA (Child Abuse and Prevention Treatment Act/Comprehensive Addiction and Recovery Act) legislation in NYS can be found at: https://health.ny.gov/prevention/captacara/index.htm.

- As with other patients, if toxicology testing is indicated clinically, urine testing is the most appropriate method of toxicology testing.

Adolescents:

- Consent for toxicology testing should be obtained from the adolescent and written consent should be requested if the adolescent chooses to share the test results with their parents/guardians. If consent is not given, this information can be shared only as per 42 CFR, Part 2 and HIPAA regulations.
- Toxicology panels should include the primary substance used as well as the most common substances used by adolescents (e.g., alcohol, cannabis, amphetamines, prescription opioids). Inhalants, also commonly used by adolescents, are not captured easily by toxicology testing.

Additional resources:

NYS DOH AIDS Institute and John Hopkins University Clinical Guidelines Program Substance Use Disorder Treatment in Pregnant Adults: https://www.hivguidelines.org/substance-use/sud-treatment-pregnancy/

OASAS Learning Thursday on Developing Plans of Safe Care (POSC) with a Patient-Centered Approach: https://www.youtube.com/watch?v=Ke-Kausu2g8&list=PLNIxVjyAHXCMsEjQIiDvN4CC2pD6_Y9KF&index=2&t=4s

Person-Centered Care Guidance for OASAS Certified Programs: Person-Centered Care

Standards for Person-Centered Medication Treatment at OASAS Certified Programs: https://oasas.ny.gov/system/files/documents/2019/10/medical-standards-for-certified-programs.pdf

Standards for OASAS Certified Programs: https://oasas.ny.gov/system/files/documents/2019/07/Standards%20for%20OASAS%20Certified%20Programs.pdf

Urine Collections and Testing procedures and Alternative Methods for Monitoring Drug Use in Center for Substance Abuse Treatment. *Substance Abuse: Clinical Issues in Intensive Outpatient Treatment*. Treatment Improvement Protocol (TIP) Series 47. DHHS Publication No. (SMA) 06-4182. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2006. https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182?referer=from_search_result

OASAS Plan of Safe Care for Infants and Their Caregivers Local Services Bulletin:https://oasas.ny.gov/plans-safe-care-infants-and-their-caregivers

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[2] The ASAM appropriate use of drug testing in clinical addiction medicine, 2022 Available at: https://www.guidelinecentral.com/share/pocketcard/594416327eaca/#ia4c8134a

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[6] Maina IW, Belton TD, Ginzberg S., et al. (2018). A decade of studying implicit racial/ethnic bias in healthcare providers using the implicit association test. *Soc Sci Med.* 199:219-229.

[7] Hall WJ, Chapman MV, Lee KM, et al. (2015). Implicit racial/ethnic bias among health care professionals and its influence on health care outcomes: a systematic review. *Am J Pub Health.* 105(12):e60–e76.

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