MCCMH Policy 8-004

Chapter: **QUALITY IMPROVEMENT**

Title: **REPORTING AND RESPONDING TO MEDICATION ERRORS AND ADVERSE DRUG EVENTS**

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Chief Executive Officer Date

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I. ABSTRACT

This policy establishes the standards and procedures of Macomb County Community Mental Health (MCCMH), an official agency of the County of Macomb, to identify, document, report, and respond to medication errors and adverse drug events; to monitor and evaluate medication errors or potential errors; and to minimize medication errors to ensure safer processes for persons served through trend analysis, education, and improvement in systems of care.

II. APPLICATION

This policy applies to all community-based providers both directly-operated and within the contract network of MCCMH.

III. POLICY

It is the policy of MCCMH to improve the safety, quality, and accuracy of medication services by identifying, responding, reporting, and monitoring medication errors and adverse drug events affecting MCCMH persons served.

IV. DEFINITIONS

A. Adverse Drug Event

An injury resulting from the use of a drug. This may be due to an adverse drug reaction (a response to a drug that is noxious and unintended, which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.) This may include an allergic reaction or be the result of a medication error.

B. Clinically Responsible Provider
The service provider directly responsible for the care management of an MCCMH person served at the time of the medication administration, which resulted in a medication error or the adverse drug event.

C. Critical Incident
Where an injury to a person served or medication error results in face-to-face emergency treatment being provided by medical staff at any treatment facility, including personal physicians, medical centers, urgent care clinics/centers, and emergency rooms.

D. Emergency Medical Treatment
Where a medication error results in face-to-face emergency treatment being provided by medical staff at any treatment facility, including personal physicians, medical centers, urgent care clinics/centers, and emergency rooms.

E. Medication Error
A mistake that results when a person served who is prescribed medication takes the wrong medication, wrong dosage, or when staff failed to administer the medication at the prescribed timing. It does not include instances in which the person served refused medication.

F. Sentinel Event
An unexpected occurrence involving death or a serious physical or psychological injury (emotional harm) or the risk thereof. Serious injury specifically includes the loss of limb or function. The phrase, "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome (i.e., if the event had continued, death or serious physical or psychological injury would have occurred as determined by a physician or registered nurse). A sentinel event does not include a death due to natural causes. Individuals involved in the review of sentinel events must have the appropriate credentials to review the scope of care. For example, sentinel events that involve a person's death, or other serious medical conditions, must involve a physician or nurse.

V. STANDARDS

A. General

1. Each clinically responsible provider involved in the administration of prescribed medications to persons served shall maintain policies and procedures for the management of medication-related incidents; including a clear chain of responsibility for immediate reporting of incidents to appropriate clinical and administrative staff

and assuring the provision of monitoring and emergency medical services to persons served, as needed.

2. Medications shall be properly prescribed, stored, administered, and dispensed in accordance with MCCMH policies and procedures and federal and state standards of care in medication, nursing, and pharmacy.

3. An MCCMH clinically responsible provider shall record the administration of all medication in the individual's clinical record and/or medication administration record (MAR).

4. MCCMH clinically responsible providers shall ensure that all medication errors and adverse drug reactions are immediately and properly:

    a. Reported to a physician, and

    b. Documented in the individual's medical record.

B. Reporting and Documentation

1. Medication errors and adverse drug events that, per the definition, are classified as critical incidents and/or sentinel events shall be reported in accordance with the standards and procedures outlined in MCCMH MCO Policy 9-321, "Consumer Incident, Accident, Illness, Death or Arrest Report Monitoring," with associated documentation forwarded to the MCCMH Office of Recipient Rights (ORR) fax line or submitted through MCCMH's electronic medical record (EMR) system (FOCUS) within the required timeframe.

2. Medication errors that did not require emergency medical treatment or were not classified as sentinel events and/or critical incidents shall also be reported in accordance with the standards and procedures outlined in in MCCMH MCO Policy 9-321, "Consumer Incident, Accident, Illness, Death or Arrest Report Monitoring."

    a. The MCCMH Quality Department shall share the non-sentinel and/or critical incidents with MCCMH's Nursing Administrator or designee within 48 hours of incident report (IR) review by adding them as an additional reviewer in the electronic medical record (EMR) system.

    b. The Nursing Administrator shall elevate matters abiding by this policy to the Chief Medical Office (CMO) and the Clinical Risk Management Committee (CRMC) when identified as problematic or having a consistent pattern of errors.

3. Staff who work for directly-operated clinics and designated collaborating organizations (DCOs) shall notify MCCMH's Nursing Administrator or designee of any medication errors prior to the end of their shift on the date of the occurrence or the date the occurrence was discovered. The reporting staff shall also ensure the submitted incident report is marked for the Nursing Administrator or designee.

4. Clinical documentation of actions taken and services provided to the individual shall conform to the timeframes and procedures contained in MCCMH Policy 2-010, "Standards for Clinical Services Documentation."

5. Clinical documentation of a possible allergic reaction from a drug shall conform to the standards and procedures of MCCMH Policy 2-070, "Medical Alert - Allergies."

C. Provider Level Review of Medication Errors and Adverse Drug Events

1. When a suspected medication error of any defined category in this policy or a suspected adverse drug event has been discovered, the MCCMH clinically responsible provider shall ensure that staff who observed or discovered the incident(s):

    a. Obtain appropriate assessment of the individual's clinical condition and ensure provision of emergency medical care and ongoing monitoring as needed.

    b. Immediately and properly:

        i. Notify a physician of the incident (preferably the prescribing physician and the physician who signed the individual's person-centered plan).

        ii. Record the medication error and/or adverse drug event in the individual's clinical record. If the event was a possible allergic reaction from a drug, documentation shall conform to the standards and procedures of MCCMH MCO Policy 2-070, "Medical Alert - Allergies."

    c. By the end of their shift, the staff is responsible for:

        i. Completing the Consumer Incident, Accident, Illness, Death or Arrest Report and the Medication Error Form (Exhibits A and C, respectively, of MCCMH MCO Policy 9-321).

        ii. Forwarding all reports (Consumer Incident, Accident, Illness, Death, or Arrest Report; Medication Error Report) to the MCCMH Office of Recipient Rights, pursuant to MCCMH MCO Policy 9-321.

2. Medication errors and adverse drug events that are defined as sentinel events and/or critical incidents shall be reviewed as follows:

    a. The provider shall send a completed Root Cause Analysis/Risk Event Review or Mortality Review, with its corrective action plan, as delineated in MCCMH Policy 8-003 "Incident, Accident, Illness, Death, or Arrest Report Monitoring," within ninety (90) calendar days of initiating the review or within forty-five (45) calendar days of reviewing of additional documentation or direction from MCCMH.

    b. When completing a Root Cause Analysis (RCA) for a sentinel and/or critical medication error, the clinically responsible provider may, whenever possible, include the person served or his/her the legal guardian as deemed appropriate and professionals from the following expertise: 1) A registered nurse 2) A psychiatrist, physician, mid-level licensed prescriber, or medical director of the program 3) Clinically responsible provider's quality director/administrator or designee 4) Other stakeholders as determined necessary (i.e., pharmacist, etc.).

3. Medication errors that are not defined as sentinel events and/or critical incidents shall be addressed as follows:

    a. Clinically responsible providers shall initiate reviews of each occurrence of medication errors that do not meet criteria of critical incidents and/or sentinel events within ten (10) business days of the date of the occurrence.

    b. The review process shall include the development of a corrective action plan or rationale for why a corrective action plan has not been developed.

    c. The review shall utilize the "Medication Error and Adverse Drug Event Analysis and Action Plan for Non-Sentinel or Critical Incident Medication Errors" (Exhibit A). The completed form shall be forwarded to the MCCMH Nursing Administrator or designee within thirty (30) business days of the date of the occurrence.

    d. At least two (2) professionals listed from the roles below shall be included when completing the "Medication Error and Adverse Drug Event Analysis and Action Plan for Non-Sentinel or Critical Incident Medication Errors" (Exhibit A). 1) A registered nurse 2) A psychiatrist, physician, mid-level licensed prescriber, or medical director of the program 3) Clinically responsible provider's quality director/administrator or designee 4) Other stakeholders as determined necessary (i.e., pharmacist, etc.)

e. Active steps, pursuant to the clinically responsible provider's corrective action plan, shall be taken immediately to reduce or ameliorate the further occurrence of the medication error/discrepancy or adverse drug event.

4. Any event that occurs in a specialized residential setting (SRS) shall be reported per contract expectations and as described in MCCMH Policy 9-321, "Incident, Accident, Illness, Death, or Arrest Report Monitoring." MCCMH's Quality Department may elevate reports to the Clinical Risk Management Committee (CRMC) if identified as problematic or if there is a consistent pattern of errors.

5. When medication errors of any category defined in this policy or adverse drug events under review become the subject of an active recipient rights investigation, the clinically responsible provider shall not impede, interfere, or otherwise compromise the investigation of the MCCMH Office of Recipient Rights pursuant to the standards and procedures under MCCMH MCO Policy 9-510, "Recipient Rights Investigation" (e.g. clinically responsible provider may not investigate the details of the event but shall instead focus on systemic issues.)

D. MCCMH Administrative Level of Review

1. All medication errors classified as sentinel events and/or critical incidents shall be reviewed by MCCMH's Clinical Risk Management Committee (CRMC) per MCCMH Policy 8-003 "Reporting and Responding to Critical Incidents, Sentinel Events and Risk Events."

2. Any medication error not classified as a sentinel event or critical incident shall be addressed as follows:

   a. The MCCMH Quality reviewer shall forward the incident report received to the Nursing Administrator via the EMR (FOCUS) system. The Nursing Administrator shall track data of these medication errors and respond accordingly.

   b. The Nursing Administrator or his/her designee shall share with the CRMC, at least quarterly, trends of data concerning medication errors and elevate any recommendations to the CRMC for their consideration when those trends are noted to be problematic or consistent pattern of errors.

   c. The Clinical Risk Management Committee (CRMC) shall finalize their recommendations and notify providers as described in MCCMH Policy 8-003.

3. MCCMH's Clinical Risk Management Committee's (CRMC) responsibilities, as it pertains to sentinel and/or critical medication errors and drug adverse events or those not categorized as such but reported by the Nursing Administrator or designee:

    a. The CRMC shall examine the clinically responsible providers' completed reviews and submitted action plans.

    b. The CRMC shall ensure the development, monitoring, and implementation of either (1) A corrective action plan or intervention to prevent further occurrence of the adverse drug event; or (2) A presentation of the rationale for not pursuing an intervention. A corrective action plan or intervention must identify who will implement the provisions of the plan, and the time period(s) and method(s) by which implementation will be monitored and/or evaluated.

    c. The CRMC may return corrective action plans to clinically responsible providers for further action or completion.

    d. Clinically responsible providers shall cooperate with and respond to requests by the CRMC to perform a review of an adverse drug event, and to follow the Committee's recommendations for additional action on submitted corrective action plans. The CRMC shall review the adverse drug reaction events analyses and corrective action plans as tracked by the MCCMH Nursing Administrator or designee and their recommendations depending on the problematic patterns identified during initial review.

    e. For suspected adverse drug reactions, if probability is indicated as definite, probable, or possible, the CRMC may voluntarily report the event to the Department of Health and Human Services, Food & Drug Administration.

E. Confidentiality

Consumer Incident, Accident, Illness, Death or Arrest Reports; Medication Error Forms; Medication Error and Adverse Drug Event Reviews; as well as any documents generated by the CRMC, remain confidential quality improvement documents which do not constitute summary reports and are not subject to discovery under the U.S. Department of State Freedom of Information Act (FOIA) or Michigan's FOIA. No copies of such documents shall be maintained in the clinical records of individuals but shall be kept in MCCMH administrative files.

F. Mutual Collaboration

When there is more than one report on the same incident or person served and it is uncertain which office will be responsible for follow-up, both the MCCMH Nursing

Administrator or designee and Office of Recipient Rights must coordinate the routing of such cases and ensure follow-up.

G. Analysis for Quality Review

1. The MCCMH Nursing Administrator or designee shall create at least one (1) annual report analyzing data trends from error review reports (on non-sentinel and/or critical medication errors or drug adverse events) and elevate any pertinent quality improvement recommendations, as applicable, to the CRMC. The annual report shall be submitted to the MCCMH Quality Committee including all the CRMC's finalized recommendations.

2. The CRMC shall develop a report at least annually analyzing data trends for all sentinel and/or critical medication errors and elevate any pertinent quality improvement recommendations as applicable. The annual report shall be submitted to the MCCMH Quality Committee including all the CRMC's finalized recommendations.

VI. REFERENCES / LEGAL AUTHORITY

A. MCL 333.7103

B. MCL 333.17001 et seq.

C. MCL 333.17201 et seq.

D. MCL 15.231 et seq. (Michigan Freedom of Information Act, Act 442 of 1976)

E. MDHHS Administrative Rules, R 330.7158(7)

F. Commission on Accreditation of Rehabilitation Facilities (CARF) 2022 Standards Manual

G. Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual, in effect and as amended

VII. RELATED POLICY

A. MCCMH Policy 2-010, "Standards for Clinical Services Documentation"

B. MCCMH Policy 2-070, "Medical Alert – Allergies"

C. MCCMH's Policy 3-015, "Contracted Provider Mandatory Training and Workforce Development"

D. MCCMH MCO Policy 8-003, "Reporting and Responding to Critical Incidents, Sentinel Events and Risk Events"

E. MCCMH MCO Policy 9-321, "Consumer Incident, Accident, Illness, Death or Arrest Report Monitoring"

F. MCCMH MCO Policy 9-510, "Recipient Rights Investigation"

VIII. EXHIBITS

A. Medication Error and Adverse Drug Event Analysis and Action Plan for Non-Sentinel or Critical Incident Medication Errors