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Guidance on Toxicology Use 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 throughout 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 is 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 should be used as a clinical tool rather than a surveillance mechanism. The results should be used to inform the treatment plan and 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. It is important to note that there is no universal standard in toxicology testing for substance identification, diagnosis, treatment, or monitoring. 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 frequency, circumstances for ordering definitive testing, randomness, and how providers are to decide the substances to be included in testing. When utilizing toxicology testing within an OASAS certified setting, the following principles should be integrated into treatment practices and utilized 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, protocols, and procedures.
- Programs should have detailed toxicology testing policies and procedures, which are based on person-centered principles, cultural competency/humility, a trauma-informed lens, and are nonjudgmental and non-punitive.
- Toxicology testing is not used as an alternative to a therapeutic relationship (e.g., doing toxicology testing and not asking patients about current substance use with the view that the toxicology test results are all that matter).

[1] Substance Abuse and Mental Health Services Administration. Clinical Drug Testing in Primary Care. Treatment Improvement Protocol (TIP) Series 32. https://store.samhsa.gov/system/files/sma12-4668.pdf

- Toxicology results provide another source of information to complement self-report, collateral report, and provider assessment.
- Toxicology testing is individualized, patient-specific, and based on the needs of the patient (e.g., one toxicology testing panel is not appropriate for all patients).
- Procedures should be developed for orienting patients to toxicology testing and what the patient can expect in this process. This should include why toxicology testing is done, where it is done, when it is done, and the role/rights the patient has in this process. Patients should be engaged in informed and shared decision-making. Furthermore, patients should be educated on the therapeutic uses of toxicology testing to prevent them from viewing it negatively.

Rationale for Testing:
Toxicology testing should be used for the following:

- Initial diagnosis (e.g., determining which substances have been recently used). It is important to note that the results of the initial assessment and toxicology testing should guide clinical decisions thereafter about what type(s) of toxicology testing should be utilized and what substances should be included.
- To determine placement in a level of care (i.e., crisis stabilization, inpatient rehab, outpatient, etc.).
- Monitoring progress in treatment (similar to medical or medication monitoring for another health condition).
- Monitoring progression or improvement in use of secondary substances that may not be the focus of the patient's immediate goals (e.g., a patient wants to cease benzodiazepine use, but is continuing to use cannabis).
- Return to use prevention (e.g., utilizing the toxicology test results to assist patients in making informed decisions, which could include coordination with third party mandates).
- 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).
- When documentation of current substance use is needed (e.g., employment, benefits-related, or criminal justice mandates).

When to Test
This is unique to the setting and population needs. Considerations should include:

- At intake/admission.
- As requested by the patient.
- At random intervals throughout treatment with frequency decreasing as treatment progresses. It should be noted that increasing frequency of toxicology testing is not correlated to a decrease in substance use[2].
- As clinically indicated (e.g., based on behavior changes, reports from significant others, return to the program after a period of absence). However, substances included in follow-up panels should be individualized to the substance(s) of concern for that patient (e.g., a program does not need to test for cannabis if a patient only has a history of heroin use).
- Windows of detection for specific substances should be considered when determining frequency of toxicology testing (e.g., if a patient reports chronic cannabis use, weekly testing would not be indicated clinically). Of note, fentanyl clearance may take several weeks for

[2] The ASAM appropriate use of drug testing in clinical addiction medicine; 2017 Available from: https://www.asam.org/quality-practice/guidelines-and-consensus-documents/drug-testing-appropriateness

persons with opioid use disorder (OUD) who are exposed to fentanyl on a daily basis. Treatment providers should be aware that clearance of fentanyl, and its metabolite norfentanyl, is fundamentally different from other opioids and can have serious negative implications for during early OUD treatment due to the possibility of precipitated opioid withdrawal syndrome with the use of buprenorphine or naltrexone. Improved 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 for 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 is able to 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, NYS OASAS regulations Part 822.7(f {i}) and federal regulations 42 CFR 8.12(f)(6) indicate that they must provide adequate toxicology testing or analysis for "drugs of abuse," including at least eight random toxicology tests per year. In these settings, there is a relationship between toxicology test results and eligibility for take-home doses. However, even in this context, the treatment provider should frame the toxicology testing requirements in a clinically meaningful way. OASAS encourages the use of these regulations to empower the patient, so the patient can view success in achieving negative toxicology test results as incremental steps in their recovery process. Adhering to toxicology testing requirements and expectations serves to provide structure and important feedback to patients about their treatment progress.

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 matrix samples 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 others (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 must understand how interactions with prescribed and over-the-counter medications, herbal supplements, and certain foods might impact the results.
- Prior to the 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,

[3] Huhn, Andrew S., Hobelmann, J. Gregory, Oyler, George A., Strain, Eric C. (2020). Protracted Renal Clearance of Fentanyl in Persons with Opioid Use Disorder. *Drug and Alcohol Dependence* (2020), 214, 108147, https://pubmed.ncbi.nlm.nih.gov/32650192/.

patient-centered way. Patients are more likely to disclose any interim use once trust has been established and if the dialogue is done in a non-judgmental, respectful manner.

- All samples are collected using an infection control protocol that reduces health and safety risks to all persons handling the sample.
- Obtain toxicology testing samples in a person-centered, respectful, culturally competent/humble, and trauma-informed manner that minimizes the risk of adulteration, substitution, or dilution (e.g., private area with minimal items that can be used to tamper with the sample; dye in toilet water; non-flushing toilet; etc.). Staff should be trained in collection techniques to reduce threats to the integrity of the toxicology 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 also be reserved for when there is a specific clinical reason for it.
- ***Direct observation of urine sample collection 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 toxicology samples. (An example might include a patient mandated to treatment and toxicology testing, whose mandating entity requests an observed toxicology test, and the patient agrees to this and requests it of the treatment provider in order to demonstrate absence of substance use to the mandating entity.) In these cases, programs should have policies and procedures to observe toxicology sample collection in a person-centered, respectful, culturally competent/humble, and trauma-informed manner, and should train staff in said policies and procedures. ***Direct observation of urine sample collection should not be part of usual clinical practice.***
- Staff should have access to resources for specific questions about which substances, environmental exposures, or testing procedures may or may not cause false-positive or false-negative results. This would include knowledge about when and how to consult with a toxicologist or a Medical Review Officer at a laboratory or with additional laboratory personnel.
- Please see guidance from the Center for Medicare and Medicaid Services (CMS) here and the New York State Department of Health (NYS DOH) here for information about proper billing for toxicology testing.

Substances/Toxicology Tests to Include and Interpretation of Results

- Toxicology testing is designed to identify whether a substance was taken within a specific period of time. It should be used in conjunction with self-report and clinical assessment to obtain a full clinical picture.
- For initial presumptive toxicology panels, programs should include the most common substances used in the local community and/or the patient's demographic group, any substances of particular public health concern (e.g., fentanyl), and any substances of particular

[4] DuPont RL, Shea CL, Barthwell AG, Baxter LE, Beaubler A, et al.2013. Drug testing: a white paper of the American Society of Addiction Medicine (ASAM) Pages 28,29 and 40. Chevy Chase, MD, USA.

clinical concern for a patient, as well as to confirm the presence of therapeutic medications (e.g., methadone, buprenorphine, prescribed benzodiazepines).

- For ongoing presumptive toxicology testing, 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 very wide range of substances on a routine basis. This is potentially wasteful (e.g., routinely testing for cocaine, heroin, benzodiazepines, other opioids, and cannabis when a patient has a history of only using heroin and alcohol). 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 only should be included if the toxicology tests have a reasonable degree of sensitivity and specificity and can therefore usefully inform clinical care beyond self-report, collateral report, and clinical evaluation. For instance, while presumptive toxicology testing for fentanyl and its analogues is reliable, and could potentially enhance clinical care in multiple ways, testing for synthetic cannabinoids adds little value beyond asking about synthetic cannabinoid use, given poor sensitivity (due to the wide array of potential synthetic cannabinoid compounds) and the characteristic clinical signs of synthetic cannabinoid use/intoxication.
- Alcohol metabolites should not be included in routine toxicology panels unless a clinician determines that alcohol is a concern and toxicology testing would be clinically appropriate.
- Programs should use definitive (confirmatory) toxicology testing to confirm positive presumptive results that are not confirmed 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 of use 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 (via patient report or definitive/confirmatory toxicology testing).
- Negative presumptive tests results do not need to be sent for definitive (confirmatory) toxicology testing unless there are specific clinical reasons such as suspicion of resumption of use (e.g., behavioral signs of substance use or new track marks).
- Obtaining quantitative substance levels through definitive toxicology testing is almost never clinically meaningful or helpful and should generally be avoided. However, there are exceptions, such as obtaining a buprenorphine-to-norbuprenorphine ratio when confirming that an individual is taking prescribed buprenorphine vs adulterating a sample.

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

- Any provider, practitioner, or other person that collects and performs testing on a sample from the human body for the diagnosis, prevention, or treatment of any disease or impairment of the health of human beings is a laboratory.
- 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 "Waived" cannot be used with an LSL Registration and an application for a NYS Clinical Laboratory permit must be submitted.
- Staff administrating 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 and/or Off-Site Laboratory Testing can be found at https://oasas.ny.gov/service-lab-faqs

Clinical Use of Toxicology Results

- Policies and procedures should specify clearly what the toxicology test results will be used for and what they should not be used for (e.g., treatment plan updates and treatment adherence vs. punishment and surveillance).
- The use of toxicology testing should be normalized as a therapeutic tool used to support an individual's recovery.
- Talking to patients about discrepancies in self-reports versus laboratory reports of substance use is of utmost importance. This can be useful for many reasons. For instance, some substances may have numerous components (e.g., fentanyl and amphetamines mixed with heroin) that patients may be unaware of. Programs should ensure that all toxicology results are discussed and documented in the medical/health record.
- All toxicology 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, decrease denial, and help reinforce a patient's treatment goals and objectives rather than constituting a reason for program discharge or an administrative taper of medication for addiction treatment).
- It is important for programs and providers to use non-stigmatizing and clinically appropriate terms; for example, "positive toxicology result" rather than "dirty urine".
- Refusal by a patient 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 recovery 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 an individual's goals and objectives.

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 on 42 CFR Part 2 consent here and here. Additional languages for these forms can be found on the OASAS website.
- If a patient requests that their toxicology 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. https://www.samhsa.gov/sites/default/files/how-do-i-exchange-part2.pdf
- Patients retain the right to rescind their permission to release their results at any time (other than certain criminal justice consents).

https://oasas.ny.gov/trs-49

- 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 test results with outside entities, it is optimal that positive presumptive results be verified with a definitive (confirmatory) toxicology test unless the patient confirms substance use through 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 threat to the provider-patient relationship. See OASAS Local Services Bulletin No. 2014-02 for more information. https://www.oasas.ny.gov/legal/working-criminal-justice-entities

Special Populations:

Transgender/Gender Non-conforming Persons:

- Programs should be conscious of gender identity and how a patient who is transgender/gender non-conforming may react to aspects of the toxicology testing procedures (e.g., the gender of monitoring staff). Patients should be asked about what gender they prefer for staff monitoring and every attempt should be made to honor their choices.

[5] Jarvis, M., Williams, J., Hurford, M., Lindsay, D., Lincoln, P., Giles, L., ... Safarian, T. (2017). Appropriate use of drug testing in clinical addiction medicine. *Journal of Addiction Medicine, 11*(3), 163–173

5 Maina, I.W., Belton, T.D., Ginzberg, S., et al. (2018). A decade of studying implicit racial/ethnic bias in healthcare providers using the implicit association test. *Social science & medicine (1982)* 199, 219-229. doi:10.1016/j.socscimed.2017.05.009

6 Hall, W.J., Chapman, M.V., Lee, K.M., et al. (2015). Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systematic Review. *American Journal of Public Health* (105), e60–e76. doi:10.2105/AJPH.2015.302903

- Be aware of how increased exogenous sex hormones, such as testosterone or estrogen, may impact the toxicology testing process and the toxicology test results. For instance, testosterone is an essential medication for individuals identifying as male but is also a controlled substance that can be misused and diverted.

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 <u>not</u> recommend* routine toxicology testing during pregnancy and delivery, or for the newborn**. Toxicology testing should only be performed when medically indicated as part of the work up for the pregnant person and infant to determine the 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]. 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 any toxicology testing when indicated, are performed. 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 for substance exposure to a newborn; 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 via self-report, verbal screening, toxicology results, or newborn symptoms, is not evidence of child neglect, child maltreatment or child abuse.**
  *A link to 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: https://health.ny.gov/prevention/captacara/index.htm.
- As for other patients, urine testing is the most appropriate method of toxicology testing if indicated.

Adolescents:

- Consent for toxicology testing should be obtained from the adolescent and written consent should be requested to share the results with the parents/guardians. If consent is not given, this information can only be shared 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 this patient population (e.g., cannabis, alcohol, amphetamines, prescription opioids). Inhalants, also commonly used in this patient population, are not captured easily on 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/person-centered-medication-treatment

Standards for OASAS Certified Programs
https://oasas.ny.gov/legal/standards-certified-programs

Urine Collections and Testing procedures and alternative methods for monitoring drug use
https://store.samhsa.gov/system/files/sma13-4182.pdf

CMS billing guidance
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35006&DocID=L35006

NYS DOH billing guidance
https://www.health.ny.gov/health_care/medicaid/program/update/2017/2017-04.htm#drugtest

ASAM White Paper
https://www.asam.org/Quality-Science/quality/drug-testing

Appropriate Use of Drug Testing Guidelines Pocket Guide Digital Subscription
https://www.guidelinecentral.com/share/pocketcard/594416327eaca/#ia4c8134a

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

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