BAY-ARENAC BEHAVIORAL HEALTH AUTHORITY
POLICIES AND PROCEDURES MANUAL

Chapter: 2	**Continuous Quality Improvement**		
Section: 1	**Adverse Events**		
Topic: 6	**Reporting and Investigation of Adverse Events**		
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Policy

It is the policy of Bay-Arenac Behavioral Health Authority (BABHA) that all adverse events, such as unusual events (including risk), critical incidents (including all deaths) and sentinel events that involve harm or injury or the risk of harm or injury are reported to the Office of Recipient Rights (ORR). In addition, it is the policy of BABHA to review and respond competently and in a timely manner to the occurrence of adverse events, and to act effectively to reduce the potential for recurrence of similar adverse events in the future. Further, is the policy that all adverse events are reviewed and monitored internally by BABHA; certain events have been identified for monitoring and reporting as required by Mid-State Health Network (MSHN) and/or Michigan Department of Community Health (MDCH) and/or Commission on Accreditation of Rehabilitation Facilities CARF.

Purpose

This policy and procedure is established to:

- Provide guidance when reporting or investigating any adverse events such as unusual events (including risk), critical incidents (including all deaths), and sentinel events that involve harm or injury or the risk of harm or injury for all persons served;
- To ensure there is a systematic and comprehensive mechanism for identifying, reporting, and analyzing any adverse event;
- To provide a process for improving performance by preventing a future similar occurrence
- To enhance the risk management capacity of the organization.
- In addition to review and document the appropriate response to all reports of adverse events, reports will be tracked, aggregated, and reviewed annually, at minimum, by organizational leadership for the purposes of effective risk management and performance improvement.

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Education Applies to:

☒ All BABHA Staff
☐ Selected BABHA Staff, as follows:
☒ All Contracted Providers: ☐ Policy Only ☒ Policy and Procedure
☐ Selected Contracted Providers, as follows:
☐ Policy Only ☐ Policy and Procedure
☐ BABHA's Affiliates: ☐ Policy Only ☐ Policy and Procedure
☒ Other: Vocational Providers, Residential Providers and Club Houses

Definitions

Adverse event: An event that is inconsistent with, or contrary to, the expected outcome of the organizations functions that warrants review under this policy and procedure. Subsets of adverse events qualify as "reportable events" according to external reporting systems such as the MDCH Event Reporting system and CARF. Adverse events include four classifications: unusual events, risk events, critical incidents, and sentinel events. The classifications separate these events based on level of risk as defined by external regulatory bodies.

Sentinel Event: An unexpected occurrence involving death or serious physical or psychological injury or risk thereof. Serious injury specifically includes loss of limb or function. The phrase 'or risk thereof', includes any process variation for which a reoccurrence would carry a significant chance of serious adverse outcome (CARF sentinel event definition, 2012 Behavioral Health Standards manual pg. 393). Is an unexpected occurrence involving death (not due to the natural course of a health condition) or serious physical or psychological injury or risk thereof. Serious injury specifically include permanent loss of limb or function. The phrase, 'or risk thereof', includes any process variation for which recurrence would carry a significant chance of a serious adverse outcome. (JCAHO, 1998) any injury or death that occur from the use of any behavior intervention is considered a sentinel event (Medicaid Managed Specialty Supports and Services Concurrent 1915(b)/(c) Waiver Program FY15)

Critical Events: Events that have resulted in harm to individuals who are actively receiving services. Critical events include the following events: suicide, non-suicide death, emergency

medical treatment due to injury or medication error, hospitalization due to injury or medication error, and/or arrest of a consumer. (Attachment pg. 7.9.1)

Risk Events: Critical events that put individuals at risk of harm; these events minimally include the following: actions taken by individuals who cause harm to themselves, actions taken by individuals who cause harm to others, or two or more unscheduled admissions to medical hospital (not due to planned surgery or the natural course of a chronic illness, such as when an individual has a terminal illness) within a 12 month period. (Attachment pg. 7.9.1)

Unexpected Deaths: Include those that resulted from suicide, homicide, an undiagnosed condition, were accidental, or were suspicious for possible abuse or neglect. (Attachment pg. 7.9.1)

Near Miss: A situation in which a serious consequence was avoided however a review maybe required to promote a safer environment. (CARF-2014 Behavioral Health Standards Manual pg. 66)

Root Cause Analysis (RCA): RCA or root cause investigation, is a process for identifying the basic or causal factor(s) underlying variation in performance, including the occurrence or possible occurrence of an adverse event. A RCA focuses primarily on systems and processes, not individual performance. A RCA involves:

1. Determination of the factors (human, systems, etc.,) most directly associated with the adverse event and the associated processes.
2. Review of the underlying systems and processes to determine where redesign might reduce risk.
3. Identification of risk points and their potential contributions to this type of event.
4. Determination of potential improvement in processes or systems that would tend to decrease the likelihood of such event in the future, or a determination, after analysis, that no such improvement opportunities exist.
5. To ensure credibility, attention to internal consistency in the questions asked/unasked and consideration of the organization as a whole entity, and
6. Review of available relevant literature

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Reviewable Events

1. Death-Suicide, Non-Suicide
2. Emergency Medical Treatment-Injury, Medication Error
3. Hospitalization-Injury, Medication Error
4. Arrest
5. Emergency Use of Physical Intervention
6. Use and Unauthorized possession of weapons
7. Elopement-Wandering
8. Police calls by staff of specialized residential setting, general AFC, or other provider agency for behavioral assistance. With an individual (critical incident);
9. Two or more unscheduled admissions to a medical hospital not due to planned surgery or natural course of a chronic illness, such as when an individual has a terminal illness within a 12 month period (risk event).
10. Harm to self
11. Harm to others
12. Harm from others
13. Alleged/substantiated abuse or neglect
14. Assault of consumer (sexual and/or physical)
15. Falls
16. Use of seclusion
17. Use of restraint
18. Communicable disease
19. Infection control
20. Aggression or violence
21. Vehicular accidents
22. Bio hazardous accidents
23. Unauthorized use and possession of legal or illegal substances
24. Suicide or attempted suicide, and
25. Adverse medication reaction or side-effects
26. Medication errors, including those by service staff involving: Wrong medication, wrong dosage, double dosage, missed dosage, wrong person, wrong time, or wrong route.
27. Other events which seriously disrupt or adversely affect the course of treatment or care of a person served, and require further clinical or administrative attention.

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28. Environment of Care (EOC) issues for residential providers as noted in the EOC policies and procedures, Licensing Rules, and Supplement for Residential Care Providers, including, but not limited to:

    i. Fire occurring in the treatment or service facility, with or without damage; and
    ii. Safety issues which include physical plant and environmental hazards in supervised care settings.

29. *Death occurred as result of suspected staff member action or inaction, or is subject of recipient rights, licensing, or police investigation (event notification).
30. *Every person served whose death occurred within one year of discharge from a state operated service (event notification).
31. **Relocation of a consumer's placement due to licensing issues (event notification).
32. **An occurrence that the relocation of any CMHSP or provider panel service site, governance, or administrative operation for more than 24 hours (event verification).
33. **The conviction of a CMHSP or provider panel staff members for any offense related to the performance of their job duties or responsibilities (event notification).

    * Must notify MDCH within 48 hours and provide the following information:

    a. Name of person
    b. Beneficiaries ID number
    c. Consumer ID if there is no beneficiary ID number
    d. Date, time and place of death (if licenses foster care facility, include the license #)
    e. Preliminary cause of death
    f. Contact person's name and E-mail address

    ** Must notify MDCH within 5 days

Procedure

All BABHA employees, contracted service providers, or volunteers, who witness or discover an adverse event for all persons served, and if the incident occurred at a BABHA direct operated or contracted service delivery site or is otherwise related to the behavioral health status and our service delivery of the person served, will complete:

- Arrest Form for all arrests
- Death Report Form and an Incident Report Form for all deaths.
- An Incident Report (I/R) Form to report all other adverse events such as those noted above

Reporting Arrests (Arrest Report Form):

1. As primary responsible workers become aware of an arrest of a person served:

   a. They will complete an arrest report form before the end of the shift in which notified, and
   b. Scan the arrest report form to the chart and forward the report to the Clinical Service Program Manager (Emergency Services).

2. The Clinical Services Program Manager (Emergency Services) will review, and if appropriate, identify and act upon jail diversion opportunities.

3. The Clinical Services Program Manager (Emergency Services) will submit arrest data to the PI Department for review and submission to the PIHP.

Reporting and Investigating Deaths (Death Report Form):

A verbal report of all deaths and suicides **of any person receiving services by BABHA or its contracted clinical service providers, and/or receiving an emergency service within the previous 30 days shall be immediately made to the responsible Service Director, or his/her designee, the Office of Recipient Rights or designee.**

1. The primary responsible worker (includes clinical contracted service providers) shall complete a **Death Report Form** within the electronic medical record system and an incident report form within 24 hours of being notified of the death or suicide, (do not wait for a death certificate) and will forward the report to their supervisor or designee for review and signature, who will then forward to the ORR and to the record of the person served. The ORR will forward a copy through Phoenix to the Clinic Practice Manager and Quality Manager for continue processing. If it is determined that the circumstances of a death warrant an investigation, one will be initiated by the Clinic Practice Manager and/or the

Quality Manager in conjunction with the Medical Director and the Health Care Practices Committee (HCPC). The death report shall include the basic information of name, case number, gender, date of birth, date and place of death, along with the name, title, and agency of the person completing the report. In addition, the report will document the following:

a. Diagnoses, including medical and psychiatric of the person served
b. Cause of death (based upon the death certificate)
c. Recent change in medical or psychiatric status including notations/summary statement of most recent hospitalizations
d. Summary of condition and treatment (programs and services being provided to the person served preceding death)
e. Medications prescribed by a Psychiatric Professional within the last 30 days
f. Any other relevant history and
g. Death certificate.

Death certificates must be obtained, scanned to the medical record and attached to the death report under the oversight of the Clinic Practice Manager.

2. The death report will be reviewed by the ORR to determine if a recipient rights investigation is warranted and inform the CEO if an investigation is being conducted.

3. If the ORR determines that an investigation is warranted, then the death will be documented on a Recipient Rights Complaint and the investigation will proceed through the Recipient Rights investigative process. ORR will notify the Quality Manager for immediate notification (electronically within 48 hrs.) to MDCH.

4. All Death Reports (except OBRA related reports) will be reviewed at the HCPC meeting. The Medical Director will make a determination if the death was accidental, expected or unexpected (see related HCPC event determination form), and if not already determined, if a RCA is required.

5. If the BABHA Medical Director is the primary provider involved, an alternated designated physician will make determinations if the death was accidental, expected or unexpected

6. The Clinic Practice Manager will ensure the needed information is completed and entered into the appropriate BABHA data base, and a copy is placed in the Death Report folder. The CEO will then be notified of the death.

<u>Reporting Unusual (Including Risk) and Critical Incidents (I/R Form)</u>:

1. Upon notification of an incident involving a person served assigned to them, primary care managers (i.e., the Primary Care Worker or Therapist) who are employees of BABHA will:

    a. If apparent serious injury, abuse or neglect has occurred, provide verbal notification to the applicable supervisor or designee and upon verbal notice of the incident, the supervisor or designee will notify the appropriate Director, the Recipient Rights Officer, within 24 hours of notification.
    b. If the incident was a risk, critical, or sentinel event, as defined in this procedure, immediately notify their supervisor, or in their supervisor's absence, their designee. The supervisor or designee is responsible for informing the Director of Integrated Services and the Quality Manager, if appropriate.
    c. If the incident was not a risk, critical, or sentinel event, it is not necessary for primary care workers to notify their supervisor.
    d. Primary care workers will review and initial incident reports during their visits to day program sites, specialized residential homes, or other services sites.
    e. Primary care workers will document actions taken in response to incidents via progress notes or periodic reviews, without referencing the incident report itself.

2. For all adverse events, including unusual/risk, critical, and sentinel (as defined above), an Incident Report (I/R) form will be completed by the person who observed the incident no later than the end of the shift of when they observed the incident. The staff person will forward a copy to their supervisor and appropriate Director and send the original faxed copy to the Office of Recipient Rights (ORR) within 24 hours. The ORR will initiate action from the original faxed copy of the incident report form received.

3. All BABHA employees who are informed of an unusual incident observed by someone else, are responsible for ensuring the incident was reported as required in the procedure above if the incident occurred at a BABHA direct operated or contracted service delivery site or is

otherwise related to the behavioral health status and our service delivery of the person served.

4. When two or more BABHA employees, contracted service providers, or volunteers witness an incident requiring an I/R form completion, one form shall be filed and signed by all of the personnel involved. Any personnel unwilling to sign the report for whatever reason may choose to file a separate report. Names of the witnesses and others present shall be included in the report(s). Initials or case numbers will be used for people served witnessing the incident.

Investigation of Adverse Events:

1. Identification: All adverse events, including, but not limited to, unusual events (including risk), critical incidents (including all deaths) and sentinel events for all persons served will be reviewed.

    a. The Clinic Practice Manager will be notified of adverse events that are potential sentinel events upon receipt. The Clinic Practice Manager and/or Quality Manager in consultation with the Medical Director, will make a determination regarding the event and follow up accordingly. At a minimum, sentinel events, as defined in the MDCH contract, must be reviewed and acted upon as appropriate, with determinations occurring within three days of critical incidents, and root cause analyses for sentinel events commencing within two subsequent business days of the sentinel event determination.
    b. Events of significance will be reviewed by the HCPC to determine if an investigation of the event is warranted.

2. Analysis: All unusual/risk, critical/death, and sentinel events will be reviewed to determine if the event is related to the practice of care and whether or not the performance of a root cause analysis is warranted. The decision to perform a RCA is determined by the Clinic Practice Manager and/or Quality Manager in consultation with the Medical Director, and/or in conjunction with the HCPC.

    a. If determined to be appropriate, a RCA will be conducted in a timely and thorough manner. The Clinic Practice Manager or designee, will be assigned lead responsibility for ensuring the completion of each RCA and any resultant action plan. The RCA will be

initiated within two business days of the occurrence of the event and completed not more than 30 days after knowledge about the event. The RCA will be completed based upon the Tool/Guide to Assist Behavioral Health Care in the Completion of a Root Cause Analysis and the Framework to Assist Behavioral Health Care in the Completion of a Root Cause Analysis as attached to this policy and procedure.

b. Persons involved in the review of events will have appropriate credentials to review the scope of care. For example, events that involve a death of a person served or other serious medical conditions will involve a physician or nurse.

3. Action Planning and Follow-Up: The goal of reviewing adverse events will be to focus the attention of the organization on potential underlying causes of the event so that changes can be made in systems or processes in order to reduce the probability of such an event in the future. Following completion of a RCA or investigation, BABHA will develop and implement either a plan of action or intervention to prevent further occurrence of the sentinel event; or document the rationale for not pursuing an intervention. The plan will address responsibility for implementation and oversight, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.

   a. An action plan will be developed by the staff completing the RCA, which will require approval by the HCPC. The action plan will include timeframes, and responsible parties.
   b. The Medical Director for BABHA will review and approve, along with the HCPC, any and all RCA.
   c. The HCPC will monitor the completion and effectiveness of action plans.
   d. All documentation related to investigations will be maintained by the Clinic Practice Manager.
   e. Debriefing following clinical emergency situations:

      i. The appropriate staff from the treating clinical team and the Medical Director as well as other individuals from BABHA's Health Care Practices Committee (HCPC) will be involved in the debriefing process.
      ii. Documentation of the debriefing will be part of the HCPC meeting minutes.
      iii. In addition to the debriefing, staff who are part of the treatment team (clinical or administrative) will be given the opportunity for individualized debriefing through the BABHA employee assistance program. The clinic site supervisor will be responsible for coordinating the necessary resources to provide debriefings.

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Review of Adverse Events:

An annual summary of aggregate-level fiscal year adverse events is reviewed by the BABHA HCPC and applicable leadership before the end of the calendar year. This summary contains information on: 1) causes; 2) trends; 3) actions for improvement; 4) results of performance improvement plans; 5) necessary education and training of personnel; 6) prevention of recurrence; 7) internal reporting requirements; and 8) external reporting requirements.

Record Keeping and Reporting:

BABHA will maintain a system for recording the occurrence of events and the organization's resultant analysis, action planning and follow-up. Periodically, or at least annually, formal reporting will occur via the HCPC to appraise the organization's leadership and governance concerning the management of the event and all efforts to improve and correct underlying causes.

1. Adverse events will be reported to the PIHP/MDCH and CARF, BABHA's accrediting body, as required.

    a. MDCH Event Notification: Events identified to fall under Event Notification for immediate reporting to MDCH. This report shall be submitted electronically within 48 hours of either the death, or the CMHSP's receipt of notification that rights, licensing, and/or police investigation has commenced to QMPMeasures@michigan.gov
    b. Regional Reporting Process: If the adverse event is determined to be reportable based on event type, services, or living situation, the Performance Improvement Coordinator will report to MSHN any and all reportable events prior to the end of each month or as required by MSHN.
    c. Accrediting Body Reporting Process: Significant events, including sentinel events as defined by CARF, that involve or may affect accredited programs and the organization's response to these events must be communicated to CARF within 30 days of their occurrence (Behavioral Health Standards Manual 2013).

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Additional Information Regarding Adverse Event Reporting and Records:

1. All BABHA employees, contracted service providers, and volunteers, shall also adhere to any additional reporting requirements of 1982 Public Act 519, Adult Protective Service Act, 1975 Public Act 238, as amended, Child Protection Act, and 1988 Public Act 32, Mandatory Report Abuse Act.

2. BABHA employees of some programs and some contracted service providers (e.g., residential services and children's programs) should familiarize themselves with applicable procedures for reporting certain types of incidents to the appropriate licensing or regulatory bodies (Department of Human Services (DHS), OSHA, etc.). In order to avoid duplicate documentation, it is acceptable to complete the required licensing or regulatory body report and submit it to that agency, with a copy of that report attached to a blank I/R form and submitted in accordance with this policy.

3. Report Retention:

    a. The original of the completed/signed IR form will be retained in the home or program where the incident occurred.
    b. The copy of the IR form faxed to the Office of Recipient Rights (ORR) will be maintained by the ORR for a set period of time as determined by the Recipient Rights Officer.
    c. An IR form generated pursuant to MCL 330.1143a does not constitute a summary report as intended by this section and shall not be maintained in the clinical record of a people served. Incident report forms will NOT be stored in BABHA clinical records rooms for administrative purposes.

4. Confidentiality:

    a. Failure to treat an I/R form in a confidential manner, such as circulation to persons without a need to know, will result in appropriate disciplinary action toward the staff that breached the confidentiality of the document.
    b. All records, data and knowledge, including minutes collected for or by individuals or committees assigned a quality assurance function are confidential, are <u>not</u> public record, and therefore:

i. Do not appear in the record of the person served,
ii. Are not subject to court subpoena pursuant to MCL, 333.20175(8), and
iii. Disclosure or duplication outside of indicated procedures is prohibited.

a. Clinical staff documenting in a clinical record regarding actions taken in response to an incident shall not cite (document) or otherwise reference an incident report, in order to ensure the incident report remains fully separate from the clinical record.

Attachments

- Tool/Guide to Assist Behavioral Health Care in the Completion of a Root Cause Analysis Framework to Assist Behavioral Health Care in the completion of a Root Cause Analysis
- Adverse Event Project Description

Related Forms

- Arrest Report Form, Death Report Form, Incident Report (I/R) Form, Health Care Practices Committee Event Determination Form

Related Materials

- Mid-State Health Network (MSHN) Critical Incident Policy

References/Legal Authority

Commission on Accreditation for Rehabilitation (CARF) Michigan Department of Community Health (MDCH) Medicaid managed Specialty Support and Services contract Attachment P.6.7.1.1; Attachment 6.5.1.1

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Submission Form

Approving Body/Committee/Supervisor:	Author/Reviewer:	Approval/Review Date:
PNLT HCPC/J. Pinter	M. Bartlett/K. Lane S. Gettel/A. Folsom	5/20/13 3/18/2015

Result:
Deletion ☐ New ☒ No Changes ☐ Replacement ☒ Revision ☐

List reason for deletion/replacement/revision here. If replacement, list policy to be replaced.
Combined the following policies and procedures: C03-S04-T01 Reporting Unusual Incidents – Policy Supersedes Date: 1-21-03; Procedure Supersedes Dates: 12-20-11, 5-6-10, 9-23-09, 2-10-09, 11-20-08, 9-15-08, 3-11-08, 11-16-04, 1-20-04, 10-21-03, 1-21-03, 1-6-01, 12-19-91. C03-S04-T02 Death Reporting – Policy Supersedes Dates: 9-16-04, 8-19-99; Procedure Supersedes Dates: 12-20-11, 1-15-11, 8-27-09, 1-23-09, 11-19-08, 9-15-03, 2-14-05, 8-17-04, 5-26-00, 3-18-99. C03-S06-T01 Investigation of Incidents and Sentinel Events – Policy Supersedes Dates: 10-16-08, 3-16-02, 7-16-98; Procedure Supersedes Dates: 1-20-11, 5-13-09, 4-21-09, 11-11-08, 10-16-08, 4-24-08, 1-20-04, 10-21-03, 4-16-01, 7-29-98. Policy C03-S04-T01 was deleted. C02-S03-T06 Reporting and Investigation of Adverse Events supersedes dated 3-18-2015.