I. Abstract

This policy establishes the standards for identifying, reporting and reviewing medication-related incidents pertaining to consumers of the Macomb County Community Mental Health (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. To improve the quality and accuracy of its medication services, a system for identification, reporting and monitoring of medication-related incidents occurring to its service consumers shall be established and maintained;

B. Suspected adverse drug events shall be reported and reviewed to provide ongoing monitoring and determination of potential areas for improvement of the quality of care; and
C. When a MCCMH network provider believes a consumer’s condition presents the need for immediate medical attention, he/she shall immediately telephone 911 or follow other provider designated emergency procedures prior to complying with the procedures set forth below.

IV. Definitions

A. Medication Administration
The process of giving a physician-prescribed oral medication, injection, intravenous (IV) or topical medication treatment to a consumer.

B. Adverse Drug Events
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.

C. Medication-Related Incidents
Any event that may cause or lead to inappropriate medication use or consumer harm and includes, but is not limited to, the following:

1. Suspected reaction to medication (adverse drug events);
2. Staff administration of incorrect medication;
3. Staff administration of incorrect dosage;
4. Staff failure to administer medication as prescribed/scheduled.

NOTE: Long-acting IM medications (haloperidol, fluphenazine) may be administered within three days of scheduled injection date without constituting a medication administration error. The time frame may be adjusted on an individual basis by the prescribing psychiatrist and shall be documented with the medication order.

5. Other: Those situations which are extremely serious and do not fit into any of the above categories, but need to be recorded.

V. Standards

A. Each network 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 staff and assuring the provision of monitoring and emergency medical services to the consumer as needed.
B. Medication-Related Incidents

1. When a medication-related incident has been discovered, appropriate assessment of the consumer's clinical condition shall be secured with emergency medical care and on-going monitoring provided as needed.

2. The medication-related incident shall be immediately recorded in the consumer's service progress notes. A notation in the consumer's medical records shall be made.

3. The prescribing physician and the physician who signed the consumer's Person-Centered Plan shall be immediately notified of all medication-related incidents.

C. Reporting Medication-Related Incidents

1. All MCCMH providers shall cooperate in the identification and reporting of suspected adverse drug events and other medication-related incidents of MCCMH service consumers and shall adhere to the time frames and procedures contained in this policy and in MCCMH MCO Policy 9-321, “Consumer Incident, Accident, Illness, Death or Arrest Report Monitoring.” 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.” 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.” Reporting of consumer deaths shall conform to the time frames and procedures contained in MCCMH MCO Policy 8-003, “Sentinel Events, Root Cause Analysis, and Mortality Review.”

2. MCCMH network providers shall report on the following, as applicable:
   a. Consumer Incident, Accident, Illness, Death or Arrest Report (Exhibit A)
   b. Medication Error Form (Exhibit B);
   c. Provider Report of Death (Exhibit C);
   d. Adverse Drug Events form (Exhibit D) - It is not incumbent upon the reporting network 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.

3. 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.

D. Monitoring Medication-Related Incidents

1. The MCCMH Recipient Rights Director shall provide regular reports regarding medication-related incidents to the MCCMH CRMC, and, in conjunction with the CRMC Chairperson, provide quarterly reports to the MCCMH Quality Council on the incidence and observable trends regarding medication-related incidents reported.

2. When there has been an adverse drug event, the MCCMH Clinical Risk Management Committee (CRMC), as applicable, shall complete the appropriate section of the Adverse Drug Event Forms (Exhibit D) 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-related incidents.

3. The MCCMH CRMC shall monitor and make recommendations regarding risk management of medication-related incidents, and any observable trends thereof, to the MCCMH Quality Council.

E. Confidentiality

1. Consumer Incident, Accident, Illness, Death or Arrest Reports; Medication Error Forms; Provider Reports of Death; and Adverse Drug Event Forms; as well as any documents generated by 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.

VI. Procedures

A. After providing the consumer with any needed assistance, any MCCMH network provider who observes symptoms which may be associated with the need for urgent medical attention or the death of an MCCMH service consumer shall immediately notify the prescribing physician and the physician who signed the consumer's Person-Centered Plan.

B. Where symptoms associated with the need for urgent medical attention of an MCCMH service consumer become known to be the result of an allergy to a drug, this fact shall be noted in and on the consumer's clinical record according to MCO Policy 2-070, “Medical Alert - Allergies.” Users of the MCCMH FOCUS electronic medical record system shall make a notation in the Health and Safety Warning section of the consumer’s electronic record as appropriate.
C. A MCCMH network provider staff who observes a medication-related incident (including an adverse drug event), shall by the end of his/her shift, do the following:

1. Complete a Consumer Incident, Accident, Illness, Death or Arrest Report (Exhibit A), and the Medication Error Form (Exhibit B);

2. If applicable, complete Part I of Adverse Drug Event (Exhibit D), and;

3. Document his/her observations in the consumer’s clinical record.

D. In the event of death, the Provider Report of Death (Exhibit C) shall additionally be completed.

E. The network provider staff shall direct all reports (Consumer Incident, Accident, Illness, Death or Arrest Report; Medication Error Report; and, if applicable, Adverse Drug Event and/or Provider Report of Death) to the MCCMH Office of Recipient Rights, pursuant to MCCMH MCO Policy 9-321.

F. The MCCMH Office of Recipient Rights Director shall present the incident reports, medication error forms, reports of death from medication-related incidents, and reports of adverse drug events, at the next scheduled meeting of the CRMC. The members shall review all reports, as applicable, and present a quarterly report to the MCCMH Quality Council on the incidence and observable trends regarding medication-related incidents reported.

G. Where an adverse drug event form has been submitted (Exhibit D), the CRMC shall complete Section II if, based upon its clinical judgment, an adverse drug event may have occurred and shall forward a copy to the appropriate network provider. If the side effects do not meet the adverse drug event definition, the CRMC shall not complete the form.

F. 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.

VI. References / Legal Authority

A. MCL 333.7103

B. MCL 333.17001 et seq.

C. MCL 333.17201 et seq.

E. MDCH Administrative Rules, R 330.7158(7)

F. ASHP guidelines on adverse drug event monitoring and reporting, 52 Am J Health-Syst Pharm 417 (1995)


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

I. MCCMH MCO Policy 9-321, “Consumer Incident, Accident, Illness, Death or Arrest Report Monitoring”

VIII. Exhibits

A. Consumer Incident, Accident, Illness, Death or Arrest Report

B. Medication Error Form

C. Provider Report of Death

D. Adverse Drug Events
### Consumer Incident, Accident, Illness, Death, or Arrest Report

**Macomb County Community Mental Health Services**

<table>
<thead>
<tr>
<th>Facility/Home</th>
<th>Facility Code</th>
<th>Consumer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility Address</td>
<td>Zip</td>
<td>Case Number</td>
</tr>
<tr>
<td>City</td>
<td>Licensee/Organization</td>
<td>Licensee Number</td>
</tr>
</tbody>
</table>

#### Persons Involved/Witnessed

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Phone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Address</td>
<td>Phone Number</td>
</tr>
</tbody>
</table>

**Date of Incident:**

**Time:**

**Location:**

### Check Type of Incident

A. □ Suicide
B. □ Death (non suicide)
C. □ Use of physical management (Must also complete and attach Use of Physical Management Form)
D. □ Emergency medical treatment due to injury or physical illness
E. □ Hospitalization (Medical) due to injury or physical illness
F. □ Property destruction – over $100
G. □ Serious display of verbal or behavior hostility
H. □ Emergency medical treatment due to medication error (Must also complete and attach Medication Error Form)
I. □ Hospitalization (Medical) due to medication error (Must also complete and attach Medication Error Form)
J. □ Suspected adverse reaction to medication (Must also complete and attach Medication Error Form)
K. □ Staff administration of incorrect medication (Must also complete and attach Medication Error Form)
L. □ Staff administration of incorrect dosage (Must also complete and attach Medication Error Form)
M. □ Staff failed to administer medication (Must also complete and attach Medication Error Form)
N. □ Arrest of consumer
O. □ Allegations of, apparent, or suspected abuse and neglect (Must immediately notify the Office of Recipient Rights at (586) 469-6528 or immediately fax a Recipient Rights Complaint form to (586) 466-4131 for abuse and neglect and all other possible rights violations)

P. □ Other

### Explain What Happened:

ACTION TAKEN BY STAFF/TREATMENT GIVEN [INCLUDING TREATING PHYSICIAN; MEDICAL FACILITY; DIAGNOSIS OR CAUSE OF DEATH]:

ACTION TAKEN TO REMEDY AND/OR PREVENT RECURRENCE OF INCIDENT, ACCIDENT, ILLNESS, DEATH, OR ARREST:

### Persons Notified (Name) Date/Time

<table>
<thead>
<tr>
<th>Persons Notified (Name)</th>
<th>Date/Time</th>
<th>Persons Notified (Name)</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Foster Care Licensing:</td>
<td></td>
<td>Adult/Children Protective Service:</td>
<td></td>
</tr>
<tr>
<td>Physician or RN:</td>
<td></td>
<td>Office of Recipient Rights:</td>
<td></td>
</tr>
<tr>
<td>Case Manager/Supports Coordinator:</td>
<td></td>
<td>Law Enforcement:</td>
<td></td>
</tr>
<tr>
<td>Supervisor:</td>
<td></td>
<td>Other (Specify):</td>
<td></td>
</tr>
</tbody>
</table>

### Signature of Person Completing Report

PRINT NAME AND TITLE DATE

### Signature of Licensee/Administrator

PRINT NAME AND TITLE DATE

---

Consumer Incident, Accident, Illness, Death or Arrest Report (rev. 2/11), MCO Policy 2-052, Exhibit A
**MEDICATION ERROR FORM**

**THIS FORM IS COMPLETED IN ADDITION TO AN INCIDENT REPORT**

Consumer: ______________________________ Case Number: __________________ Date: ___________

*Medication error* is defined as *any* of the following: (a) staff administration of incorrect medication (b) staff administration of incorrect dosage (c) Staff failed to administer medication – this does **not** include medication refusals

<table>
<thead>
<tr>
<th>All Medication(s) Name and Dosage Received:</th>
<th>All Medication(s) Name and Dosage Prescribed:</th>
<th>Medication(s) Name and Dosage Staff Failed to Administer (if applicable):</th>
</tr>
</thead>
</table>

Did the consumer suffer an adverse reaction as a result of the medication error?  □ No  □ Yes
If yes, describe:

Was the consumer hospitalized (medical) or receive medical treatment due to medication error?  □ No  □ Yes
If yes, describe:

<table>
<thead>
<tr>
<th>SIGNATURE OF PERSON COMPLETING REPORT</th>
<th>PRINT NAME AND TITLE</th>
<th>DATE</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>SIGNATURE OF LICENSEE/ADMINISTRATOR</th>
<th>PRINT NAME AND TITLE</th>
<th>DATE</th>
</tr>
</thead>
</table>

Medication Error Form (rev. 2/11), MCO Policy 2-052, Exhibit B
MACOMB COUNTY COMMUNITY MENTAL HEALTH
PROVIDER REPORT OF DEATH

(to be completed by the clinically-responsible provider)

VENDOR ORGANIZATION NAME:

PROVIDER NAME:

<table>
<thead>
<tr>
<th>Consumer Information:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer:</td>
<td>Clinical Record #:</td>
</tr>
</tbody>
</table>

Incident Report sent to MCCMH ORR: [ ] YES [ ] NO

Status of case at time of death: [ ] Open [ ] Closed Date closed:

Was the consumer discharged from a state operated service within six months of the death?
[ ] No [ ] Yes, name of facility: Date of D/C:

Most Recent Address:

Is this a 24-Hour Supervised Residential Arrangement? [ ] Yes [ ] No

Name of Residence:

Type of supervised residence:
[ ] CLF [ ] SIP / Portable Support [ ] AFC [ ] Child Foster Care [ ] Respite Home

Gender: [ ] M [ ] F Date of Birth: Date of Death:

Mortality Review Required: (Check all that apply)

[ ] Provider Premises [ ] MCCMH Transportation Accident [ ] Apparent Suicide [ ] Apparent Homicide

[ ] Current ORR Investigation circumstances of death [ ] Police Investigation into [ ] Elopement from MCCMH funded 24-hr. Care

Other:

Most recent diagnosis (DSM-IV):

<table>
<thead>
<tr>
<th>DSM-IV DIAGNOSIS:</th>
<th>CODE</th>
<th>AXIS IV:</th>
</tr>
</thead>
<tbody>
<tr>
<td>AXIS I (A)</td>
<td></td>
<td>1 Primary Support</td>
</tr>
<tr>
<td>AXIS I (B)</td>
<td></td>
<td>2 Social Environment</td>
</tr>
<tr>
<td>AXIS I (RO)</td>
<td></td>
<td>3 Educational</td>
</tr>
<tr>
<td>AXIS II (A)</td>
<td></td>
<td>4 Occupational</td>
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<tr>
<td>AXIS II (B)</td>
<td></td>
<td>5 Housing</td>
</tr>
<tr>
<td>AXIS II (RO)</td>
<td></td>
<td>6 Economic</td>
</tr>
<tr>
<td>AXIS III (A)</td>
<td></td>
<td>7 Health Care Access</td>
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<tr>
<td>AXIS III (B)</td>
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<td>8 Legal</td>
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<td>9 Other:</td>
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<td>AXIS V:</td>
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<td>Current</td>
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<td>Highest in Last Yr</td>
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<td>Expected at Dis</td>
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MCCMH Provider Report of Death (rev.11/08), MCO Policy 2-052, Exhibit C, p. 1 of 3
Date of most recent med. review:

Medications:

<table>
<thead>
<tr>
<th>All current meds (prescribed, OTC, physical, psychiatric)</th>
<th>Dosage</th>
<th>Blood levels</th>
<th>Date</th>
<th>Prescribing physician</th>
<th>Prescribed</th>
<th>Consumer used</th>
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<tr>
<td></td>
<td></td>
<td>(If applicable, e.g., Lithium, Clozaril, Anticonvulsant)</td>
<td></td>
<td></td>
<td>W/N 30 days</td>
<td>W/N 24 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>U/K</td>
<td>W/N 30 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>U/K</td>
<td>W/N 24 hours</td>
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</table>

(Use additional sheet(s) as needed)

Other substances used, e.g., alcohol, recreational drugs:

Current MCCMH-Arranged Services (provided/scheduled within 30 days prior to death - Computer printout of services is acceptable):

<table>
<thead>
<tr>
<th>Services</th>
<th>Scheduled (date)</th>
<th>Delivered Y/N</th>
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Most recent face-to-face contact with consumer, if any, within last 30 days prior to death (date and type of service):
All crisis interventions (e.g. emergency medication review, visit to hospital ER) within 30 days prior to death:

How was the consumer doing just prior to death or, if discharged, how was consumer doing at time of discharge?

If case was closed at time of death, condition at discharge:

[   ] Greatly Improved   [   ] Unchanged
[   ] Moderately Improved [   ] Regressed
[   ] Slightly Improved   [   ] Unknown

Please circle consumer's condition at discharge.

- 0  1  2  3  4  5  6  7  8  9  10 +
(Worst)          (Best)

Other relevant information:

Prepared by: ________________________________________________

Name / Credential / Date (print)

Signature: __________________________________________________

ATTACH A COPY OF THE FOLLOWING MOST RECENT DOCUMENTS:

- Comprehensive Assessment
- Health Assessment
- Psychiatric Evaluation
- Medication Review
- Person-Centered Plan
- Person-Centered Plan Review
- Medication list
- Care Coordination Documentation
- Other Documentation (e.g. Progress Notes, Closing Summary, etc.)
SECTION I:

Program Name: ______________________________

Consumer: ____________________________________________  Case#: __________________________

Diagnosis (include AXIS I, II & III): ____________________________________________________________

Prescribing Physician: ____________________________________  MCCMH Psychiatrist: ____________________

Date of Adverse Drug Event: ____________________________

List all medications Consumer is currently taking (include IM medication(s) administered/prescribed within last 30 days. Please check all suspected medication.

<table>
<thead>
<tr>
<th>Prescribed Medication</th>
<th>Dosage Schedule (last 24 hours)</th>
<th>Route of Administration</th>
<th>Date / time of last dose prior to ADE</th>
<th>Suspected Medication</th>
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<tbody>
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Describe Adverse Drug Event: ________________________________________________________________

_______________________________________________________________________________________

Prescribing Physician: ____________________________________ notified by: ____________________ on (date/time) __________

Intervention / treatment ordered: ____ no ____ yes, by whom: ________________________________

Describe: ____________________________________________________________

<table>
<thead>
<tr>
<th>QUESTIONS</th>
<th>Yes</th>
<th>No</th>
<th>Do not know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did the adverse event appear after the suspected medication(s) was/were administered?</td>
<td></td>
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</tr>
<tr>
<td>Did the adverse event improve when the medication(s) was/were discontinued?</td>
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<tr>
<td>Was medication used to treat this event?  Name: __________________________</td>
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<tr>
<td>Was the event dose-related?</td>
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</tr>
<tr>
<td>Did the consumer have a similar event to the same or similar medication(s) in the past?</td>
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<tr>
<td>Did the adverse event result in hospitalization?</td>
<td></td>
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<tr>
<td>Was the adverse event life threatening or did it result in serious injury or death?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Completed by: __________________________  Supervisor: ______________________________________

Signature / Credentials / Date  Signature / Credentials / Date

Adverse Drug Event, (rev.10/98), MCCMH MCO Policy 2-052, Exhibit D