STATE OF HAWAII
DEPARTMENT OF HEALTH
P. O. BOX 3378
HONOLULU, HI 96801-3378

DEVELOPMENTAL DISABILITIES DIVISION

TITLE: Adverse Event Report for People Receiving Case Management Services with the Developmental Disabilities Division

Policy # 3.07

PURPOSE:

To provide a uniform process and procedures for documenting, reporting and follow-up of adverse events, involving participants of the Developmental Disabilities Division (DDD) receiving case management services.

DEFINITIONS & ACRONYMS:

"Suspected abuse and neglect" as defined in state statute for

- Adults - Section 346-222, Hawaii Revised Statutes (HRS), http://www.capitol.hawaii.gov/hrscurrent/Vol07_Ch0346-0398/HRS0346/HRS_0346-0222.htm; and
- Children - Section 350-1, HRS, http://www.capitol.hawaii.gov/hrscurrent/Vol07_Ch0346-0398/HRS0350/HRS_0350-0001.htm;

"Expected death" means:

- Death resulting from a documented medical diagnosis or terminal illness;
- Death resulting from an irreversible deterioration of health; or
- Death resulting from certain congenital conditions;

"Financial exploitation" as defined in State Statute Section 346-222, HRS (above);

"Medication errors" means medication administration involving one or more of the following and/or an unexpected reaction to the medication or treatment:

- Wrong medication – participant receives and takes medication which is intended for another person, discontinued, or inappropriately labeled;
- Wrong dose – participant receives the incorrect amount of medication;
- Wrong time – participant receives medication dose at an incorrect time interval;
- Missed dose – participant does not receive a prescribed dose of medication or when a participant refuses to take medication;
- Wrong route/method – participant does not receive the medication by the route prescribed (i.e., by mouth, injection, under the tongue (sublingually), rectally); or

- Failure to document or incorrect documentation – failure to initial the Medication Administration Record (MAR) by the person assisting with the medication (i.e., failure to initial the MAR each time a medication is given) or failure to transcribe the prescription onto the MAR correctly (i.e., failure to transfer information such as the drug name, dose, route, or frequency from an order or prescription to the MAR).

"Medical or dental treatment" means treatment rendered by ambulance or emergency medical personnel, urgent care or emergency room medical or dental staff, or results in hospitalization;

"Restraint" means a physical, chemical or mechanical intervention used as a last resort on an emergency basis to protect the participants from imminent harm to themselves and/or others using the least restrictive intervention possible and for the shortest duration necessary.

THE FOLLOWING ARE NOT CONSIDERED RESTRAINTS:

- Interventions used for the purpose of conducting routine physical or dental examination or diagnostic tests or completing a medical or dental treatment procedure;
- A device used to protect the participant's safety as indicated in the Individualized Service Plan (ISP) per a physician's recommendation and reviewed by the Behavior Support Review Committee (BSRC); or
- Vehicular passenger restraint systems required by state law (HRS §291-11.6).

1. **"Chemical Restraint"** means a psychotropic medication prescribed by a licensed health care professional with prescriptive authority:
   a. On a routine basis without an appropriate Diagnostic and Statistical Manual (DSM) diagnosis for the purpose of behavioral control; or
   b. Incidental use of medications, sometimes called PRN or as needed medication, to restrict the freedom of movement or temporarily sedate the individual.

THE FOLLOWING ARE NOT CONSIDERED CHEMICAL RESTRAINTS:

- Medications prescribed for the treatment of a diagnosed disorder found in the current version of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM);
- Adjusting the dose of a prescribed medication or prescribing a new medication to achieve better symptom control for the diagnostic disorder per the current DSM;
- Medications prescribed to control seizures; and
- Medications for medical or dental procedures.

2. **"Mechanical Restraint"** means an intervention involving a device, material or equipment that is involuntarily applied to the participant's body or immediate environment (i.e., wheelchair, chair, bed, toilet, vehicle, etc.) that immobilizes, restricts, limits, or reduces any bodily movement in emergency situations to prevent the participant from harming themselves or others. See definition of "Restraints" for interventions that are not considered a Mechanical Restraint.

3. **"Physical Restraint"** means an intervention in which physical force is applied to the participant and involuntarily restricts their freedom of movement or normal access to a portion or portions of their body. See definition of "Restraints" for interventions that are not considered a Physical Restraint.

"Seclusion" means a restrictive intervention in which a person is involuntarily confined in a room or area from which they are prevented from having contact with others or leaving by closing a door or using another barrier. **Seclusion is prohibited and shall not be utilized with participants.**

"Restrictive Intervention" or "Restrictive Procedure" means a practice that limits a participant's freedom of movement, access to other locations, property, individuals, or rights. This includes, but is not limited to, Chemical, Mechanical, and Physical Restraints.

"Unexpected death" means:

- Death that was not expected or anticipated according to any previously known terminal medical diagnosis;
- The result of an accident (car, fall, choking, etc.), even if the person had a known terminal condition;
- Due to suspected/alleged homicide or suicide; or
- Due to suspected/alleged abuse or neglect.

Adult Foster Home (AFH)
Adult Protective Services (APS)
Adverse Event Report (AER)
Behavior Support Review Committee (BSRC)
Case Manager (CM)
Case Management Branch (CMB)
Child Protective Services (CPS)
Child Welfare Services (CWS)
Clinical Interdisciplinary Team (CIT)
Community Resources Branch (CRB)
Consumer Complaints Resolution Unit (CCRU)
Consumer-directed (CD)

Consumer Directed Personal Assistant (CDPA)
Department of Human Services (DHS)
Developmental Disabilities Division (DDD)
Diagnostic and Statistical Manual (DSM)
Hawaii Revised Statutes (HRS)
Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Hospital and Community Dental Services Branch (HCDSB)
Individualized Service Plan (ISP)
Long Term Adult Supports and Resources (LASR)
Medication Administration Record (MAR)
Office of Healthcare Assurance (OHCA)
Outcomes and Compliance Branch (OCB)
Outcomes Section (OS)
Program Services Evaluation Unit (PSEU)
Registered Nurse (RN)

POLICY:

Adverse events include incidents listed below and shall be reported:

- Suspected abuse and neglect;
- Financial exploitation;
- Injuries of a known or unknown cause sustained by the participant requiring medical or dental treatment or hospitalization;
- Medication errors;
- Changes in the DDD participant's behavior, including but not limited to aggression, self-injurious behaviors, property destruction, or sexualized behaviors that may require a new or updated behavior support plan as a result of the intensity and/or severity of the behavior;
- Changes in the DDD participant's health condition requiring medical or dental treatment or hospitalization;
- Expected death of a DDD participant;
- Unexpected death of a DDD participant;
- Whereabouts unknown regardless of the amount of time the participant is missing or unaccounted for;
- Any use of restraints, which includes chemical, mechanical and physical restraints;
- Any use of seclusion is prohibited and shall not be utilized with participants; and
- Any use of prohibited restrictive intervention or restrictive procedure.

Waiver providers, LASR providers, DDD CMs, HCDSB staff, CD Employers, AFH Certified Caregivers, individuals involved with the participant (e.g. families, guardians, if applicable), and workers shall report occurrences of adverse events on the AER form and in accordance with timelines specified in this policy.

For disclosures for reporting of abuse of adults, refer to *DDD Policy 03.03, Health Insurance Portability and Accountability Act of 1996 (HIPAA).* For statutory mandatory requirements for reporting of non-waiver adult and child abuse and neglect, refer to *DD policy 2.05 entitled "Mandatory Reporting of Abuse and Neglect."*

Participants may self-report abuse to their CMs or to the CCRU in DDD's OCB. The CM or CCRU staff shall then submit an adverse event report.

PROCEDURES:

A. DUTIES AND RESPONSIBILITIES OF THE REPORTER

1. Verbally notify the DDD Case Manager (CM) within 24 hours or the next business day of an adverse event or when notified that an adverse event occurred.
2. Complete and submit the Adverse Event Report (AER) Form to the DDD CM within 72 hours of an event or when notified that an adverse event occurred.
3. Submit the AER form directly to the Outcomes and Compliance Branch, Outcomes Section within 72 hours for the following adverse events:
   a. Suspected abuse, neglect, financial exploitation;
   b. Death;
   c. Participant's whereabouts are unknown and efforts to locate the participant have been unsuccessful;
   d. Any use of restraint;
   e. Any use of seclusion; and
   f. Any use of prohibited restrictive intervention or procedure.
4. Notify OCB when there is media involvement including, but not limited to press inquiries, broadcast, and media coverage related to any adverse event.
5. Fax AER to the Outcomes Section at (808) 453-6585.

B. DUTIES AND RESPONSIBILITIES OF THE DDD CASE MANAGER

1. Receive verbal notification of an adverse event **within 24 hours or the next business day** by a waiver provider, LASR provider, HCDSB staff, CD employer, or AFH certified caregiver. A verbal report can also be made by a DDD participant, family member, guardian, DDD employee, and other persons who witness or become aware of a reportable event. The CM shall:
   a. Verify that immediate action was taken to safeguard the participant;
   b. Assess if there is potential for further injury or harm to the participant and/or others in the home or program setting, and notify supervisor immediately;
   c. Determine if additional supports or actions are necessary to safeguard the participant; and
   d. Coordinate services as necessary.
2. For events involving suspected abuse, neglect, or exploitation, the CM shall:
   a. Gather the following information **within 24 hours** of receiving the verbal report or the next working day for events involving suspected abuse, neglect, or exploitation:

1) Date, time, and location of the event;
2) Person(s) present and/or involved when the event occurred;
3) Alleged perpetrator, if applicable, and the relationship to the participant;
4) Extent of injury or harm;
5) Actions taken for the participant's immediate safety; and
6) Confirm if a report was made to CWS or APS. If a report was not made, verbally report incident immediately to CWS or APS as referenced in the *DD Policy 2.05 on Mandatory Reporting of Abuse and Neglect;*

b. Complete the written report to CWS or APS following the initial verbal report.
   1) For APS, fax or mail Form DHS 1640 entitled "Report Form for Adult Abuse and Neglect" to the APS office where the verbal report was made.
   2) For CPS, fax or mail Form DHS 1516 entitled "Mandated Reporter Checklist for Suspected Child Abuse and Neglect" to the CWS office where the verbal report was made.
c. Inform supervisor immediately to determine follow-up actions.
d. Conduct a face-to-face interview with the participant **within 24 hours** of receipt of the verbal report for events involving suspected abuse, neglect, or exploitation.
e. If applicable, inform the participant's legal guardian of the situation (if the legal guardian is not involved in the situation) and discuss the recommended course of action;
f. Work in collaboration with the CWS or APS representative;
g. Verbally inform the respective licensing and certifying agency if the person resides in a licensed or certified home.

3. Receive and review the written AER form **within 72 hours** of the adverse event by a waiver provider, LASR provider, HCDSB staff, CD employer, or AFH certified caregiver.
   a. Review page 1 "18. What Was Done?" to ensure immediate appropriate actions were taken to safeguard the participant's health and safety;
   b. Review description of the event in Section B: Discovery, including potential causes and/or factors contributing to the adverse event;
   c. Verify that the type of adverse event checked in Section C: Nature/Type of Adverse Event Being Reported is consistent with the description in Section B;
   d. Determine if the appropriate persons/agencies were notified based on the type of adverse event, residential setting, and guardianship status of the participant. If the appropriate persons/agencies were not notified, the CM shall notify the respective persons/agencies; and
   e. Request an updated/revised AER form from the reporter/supervisor if the form contains incomplete and/or incorrect information. The CM shall retain the original form. The updated/revised form shall be returned to the CM within 24 hours of the request.

4. Complete the following sections of the AER form **within two (2) working days** from receipt of the AER (if the form required updates/revisions, it would be two (2) working days from the date the revised form was received):
   a. Summary of Action Taken by the CM;
   b. CM Assessment;
   c. CM Plan of Action:
      1) Complete if additional actions are warranted. Describe actions taken or to be taken with timelines, including referrals to CIT or BSRC; and
      2) Update the ISP with risk factors that need to be addressed, including supports to minimize the assessed risks; and any change in needs/condition, requiring an ISP update.
   d. Consult with the unit RN or RN designee at a minimum, for all AERs involving medication errors, change in health condition, and when an adverse event results in hospitalization. The RN shall review and assist the CM in identifying appropriate follow-up actions, including, but not limited to updating the ISP when there is a change in condition/diagnoses, medication, risk factors, and when a referral to the CIT may be warranted;
   e. Document in the participant's contact notes follow-up actions taken including face-to-face contacts, home visits, etc.; and
   f. Submit AER to immediate supervisor.
5. Complete the AER form if no AER was generated or when a report is made by a participant, family member, guardian, DDD employee, or any person who witnesses or becomes aware of an event that requires reporting.
   a. For events involving suspected abuse, neglect, or exploitation, a written report shall be completed **within 24 hours** of verbal notification; or
   b. For events other than suspected abuse, neglect, or exploitation, a written report shall be completed **within 72 hours** of verbal notification.
6. The CM shall assess the effectiveness of the remediation plan of action and activities in preventing future recurrences. If the remediation actions and activities are not effective in preventing the recurrences of the adverse event(s), the CM shall make recommendations, including additional actions to be taken by the waiver provider, LASR provider, CD employer, and/or caregivers of licensed or certified homes.

C. DUTIES AND RESPONSIBILITIES OF THE CM SUPERVISOR
1. Determine if there is potential for further harm or injury to the participant and/or others based on the CM's report of the adverse event.
2. Consult with immediate supervisor who will then notify the CMB Chief, DDD Administrator, and Medical Director, as appropriate who will determine if an initial onsite assessment is warranted and identify the DDD staff who will be conducting the assessment.
3. Ensure mandatory reporting requirements are met for events involving suspected abuse, neglect, or exploitation of a participant.

4. Evaluate to determine the appropriateness of the CM's assessment and actions and complete the Supervisor Review and Comments Section **within two (2) working days** from receipt of the AER from the CM.
    a. Review the CM's summary of action taken and determine if actions were appropriate given the nature of the event. Determine if CM met timelines for review.
    b. Determine if the CM's assessment was appropriate in Section 1.
    c. Determine if the CM's plan of action was appropriate in Section 2.
    d. Determine if additional follow-up is required by the CM beyond what was documented in the CM's plan of action.
    e. Verify that the ISP was updated if the 'ISP Updated' box is checked.
5. Notify immediate supervisor of adverse events that may warrant follow-up by the CRB, OCB, or HCDSB. Given the critical nature of the adverse event, CMB Chief may consult with the respective branch chief(s) and the DDD Administrator to determine appropriate follow-up actions.
6. Distribute copies of the completed AER form **within five (5) working days** from receipt of the written report to the:
    a. Agency, CD employer, or AFH certified caregiver who reported the event;
    b. OCB - PSEU; and
    c. OCB - Certification Unit or OHCA if the event involves a caregiver of a licensed or certified home.
7. Ensure a tracking system in the Unit is continuously implemented and monitored to meet deadlines, including documentation of dates that AERs are received, reviewed, and distributed.
8. Ensure ongoing monitoring of services by the CM.

D. DUTIES AND RESPONSIBILITIES OF OCB

1. Receive, log, and evaluate all AERs to determine whether appropriate actions were taken to prevent the recurrence of the event and to ensure the participant's immediate safety.
2. Notify the DDD Administrator, CMB Chief, and CRB Chief immediately of events that may require an investigation, pose a present or imminent risk to the safety and well-being of the participant and/or others in the home or program setting due to the severity and seriousness of the event, and result or have the potential for media coverage due to the circumstances surrounding the event.
3. Notify the CM supervisor when the adverse event has been reported to the DDD Administrator and Branch Chiefs.
4. Ensure mandatory reporting requirements are met for events involving suspected abuse, neglect, or exploitation of a participant.
5. Review all available information and assess the appropriateness of reporter's remediation actions, CM's follow-up actions, and CM's plan of action, if applicable, to prevent the recurrence of the event.
    a. If PSEU determines based on PSEU's assessment that additional information is needed from the CM (i.e., form is incomplete, information is inconsistent, or critical

information is missing), PSEU supervisor will request through the CM supervisor the additional information with specified deadline to submit.

b. If PSEU determines based on PSEU's assessment that no additional follow-up is required, the AER is closed.
c. If the adverse event involves an AFH and PSEU determines that additional follow-up with the Certification Unit is warranted:
    1) PSEU supervisor will provide the OS supervisor with a written description of the certification issues; and
    2) OS supervisor will submit the request to the Compliance Section Supervisor if the request is appropriate.
d. If the adverse event involves a waiver provider or LASR provider and PSEU determines that additional follow-up is warranted, the OCB Chief will provide the CRB Chief with a written description of the issues.
e. If the adverse event involves a CD Employer and PSEU determines that additional follow-up is warranted, the OCB Chief will provide the CMB Chief with a written description of the issues.
f. If the adverse event involves HCDSB staff and PSEU determines that additional follow-up is warranted, the OCB Chief will provide the HCDSB Chief with a written description of the issues.

6. Conduct an investigation if the adverse event falls within any of the following circumstances:
    a. Any death as a result of:
        i. serious injury that required treatment in the emergency room or urgent care or resulted in a hospitalization;
        ii. medication error;
        iii. elopement;
        iv. unknown circumstances; or
        v. the use of restraints, seclusion, or prohibited restrictive intervention.
    b. Any report of serious issues, including serious violations of standards; and
    c. Any and all other situations identified by the DDD Administrator or OCB Chief as requiring an investigation.

        Note: Any adverse events involving suspected abuse/neglect will be investigated by the respective protective services agency.
7. Conduct investigation **within 72 hours** of receiving the written AER form and in accordance with internal guidelines and report findings and recommendations to the DDD Administrator, CRB Chief, CMB Chief, and OCB Chief. For death investigations, findings and recommendations will be forwarded to the Mortality Review Committee.
8. Track and analyze the AER data to identify trends/patterns and make recommendations for quality improvement through the Safety and Well-Being Subcommittee of the Quality Assurance and Improvement Program.
9. Complete and submit quarterly reports to the BSRC, CIT and DHS.

E. DUTIES AND RESPONSIBILITES OF THE DDD ADMINISTRATOR AND BRANCH CHIEFS

1. Determine if an initial onsite assessment is warranted and identify the DDD staff who will be conducting the assessment.
2. Determine what immediate actions should be taken, including timelines.
3. Determine when to implement investigations based on reports of serious issues or serious violations of standards.
4. Coordinate follow-up actions with respective branch chiefs, as necessary.
5. Ensure branch staff responds to requests for information in a timely manner.

AUTHORITATIVE & OTHER REFERENCES:

1. Adult Protective Services (APS) Definitions: Section 346-222, HRS, http://www.capitol.hawaii.gov/hrscurrent/Vol07_Ch0346-0398/HRS0346/HRS_0346-0222.htm;
2. Mandatory Reporting of Abuse/Neglect: Section 346-224, HRS, http://www.capitol.hawaii.gov/hrscurrent/Vol07_Ch0346-0398/HRS0346/HRS_0346-0224.htm;
3. Child Abuse: Section 350-1, HRS, Section 350-1, HRS, http://www.capitol.hawaii.gov/hrscurrent/Vol07_Ch0346-0398/HRS0350/HRS_0350-0001.htm;
4. Medicaid Waiver Provider Standards http://health.hawaii.gov/ddd/provider/pm/;
5. Application for a §1915(c) Home and Community Based Services Waiver, Appendix G: Participant Safeguards, approved by Center for Medicaid and Medicare Services (CMS) 7-1-2011;
6. Chapter 323B, HRS, Health Care Privacy Harmonization Act[1] http://www.capitol.hawaii.gov/hrscurrent/Vol06_Ch0321-0344/HRS0323B/HRS_0323B-.htm;
7. Chapter 587A, HRS, Child Protective Act[2] http://www.capitol.hawaii.gov/hrscurrent/Vol12_Ch0501-0588/HRS0587A/HRS_0587A-.htm.
8. DD Policy 2.03, Behavior Support Review
9. DD Policy 2.05, Mandatory Reporting of Abuse and Neglect
10. DDD Policy 03.03, Health Insurance Portability and Accountability Act of 1996 (HIPAA)

[1, 2] These hyperlinks connect to the most recent version of HRS through the Hawaii State Legislature website. Hyperlinks to HRS chapters show the first page of the chapter only, to see the rest of the contents of the chapter, click "Next" on the lower right-hand side of the page on your screen.

NOTE:
The form related to this P&P is posted with the P&P on SharePoint for your reference and use.

Approved: _____ **Date: JUL 5, 2017**

Administrator,
Developmental Disabilities Division