MCCMH MCO Policy 8-004

(combined MCCMH Policies 2-07-012 and 2-07-040 and MCCMH MCO Policy 2-052)

Chapter: **QUALITY IMPROVEMENT**
Title: **REPORTING AND RESPONDING TO MEDICATION ERRORS/DISCREPANCIES AND ADVERSE DRUG EVENTS**

See also MCCMH MCO Policy 8-003, "Reporting and Responding to Critical Incidents, Sentinel Events, and Risk Events;" and 9-321, "Consumer Incident, Accident, Illness, Death or Arrest Report Monitoring."

Prior Approval Date: N/A
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Approved by: _____ 07/02/13
Executive Director Date

I. Abstract

This policy establishes the standards and procedures of the Macomb County Community Mental Health (MCCMH) Board to identify, document, report and respond to medication errors/discrepancies and adverse drug events; to monitor, assess and evaluate medication errors or potential errors; and, through trend analysis, education and improvement in systems of care, minimize medication errors to ensure a safe medication process for consumers of the MCCMH Board.

II. Application

This policy shall apply to all community-based directly-operated and contract network providers of the MCCMH Board.

III. Policy

It is the policy of the MCCMH Board that:

A. A system for identification, reporting, responding, monitoring and analysis of medication errors/discrepancies and adverse drug events occurring to its service consumers shall be established and maintained in order to improve the safety, quality and accuracy of its medication services;

B. Responses to medication errors/discrepancies begin by identifying key elements and ends with process change in eliminating or reducing occurrences and relying on individual and organizational transparency, and that medication safety offers opportunities for quality improvement;

C. A team of stakeholders shall be established to address identifiable challenges involved in the key elements in order to reduce error incidents.

IV. Definitions

A. Clinically-Responsible Provider
A service provider with over-all responsibility for the management of the care of a consumer in MCCMH services, and, for purposes of this policy, the service provider responsible for the medication administration that resulted in the medication error/discrepancy or the adverse drug event.

B. Medication Error/Discrepancy
Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

C. 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 and 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 may be the result of a medication error.

D. Medication Safety Committee
A committee of stakeholders established for the purpose of examining individual and trended data on medication errors/discrepancies and providing recommendations to the MCCMH Executive Director for proper action.

V. Standards

A. General

1. Each clinically-responsible provider involved in the administration of prescribed medications to consumers 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 the consumer as needed.

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

3. A MCCMH clinically-responsible provider shall record the administration of all medication in the consumer's clinical record.

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

   a. Reported to a physician, and

   b. Documented in the consumer's clinical record.

B. Reporting

1. Incidences of medication errors/discrepancies and adverse drug 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) within the required time frame.

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

1. Medication errors/discrepancies are rarely the result of one person making an error, but rather are caused by a series of system failures that allowed an error to occur. Medication errors/discrepancies are opportunities for quality improvement.

2. Clinically-responsible providers shall perform reviews of medication errors/discrepancies and adverse drug events according to the provisions of this policy for all medication errors/discrepancies and adverse drug events that are <u>not</u> sentinel events, risk events or non-sentinel deaths. Medication errors/discrepancies and adverse drug events that are classified as sentinel events, risk events or non-sentinel deaths shall be reviewed according to the provisions of MCCMH MCO Policy 8-003, "Reporting and Responding to Critical Incidents, Sentinel Events, and Risk Events."

3. Clinically-responsible providers shall initiate reviews of each individual occurrence of medication errors/discrepancies and adverse drug events (that are <u>not</u> sentinel events, risk events or non-sentinel deaths) within ten (10) business days of the date of the occurrence, utilizing at a minimum, a classification of key elements, defined herein at VI.B.2.b The completed review and attached action plan (Exhibit A) shall be forwarded to the

MCCMH Office of the Manager of Nursing Services within thirty (30) business days of the date of the occurrence.

D. MCCMH Administrative-Level Review

1. Administrative-Level Review of Medication Errors/Discrepancies

a. MCCMH shall establish a Medication Safety Committee, an administrative review and monitoring body whose function is to actively participate in a comprehensive review of the provider-level medication errors/discrepancies analyses and corrective action plans addressing the 10 key elements (VI.B.2.b.) in order to provide a mechanism for monitoring safety of drug use, to encourage education of clinicians, as well as to advance knowledge regarding potential medication errors/discrepancies.

b. The membership composition shall include at least six (6) stakeholder representatives from the following:

- Primary or secondary consumer
- MCCMH network provider of mental health services
- MCCMH network provider of developmental disability services
- Registered nurse
- Medical doctor or a psychiatrist
- MCCMH Training Department representative
- MORC, Inc. Training Department representative
- MCCMH Corporate Compliance representative
- Pharmacologist representative
- MCCMH Quality Improvement representative
- Other individual stakeholders as determined necessary

c. Selection of committee membership shall be the responsibility of the MCCMH Office of the Manager of Nursing Services. There shall be no over representation from any one group of stakeholders, at the discretion of the Manager of Nursing Services. Term of service shall be annual, with the opportunity for reappointment.

d. The Medication Safety Committee will be the responsibility of and shall be chaired by the MCCMH Office of the Manager of Nursing Services. Meetings shall be scheduled on a monthly basis, or as determined by the MCCMH Manager of Nursing Services.

2. Administrative-Level Review of Adverse Drug Events

a. The MCCMH Clinical Risk Management Committee (CRMC), chaired by the MCCMH Office of the Medical Director, shall review the

provider-level adverse drug events analyses and corrective action plans addressing the 10 key elements (VI.B.2.b.) in order to provide a mechanism for monitoring safety of drug use, to encourage education of clinicians, as well as to advance knowledge regarding potential adverse drug events.

b. Where the adverse drug event probability is indicated as definite, probable, or possible, the CRMC may voluntary report the event to the Department of Health and Human Services, Food & Drug Administration.

E. Analysis for Quality Review

1. Monthly trended reports will be produced by the MCCMH Information System Management Division and provided to the Office of the Manager of Nursing Services for study and analysis as an aid toward improving quality and safety.

2. The Manager of Nursing Services, through the recommendations of the Medication Safety Committee, shall monitor and make recommendations regarding risk management of medication errors/discrepancies, and any observable trends thereof, to the MCCMH Quality Council, on an annual basis.

3. The MCCMH CRMC shall monitor and make recommendations regarding risk management of adverse drug events, and any observable trends thereof, to the MCCMH Quality Council, on an annual basis.

F. Consumer Incident, Accident, Illness, Death or Arrest Reports; Medication Error Forms; Medication Error/Discrepancy and Adverse Drug Event Reviews as well as any documents generated by the Medication Safety Committee and CRMC (as quality improvement committees), remain confidential quality improvement documents, 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 consumers, but shall be kept in MCCMH administrative files.

G. Adherence to Additional Policies and Procedures and Contractual Provisions

1. Providers shall abide by the training requirements under its contract with MCCMH and in accordance with the policies and procedures of MCCMH MCO Policy 3-015, "Mandatory Network Training."

2. Clinical documentation of actions taken and services provided to the consumer shall conform to time frames and procedures contained in MCCMH MCO Policy 2-010, "Clinical Services Documentation."

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

VI. Procedures

A. When a suspected medication error/discrepancy and/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) shall:

1. Secure appropriate assessment of the consumer's clinical condition and ensure provision of emergency medical care and on-going monitoring as needed.

2. Immediately and properly:

b. Record the medication error/discrepancy and/or adverse drug event in the consumer'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. Notify a physician (preferably the prescribing physician and the physician who signed the consumer's Person-Centered Plan of the incident).

3. By the end of his/her shift:

a. Complete 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);

b. Forward 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.

c. For suspected adverse drug events, it is not incumbent upon the reporting clinically-responsible provider to demonstrate cause and effect, but merely to report the possible association of the use of a given medication with a suspected reaction to medication. Information regarding whether incidents are extensions of the normal pharmacologic effect or mild side effects may be found in the Physicians' Desk Reference, the Drug Information Sheets, and through consultation with the prescribing physician or pharmacist.

B. Provider-Level Review of Medication Error/Discrepancy and Adverse Drug Event

1. Timeframe

   a. Within ten (10) business days of the date that the incident was discovered, the clinically-responsible provider shall initiate a review for each medication error/discrepancy and each adverse drug event that does not fall within the classification of a sentinel event, risk event or a non-sentinel death.

2. Format of Provider-Level Review with Corrective Action and Submission to MCCMH Administration

   a. The review for each medication error/discrepancy and each adverse drug event that does not fall within the classification of a sentinel event, risk event or a non-sentinel death shall utilize, at a minimum, the classification of ten key causal factors, defined below. Please see Exhibit A, Medication Error/Discrepancy and Adverse Drug Event Review, as a sample format for the review process.

   b. Ten Key Causal Factors for Review

      (1) Patient Information: Obtaining the patient's pertinent demographic (age, weight) and clinical (allergies, lab results) information that will assist practitioners in selecting the appropriate medications, doses and routes of administration. Having essential patient information at the time of medication prescribing, dispensing and administration will result in a significant decrease in preventable medication errors/discrepancies and adverse drug events.

      (2) Drug Information: Providing accurate and usable drug information to all healthcare practitioners involved in the medication-use process reduces the amount of preventable medication errors/discrepancies and adverse drug events. Not only should drug information be readily accessible to the staff through a multitude of sources (drug references, formulary, protocols, dosing scales, etc.) it is imperative that the drug information is up to date as well as accurate.

      (3) Communication of Drug Information: Miscommunication between physicians, pharmacists and nurses is a common cause of medication errors/discrepancies. To minimize the amount of medication errors caused by miscommunication it is always important to verify drug information and eliminate communication barriers.

      (4) Drug Labeling, Packaging and Nomenclature: Drug names that look-alike or sound-alike, as well as products that have

confusing drug labeling and non-distinct drug packaging significantly contribute to medication errors/discrepancies. The incidence of medication errors is reduced with the use of proper labeling and the use of unit dose systems within the program.

(5) Drug Storage, Stock, Standardization, and Distribution: Standardizing drug administration times, drug concentrations, and limiting the dose concentration of drugs available in patient care areas will reduce the risk of medication errors/discrepancies or minimize their consequences should an error occur.

(6) Drug Device Acquisition, Use and Monitoring: Appropriate safety assessment of drug delivery devices should be made both prior to their purchase and during their use. Also, a system of independent double-checks should be used within the system to prevent device related errors such as, selecting the wrong drug or drug concentration, setting the rate improperly, or mixing the infusion line up with another.

(7) Environmental Factors: Having a well-designed system offers the best chance of preventing errors; however, sometimes the environment in which one works contributes to medication errors/discrepancies. Environmental factors that often contribute to medications errors include poor lighting, noise, interruptions and a significant workload.

(8) Staff Competency and Education: Staff education should focus on priority topics, such as: new medications being used in the program, high- alert medications, medication errors that have occurred both internally and externally, protocols, policies and procedures related to medication use. Staff education can be an important error preventions strategy when combined with the other key elements for medication safety.

(9) Patient Education: Patients must receive ongoing education from physicians, pharmacists, nurses and other clinical staff about the brand and generic names of medications they are receiving, their indications, usual and actual doses, expected and possible adverse effects, drug or food interactions, and how to protect themselves from errors. Patients can play a vital role in preventing medication errors when they have been encouraged to ask questions and seek answers about their medications before drugs are dispensed at a pharmacy or administered in a hospital or other health care facility.

(10) Quality Processes and Risk Management: The way to prevent errors is to redesign the systems and processes that lead to errors rather than focus on correcting the individuals who make errors. Effective strategies for reducing errors include making it difficult for staff to make an error and promoting the detection and correction of errors before they reach a patient and cause harm.

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

d. 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.

e. The completed review and corrective action plan, or rationale for why a corrective action plan has not been developed, shall be forwarded to the MCCMH Office of the Manager of Nursing Services within thirty (30) business days of the date of the occurrence.

3. When a medication error/discrepancy or adverse drug event under review is the subject of an active recipient rights investigation, the clinically-responsible provider shall be careful that it not impede, interfere or otherwise compromise the investigation of the MCCMH ORR 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, etc.)

4. For timeframes and format of reviews of medication errors/discrepancies and adverse drug events that are classified as sentinel events, risk events or non-sentinel deaths see MCCMH MCO Policy 8-003.

F. MCCMH Administrative-Level Review Process

1. The MCCMH Office of Recipient Rights shall forward incident reports received identifying medication errors/discrepancies and adverse drug events to the MCCMH Office of the Manager of Nursing Services.

2. The MCCMH Office of the Manager of Nursing Services shall forward documentation received relating to adverse drug events to the MCCMH Medical Director for CRMC review, and shall retain documentation received relating to medication errors/discrepancies for Medication Safety Committee review.

3. Process Specific to Review of Medication Errors/Discrepancies

   a. Where the incident is identified as a medication error/discrepancy, the MCCMH Office of the Office of the Manager of Nursing Services shall:

      (1) Process and categorize medication errors/discrepancies as reported on Incident, Accident, Illness, Death or Arrest Reports and accompanying Medication Error Forms according to clinical significance;

      (2) Document all medication errors/discrepancies into a data spreadsheet;

      (3) Review clinically-responsible providers' completed medication error/discrepancy review reports;

      (4) Collect individual and trended data for presentation at the next meeting of the Medication Safety Committee.

   b. The Medication Safety Committee shall examine individual data addressing the ten key elements in medication error/discrepancy through assessments of the clinically-responsible providers' completed reviews and submitted corrective action plans.

   c. The Medication Safety Committee shall ensure the development, monitoring and implementation of either (1) a corrective action plan or intervention to prevent further occurrence of the medication error/discrepancy or (2) presentation of a 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.

   d. The Medication Safety Committee may return corrective action plans to clinically-responsible providers for further action or completion.

   e. Clinically-responsible providers shall cooperate with and respond to requests by the Medication Safety Committee to perform a medication error/discrepancy review, and to follow the Committee's recommendations for additional action on submitted corrective action plans. Responses shall be made within ten (10) business days of receiving the request.

4. Process Specific to Review of Adverse Drug Events

a. The MCCMH Medical Director, as chair of the CRMC, shall present all related forms to the CRMC members at the next scheduled meeting.

b. The CRMC shall examine individual data addressing the ten key elements in the adverse drug event through assessments of the clinically-responsible providers' completed reviews and submitted corrective action plans.

d. 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) presentation of a 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.

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

f. 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. Responses shall be made within ten (10) business days of receiving the request.

g. Where the adverse drug event probability is indicated as definite, probable, or possible, the CRMC may voluntary report the event to the Department of Health and Human Services, Food & Drug Administration on-line at: https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm.

5. When there is more than one report on the same incident or consumer and it is uncertain which office responsible for follow-up, both the Office of the Manager of Nursing Services and Office of Recipient Rights must coordinate the routing of such cases as well as the follow-up.

G. Analysis for Quality Review

1. The MCCMH Information System Management Division shall produce monthly trended reports on medication errors/discrepancies and submit to the MCCMH Office of the Manager of Nursing Services.

2. The Office of the Manager of Nursing Services shall create an annual report analyzing data received from trended reports (on medication errors/discrepancies) and the recommendations of the Medication Safety

Committee. The annual report shall be submitted the MCCMH Quality Council.

3. The CRMC shall present an annual report to the MCCMH Quality Council on the incidence and observable trends reported on adverse drug events.

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. MDCH Administrative Rules, R 330.7158(7)

F. "About Medication Errors," The National Coordinating Council for Medication Error and Prevention, web (2013) http://www.nccmerp.org/aboutMedErrors.html

G. Institute for Safe Medication Practices, web (2013) http://www.ismp.org/faq.asp#Question_3

H. Commission on Accreditation of Rehabilitation Facilities (CARF) 2013 Standards Manual, §1.H., "Health and Safety," 8., 9.; §2. E., "Medication Use," 5.

I. Michigan Department of Community Health, Medicaid Provider Manual, Mental Health / Substance Abuse

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

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

VIII. Exhibits

A. Medication Error/Discrepancy and Adverse Drug Event Analysis and Action Plan

Medication Error/Discrepancy and Adverse Drug Event Analysis and Action Plan Cover Sheet

Please check one:

☐MEDICATION ERROR/DISCREPANCY ANALYSIS AND ACTION PLAN

☐ADVERSE DRUG EVENT ANALYSIS AND ACTION PLAN

Date:
Program:
Consumer Name:
Case number:
Date Medication Error occurred:
Date Medication Error Analysis completed:

Meeting Attendees:

Name, Credentials	Position

Send form with completed Medication Error/Discrepancy Analysis and Action Plan, or Adverse Drug Event Analysis and Action Plan, to the Manager of Nursing Office via **Fax: (586) 465-8320**

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The attached template is provided as an aid in organizing the steps in a Medication Error/Discrepancy or Adverse Drug Event analysis. Not all possibilities and questions will apply in every case, and there may be others that will emerge in the course of the analysis. However, all possibilities and questions should be fully considered in your quest for "Medication Errors" and risk reduction. Extra sheets may be used if needed.

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A Framework for a Medication Error/Discrepancy or Adverse Drug Event Analysis and Action Plan

Stages of analysis and action plan	Medication Error (or Adverse Drug Event)	Questions	Findings
What happened?		What are the details of the event?	
Patient Information: Was essential patient information obtained at the time of medication prescribing, dispensing and administration? (i.e., patient's age, weight, allergies, lab results)		How did this element contribute to the event?	
Drug Information: Was accurate and up-to-date, usable drug information provided or made readily available to all healthcare practitioners involved in the medication-use process? (e.g. through drug references, formulary, protocols, etc.)		How did this element contribute to the event?	
Communication of Drug Information: Were barriers to communication between physicians, pharmacists, nurses and other clinical staff identified and eliminated in order to ensure verification of drug information?		How did this element contribute to the event?	
Drug Labeling, Packaging and Nomenclature: Was there proper labeling and use of unit dose systems to reduce confusion caused by improper drug labeling and non-distinct drug packaging?		How did this element contribute to the event?	

⬇			
Drug Storage, Stock, Standardization, and Distribution: Is there a standardization of drug administration times, drug concentrations, and limiting of dose concentration of drugs available in patient care areas?		How did this element contribute to the event?	
⬇			
Drug Device Acquisition, Use and Monitoring: Was appropriate safety assessment of drug delivery devices made both prior to their purchase and during their use? Is a system of independent double-checks used within the institution to prevent device related errors such as, selecting the wrong drug or drug concentration, setting the rate improperly, or mixing the infusion line up with another?		How did this element contribute to the event?	
⬇			
Environmental Factors: How did environmental factors contribute to the event, such as poor lighting, noise, interruptions and a significant workload, etc.?		How did this element contribute to the event?	
⬇			
Staff Competency and Education: Have staff received education that focuses on priority topics, such as: new medications being used in the system, high- alert medications, medication errors that have occurred both internally and externally, protocols, policies and procedures related to medication use?		How did this element contribute to the event?	
⬇			

Patient Education: Have patients received ongoing education from physicians, pharmacists, nurses and other clinical staff about the brand and generic names of medications they are receiving, their indications, usual and actual doses, expected and possible adverse effects, drug or food interactions, and how to protect themselves from errors?		How did this element contribute to the event?	
			
Quality Processes and Risk Management: Is the focus on redesigning the systems and processes that lead to errors rather than on correcting the individuals who make errors?		How did this element contribute to the event?	
			
For each of the elements identified in the analysis as needing an action, indicate the planned action, expected implementation date, and associated measure of effectiveness	**Planned Action**		**Associated measure and implementation date**