



Subject: Directly-Operated Program Management	Protocol: Monitoring Psychotropic Medication and Other Scheduled Drugs	
Last Updated: 06/25/2026	Owner: Chief Medical Office	Pages: 10

I. PURPOSE:

To provide clear, evidence-based guidelines for licensed prescribers at MCCMH directly operated services on the monitoring and management of individuals prescribed psychotropic medications. This protocol supports enhanced safety monitoring practices; however, all laboratory testing must comply with payer-specific coverage requirements, including documentation of medical necessity.

II. DEFINITIONS:

CLIA Waived Testing:

Clinical Laboratory Improvement Amendments (CLIA) waived tests are cleared by the Food and Drug Administration (FDA) for waiver testing under CLIA criteria. CLIA requires waived tests to be simple and low-risk, they are not completely error-proof. Manufacturer's instructions are to be followed for all CLIA waived tests.

CLIA Waived Rapid Urine Multi-Drug Screening:

A qualitative screening test intended for preliminary detection of substances. These tests are not considered definitive and may require confirmatory laboratory testing for accurate interpretation, based on clinical assessment and medical necessity.

III. PROCEDURE:

A. This protocol establishes minimum monitoring expectations. Clinical implementation remains subject to the licensed prescriber's professional judgment, informed consent requirements, patient rights protections, and applicable law. Additionally, ensures compliance with American Psychiatric Association (APA) and American Academy of Child and Psychiatric Association (AACAP) standards and supports:

1. The early identification and management of medication-related risks and medical comorbidities;

2. Timely and appropriate laboratory testing including metabolic panels, toxicology screenings, pregnancy screening tests, and EKGs;
 3. Interdisciplinary coordination with nursing and care teams for continuity of care;
 4. Clinical documentation standards that promote transparency and accountability and;
 5. MCCMH's commitment to quality improvement, patient safety, and integrated care across behavioral and physical health domains.
 6. Failure to complete monitoring due to patient refusal, inability to obtain external records, or other factors outside clinic control shall not constitute violation of this procedure when reasonable and documented good-faith efforts are made.
- B. Licensed prescribers at MCCMH directly operated services follow American Psychiatric Association (APA) and American Academy of Child and Psychiatric Association (AACAP) guidelines for monitoring antipsychotics and other medications that may require laboratory workups due to potential side effects. A common rationale for ordering baseline labs is to screen for potentially treatable medical conditions that may contribute to psychiatric symptoms. Please see Exhibit A Minimum Lab Monitoring Psychotropic Medications for some recommendations related to common psychotropic medications.
- C. Metabolic Monitoring Responsibilities
1. Prescribers must maintain records of metabolic syndrome monitoring for all individuals prescribed psychiatric medications known to elevate metabolic risk.
 2. Monitoring must occur at least annually or more frequently as clinically indicated.
 3. If labs have been completed by a Primary Care Physician (PCP) or other provider, the prescriber, with the support of the treatment team (e.g., nursing, case holders), must document all coordination efforts to obtain these results. If such efforts fail, the licensed prescriber is ultimately responsible for ordering the necessary labs per APA or ACCAP guidelines.
- D. Baseline Requirements for New Individuals Served Accessing Services (Over Age 12)
1. A baseline lab workup relevant to the prescribed medication should be ordered within forty-five (45) days of establishing care if no previous records are available consistent with applicable professional guidelines and clinical judgement.

2. As part of the standardized safety monitoring, individuals age 12 and older (or at onset of menses, whichever occurs first) are expected to complete:
 - A baseline CLIA waived rapid urine multi drug kit screening must be completed, with all specimens subsequently submitted to an approved external laboratory for confirmatory testing; and
 - A pregnancy screening test when clinically applicable.
 - a. These screenings establish a safety baseline and support responsible prescribing practices, including controlled substance management.
 - b. All testing must be conducted in accordance with informed consent requirements and patient's rights standards.
 - c. Nothing in this protocol authorizes physical restraint, coercion, or forced specimen collection,
3. If an individual or legal guardian declines screening:
 - The refusal must be documented by the RN.
 - The prescribing provider must be notified.
 - The prescribing provider retains sole responsibility for determining whether initiation or continuation of treatment is clinically appropriate.
 - The prescriber must document their clinical rationale.
4. If a urine toxicology screening was completed by an external provider within the past ten (10) days:
 - The prescriber must document this in the medical record.
 - RN staff must coordinate entry of results into the EMR within ten (10) calendar days of the person's last prescriber visit.
5. Screening results must be interpreted within the full clinical context, including prescribed medications, lawful medical treatments, and relevant guardian-directed care decisions.

E. Pregnancy Screening Testing Guidelines

1. Prescribers must order a pregnancy screening test for all women of childbearing age when initiating any psychotropic medication or adding a new psychotropic during treatment that may pose risks during pregnancy.

2. Exceptions apply only when documented evidence of low pregnancy risk is present (e.g., hysterectomy, effective birth control, tubal ligation, post menopause).
3. Pregnancy screening tests should be completed on-site when clinically indicated unless refusal or medical contraindication, or documented clinical rationale is present.
4. The RNs must upload the screening results in the individual's EMR using, exhibit B "Rapid Urine Multi-Drug Screening Result and Pregnancy Screening Test Communication."

F. Toxicology Screening

1. A CLIA waived rapid urine multi-drug kit screening is required before initiating treatment with any controlled substance.
2. For individuals on psychotropics, at least an annual toxicology or CLIA waived rapid urine multi-drug kit screening is required, unless the prescriber's clinical judgment determines otherwise (children under 12 may be exempted at the prescriber's discretion).
3. For those continuing care on controlled substances, toxicology screening is required at least every ninety (90) days, unless the person is enrolled in the Controlled Substance Monitoring Program, in which case testing frequency may increase at the prescriber's discretion.
4. The RNs must upload the screening results in the individual's EMR using, exhibit B Rapid Urine Multi-Drug Screening Result and Pregnancy Screening Test Communication.
5. CLIA waived rapid urine multi-drug kit screenings serve as initial screening tools only. Specimens obtained through toxicology screening must subsequently be sent to an approved external laboratory for confirmatory testing and for testing of additional substances and/or metabolites based on current treatments and risks of substances that are not visible in the preliminary screening, in accordance with this protocol.
6. For individuals undergoing baseline assessment or enrolled in controlled substance monitoring, confirmatory laboratory testing is generally expected to ensure accuracy of results, with medical necessity documented in the clinical record.

G. Monitoring Specific Conditions

1. Diabetes: Individuals with diabetes who are prescribed antipsychotics must have an HbA1c test included in their metabolic monitoring, at least annually. The result must be placed into the EMR as a numerical percentage. RN staff are responsible for entering available laboratory values into the EMR. The prescribing provider remains responsible for clinical review and interpretation.
2. Chronic Alcohol Use or Hepatitis C History: Prescribers must document liver function tests at least annually, or more often as clinically necessary.

H. Use of Verbal Orders

1. Prescribers may use verbal orders to facilitate collaboration with RN staff. These orders must:
 - a. Clearly include all relevant information for generating accurate lab and waived test requisitions.
 - b. Be documented by the RN in the Electronic Medical Record (EMR) under the appropriate section.
2. Prescribers may also issue standing verbal orders for baseline CLIA waived rapid urine multi-drug kit screening and pregnancy screening testing screenings for new individuals establishing care. All verbal and standing orders are issued under the authority of the licensed prescribing provider and remain subject to provider review and signature in accordance with regulatory requirements.
3. All confirmatory laboratory orders must include documentation of medical necessity in the clinical record. Providers may document rationale using standardized language aligned with clinical indications (e.g., baseline assessment, controlled substance monitoring, or need for accurate substance identification).

I. Psychotropic Medications Requiring Blood Monitoring

1. Psychotropics requiring blood level monitoring (e.g., Valproic Acid, Lithium, etc.) must have laboratory work completed at least annually, or more frequently in accordance with APA or AACAP guidelines, depending on the treatment stage (initiation vs. maintenance).
2. If the prescriber is unable to obtain these records from other providers, it remains their responsibility to ensure labs are ordered in a timely manner.

J. EKG Monitoring Requirements: Prescribers are responsible for:

1. Obtaining or ordering EKGs screening for individuals prescribed psychotropics that may cause QTC prolongation.
2. Ensuring all individuals with a history of cardiac conditions have at least one documented EKG screening result annually, regardless of treatment stage (initiation vs. maintenance).
3. Documenting efforts to obtain EKG screening results from external providers when applicable.
4. Ordering the EKG and related workups within the first forty-five (45) days of initiating care, if orchestrated attempts to retrieve those from other specialties fail.

K. Baseline Requirements for New Individuals Served Accessing Services (Under Age 12)

1. Metabolic syndrome labs are still expected to be recorded in the record per the time frame and expectations of this protocol for other populations.
2. The prescriber may opt out ordering CLIA waived rapid urine multi-drug kit screening, even if prescribing any controlled substance, at their discretion based on an understanding of risk and document their rationale to do so in the person's medical record.
3. A baseline pregnancy screening test should be ordered, CLIA waived or otherwise, following the expectations of any other population once the individual has had the onset of menses unless the medical history excludes this risk (i.e. youngster is on birth control, etc.). This should be appropriately documented in the medical record.
4. EKG monitoring requirements must be followed as stated for all other populations.

L. Maintenance Requirements for Individuals Served Younger than Age 12

1. Metabolic syndrome labs and other monitoring medication levels should be ordered at least yearly or as recommended per the AACAP understanding of other compounding risks in the child/adolescent's medical history.
2. Prescribers may opt out of ordering these even if the individual is on a controlled substance based on their own clinical judgement granted no risk is identified.

3. Pregnancy screenings are not needed if the female individual has not had the onset of her menses.

M. Confirmation Guidelines

1. CLIA waived rapid urine multi-drug kit screenings are used for preliminary screening purposes only.
2. For individuals undergoing baseline evaluation or enrolled in controlled substance monitoring, confirmatory laboratory testing is expected to support accurate clinical decision-making.
3. Specimens obtained through CLIA waived urine drug screening are generally expected to be submitted to an approved external laboratory for confirmatory toxicology testing.
4. Confirmatory laboratory testing must be supported by individualized clinical assessment and documented medical necessity in accordance with applicable Medicare, Medicaid, and payer requirements.
5. Ordering providers are responsible for ensuring that confirmatory testing is clinically indicated and appropriately documented. For pregnancy screening tests, lab confirmation is encouraged with any positive results. In other scenarios, the prescriber may determine the need for lab confirmation based on clinical context.

N. Guidelines for RN-performed CLIA waived rapid urine multi-drug kit screenings.

1. When an individual is prescribed a controlled substance or is enrolled in the MCCMH Controlled Substance Monitoring Program, it is important to understand that CLIA waived rapid urine multi-drug kit and/or lab results are tools for guiding clinical decision-making. Following collection of any CLIA waived rapid urine multi-drug kit screening specimen, RN staff must ensure specimens are prepared and sent to the designated external laboratory for confirmatory testing in accordance with provider orders and protocol expectations. The prescribing provider retains responsibility for confirming medical necessity and placing or authorizing the confirmatory laboratory order.
 - a. If the CLIA waived rapid urine multi-drug kit screening result is consistent with the treatment plan and/or as expected with individual's history:
 - i. Continue treatment.
 - b. If the CLIA waived rapid urine multi-drug kit screening result is inconsistent with treatment plan and/or inconsistent with individual's history:

- i. Counsel the individual.
- ii. Inform them of the need for cleaner results and increased monitoring.
- iii. Treatment can be generally continued for the current month, unless a significant clinical risk factor is identified that contradicts continued treatment. The prescribing provider must determine whether continuation of treatment is clinically appropriate based on individualized risk assessment.
- iv. If the lab-confirmed results continue to be inconsistent to the treatment plan and/or inconsistent with the individual's history:
- v. The prescriber must reconsider the treatment plan based on clinical risk.
- vi. The RN and prescriber must recommend counseling as appropriate (including referrals to appropriate treatments if toxicology reveals positive results).

O. Documentation Requirements:

1. The prescribing provider must document the clinical rationale for confirmatory laboratory testing. Acceptable documentation may include statements such as: "Confirmatory toxicology testing ordered to ensure accurate identification of substances for baseline assessment and/or controlled substance monitoring, given known limitations of screening assays."
2. Documentation Expectations for Toxicology Testing
 - a. Confirmatory laboratory testing must be supported by documentation of medical necessity in the medical record
 - b. Acceptable documentation should reflect clinical rationale, including but not limited to:
 - i. Baseline assessment for new individuals served
 - ii. Controlled substance monitoring
 - iii. Need for accurate substance identification due to known limitations of screening assays
 - Example documentation: "Confirmatory toxicology testing ordered to ensure accurate identification of substances for baseline assessment and/or controlled substance monitoring, given known limitations of screening assays."

P. Special Considerations: Capacity, Intellectual and Developmental Disabilities (IDD), and Refusal

1. This protocol establishes minimum monitoring standards. It does not replace individualized clinical judgment, applicable law, or patient rights protections.
2. Licensed prescribers are responsible for assessing capacity, obtaining informed consent, and determining clinical necessity for all testing.
3. For individuals with Intellectual and Developmental Disabilities (IDD):
 - a. Capacity and guardian authority must be evaluated in accordance with legal and clinical standards.
 - b. Testing should utilize the least restrictive and least distressing method reasonably available within clinical resources.
 - c. Staff shall not physically restrain or coerce an individual for the purpose of obtaining screening specimens.
4. If behavioral, cognitive, or physical limitations prevent completion of testing:
 - a. The RN must document the circumstances encountered.
 - b. The prescriber must be notified.
 - c. The prescriber is responsible for determining whether to defer, modify, or proceed with treatment based on individualized risk assessment.
 - d. The prescriber must document the clinical rationale for their decision.
5. Refusal of Screening:
 - a. Individuals and/or legal guardians retain the right to decline screening.
 - b. Refusal must be documented.
 - c. Treatment decisions following refusal remain at the discretion of the prescribing provider.
6. Facility Considerations:
 - a. When conducting specimen collection, staff should utilize available private space to maintain dignity and confidentiality to the extent operationally feasible. This may require coordinating and collaborating with other RN

teams whose buildings do allow for specimen collection, while respecting dignity and confidentiality.

7. Nothing in this section shall be interpreted as creating additional duties beyond those already required under applicable law, professional standards, or scope of practice regulations.

IV. REFERENCES:

- A. Waived Tests. Centers for Disease Control and Prevention, 2024
<https://www.cdc.gov/lab-quality/php/waived-tests/index.html>
- B. Larkins MC, Thombare A. Point-of-Care Testing. [Updated 2023 May 29]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK592387/>
- C. The American Psychiatric Association Practice Guideline for the Treatment of Patients With Schizophrenia, Third Edition
<https://psychiatryonline.org/doi/full/10.1176/appi.books.9780890424841.Schizophrenia03>
- D. Practice Parameter for the Assessment and Treatment of Children and Adolescents With Schizophrenia
https://www.aacap.org/App_Themes/AACAP/docs/practice_parameters/Schizophrenia_Sept13.pdf
- E. Resource Document on QTc Prolongation and Psychotropic Medications, 2018
<https://www.psychiatry.org/psychiatrists/search-directories-databases/resource-documents/2018/qt-c-prolongation-and-psychotropic-medications>

V. RELATED POLICIES:

- A. MCCMH MCO Policy 2-051, “Psychotropic Medication in Community-Based Settings”

VI. EXHIBITS:

- A. Minimum Lab Monitoring Psychotropic Medications
- B. Rapid Urine Multi-Drug Screening Result and Pregnancy Screening Test Communication

Revision #:	Revision/Review Date:	Revision Summary:	Reviewer/Reviser:
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1	5/20/2025	Creation of Procedure.	Chief Medical Officer (in collaboration with directly operated services leadership)
2	2/09/2026	Update due to changes at clinics	Chief Medical Officer (in collaboration with directly operated services leadership)
3	3/17/2026	Updated for Clarity	Chief Medical Officer (in collaboration with directly operated services leadership)
4	6/25/2026	Updated protocol to incorporate confirmatory laboratory testing expectations for CLIA waived urine toxicology screenings, with required documentation of medical necessity in accordance with payer requirements.	Chief Medical Officer (in collaboration with directly operated services leadership)