

5160-44-05**Nursing facility-based level of care home, community-based services (HCBS) programs and specialized recovery services (SRS) program: incident management.**

(A) For the purpose of this rule, the following definitions apply:

- (1) "Care management entity" means an entity delegated or contracted by the Ohio department of aging (ODA) or the Ohio department of medicaid (ODM) to perform care management activities and related functions for individuals enrolled on a waiver.
- (2) "Critical incident" means incidents identified in paragraph (E) of this rule.
- (3) "Health and safety action plan" means a document developed by the care management entity that identifies situations, circumstances, and/or behaviors that without intervention may jeopardize the individual's health and welfare and potentially risk his or her enrollment on the waiver. It sets forth the interventions to remedy risks to the health and welfare of an individual on a waiver and to ensure the individual's needs are met through the waiver.
- (4) "Incident" means an alleged, suspected or actual event that is not consistent with the routine care of, and/or service delivery to an individual.
- (5) "Individual" means a person enrolled on a waiver or in the specialized recovery services (SRS) program as defined in this rule.
- (6) "Investigative entity" means ODM, ODA, or their designee.
- (7) "Reportable incident" means an incident identified in paragraph (F) of this rule that requires entry into the incident management system, and addressed as determined appropriate by the care management entity or recovery management entity.
- (8) "Specialized recovery services (SRS) program" means Ohio's home and community based services (HCBS) state plan program set forth in Chapter 5160-43 of the Administrative Code.
- (9) "Substantiated" means, there is a preponderance of evidence to indicate the reported incident is more likely to have occurred than not to have occurred.
- (10) "Waiver" means an Ohio medicaid nursing facility-based level of care HCBS waiver program. This rule does not apply to developmental disabilities level of care waivers set forth in Chapter 5123-9 of the Administrative Code, the state-funded pre-admission screening system providing options and resources today (PASSPORT) program set forth in rule 173-39-40 of the Administrative Code.

or the state-funded assisted living program set forth in rule 173-39-51 of the Administrative Code.

(B) This rule establishes the standards and procedures for managing incidents for individuals. It applies to ODM, ODA, their designees, individuals, and providers of waiver services, and SRS. ODM and ODA may designate other entities to perform one or more of the incident management functions set forth in this rule.

(C) Upon an individual's enrollment on a waiver, and at the time of each annual reassessment, the care management entity shall obtain written confirmation that the individual received information about how to report abuse, neglect, exploitation and other incidents as defined in this rule. The written confirmation shall be documented and maintained in the individual's case record.

(D) Uniformity.

(1) ODM and ODA may establish a single incident management system, a single investigative entity, and a single process for reporting, responding to, investigating, and remediating incidents.

(2) Until ODM and ODA establish a single incident management system, ODA and ODM shall establish their own incident management systems, designated single investigative entity, and designated processes for reporting, responding to, investigating, and remediating incidents.

(E) Critical incidents. The following alleged or suspected incidents shall be investigated by an investigative entity designated by ODM or ODA. The outcome shall be documented in accordance with paragraph (D) of this rule.

(1) Abuse: the injury, confinement, control, intimidation, or punishment of an individual, including self-abuse, that has resulted in physical harm, pain, fear, or mental anguish. Abuse includes, but is not limited to:

(a) Physical, emotional, verbal and/or sexual abuse, the use of unauthorized restraint, seclusion, or restrictive intervention; or

(b) The use of authorized restraint, seclusion, or restrictive intervention that results in, or could reasonably be expected to result in, physical harm, pain, fear, or mental anguish to the individual.

(2) Neglect: when there is a duty to do so, failing to provide an individual with any treatment, care, goods, or services necessary to maintain the health or welfare of the individual, including self-neglect.

- (3) Exploitation: the unlawful or improper act of using an individual or an individual's resources for monetary or personal benefit, profit, or gain.
- (4) Misappropriation: depriving, defrauding, or otherwise obtaining the money, real or personal property (including prescribed medication) of an individual by any means prohibited by law.
- (5) Unexplained death: an unnatural or accidental death, that could not reasonably have been expected, and the circumstances or the cause of death are not related to any known medical condition of the individual, including inadequate oversight of prescribed medication or misuse of prescribed medication.
- (6) The health and welfare of the individual is at risk due to any of the following:
  - (a) Activities involving law enforcement intervention;
  - (b) The individual's health and welfare is in immediate and serious jeopardy;
  - (c) An unexpected crisis in the individual's family or environment resulting in an inability to ensure the individual's health and welfare in his or her residence; or
  - (d) The individual cannot be located.
- (7) Any of the following prescribed medication issues:
  - (a) Provider error;
  - (b) Individual's misuse resulting in emergency medical services (EMS) response, emergency room visit, or hospitalization; or
  - (c) Individual's repeated refusal to take a prescribed medication resulting in EMS response, emergency room visit, or hospitalization.
- (F) Reportable incidents. The following reportable incidents shall be addressed as determined appropriate by the care management entity or recovery management entity. The outcome shall be documented in accordance with paragraph (D) of this rule.
  - (1) Death other than unexplained death as described in paragraph (E)(5) of this rule;
  - (2) Individual or family behavior, action, or inaction resulting in the creation of, or adjustment to, a health and safety action plan;

(3) The health and welfare of the individual is at risk due to the loss of an individual's caregiver;

(4) Any of the following prescribed medication issues:

(a) Individual's misuse not resulting in EMS response, emergency room visit or hospitalization; or

(b) Individual's repeated refusal to take prescribed medications not resulting in EMS response, emergency room visit, or hospitalization;

(5) Hospitalization that results in an adjustment to the person-centered services plan; or

(6) Eviction from place of residence.

(G) Incident reporter responsibilities:

(1) ODM, ODA, or their designees, and all service providers are required to report all incidents as defined in paragraphs (E) and (F) of this rule, and shall do all of the following upon discovering an incident:

(a) Take immediate action to ensure the health and welfare of the individual.

(b) For the Ohio home care and mycare Ohio waivers, or SRS program, report the incident to the waiver care management entity or SRS program recovery manager immediately upon discovery of the incident, but no later than twenty-four hours after discovering the incident, unless bound by federal, state, or local law, or professional licensure or certification requirements to report sooner.

(c) For the PASSPORT and assisted living waivers, report the incident to the waiver care management entity immediately upon discovery of the incident, but no later than within one business day after discovering the incident, unless bound by federal, state, or local law, or professional licensure or certification requirements to report sooner.

(d) If the incident reporter is a waiver provider who has a supervisor, he or she shall immediately notify his or her supervisor.

(2) When the SRS program recovery manager becomes aware of any incident set forth in paragraphs (E) or (F) of this rule, and the individual is enrolled in the mycare Ohio managed care program, the recovery manager must immediately report

the incident to the mycare Ohio care manager or in accordance with processes required by the mycare Ohio plan.

(3) At a minimum, all incident reports shall include the following information when available:

(a) The facts relevant to the incident, such as a description of what happened;

(b) The incident type;

(c) The date of the incident;

(d) The location of the incident;

(e) The names and contact information of all persons involved; and

(f) Any actions taken to ensure the health and welfare of the individual.

(H) The care management entity, or the recovery management entity for SRS recipients who are not also enrolled in the mycare Ohio managed care program, shall do the following upon discovering an incident as deemed appropriate by ODA or ODM:

(1) Ensure immediate action was taken, as applicable to the nature of the incident, to protect the health and welfare of the individual. If such action was not taken, the care management entity or recovery management entity, shall take the action immediately, but no later than twenty-four hours after discovering the incident.

(2) As applicable to the nature of the incident, notify any of the appropriate entities with investigative or protective authority, and the appropriate additional regulatory, oversight, or advocacy agencies. Examples include:

(a) Local law enforcement if the incident involves suspected criminal conduct;

(b) The local coroner's office when the death of an individual is reportable in accordance with section 313.12 of the Revised Code;

(c) The local county board of developmental disabilities;

(d) The local public children services agency (PCSA);

(e) The local adult protective services agency;

(f) The state long-term care ombudsman;

(g) The alcohol, drug addiction and mental health services board;

- (h) The Ohio department of health (ODH), or other licensure or certification board or accreditation body if the incident involves a provider regulated by that entity;
  - (i) The Ohio attorney general if the incident may involve medicaid fraud;
  - (j) The local probate court if the incident may involve the legal guardian;
  - (k) The individual's primary provider (primary physician or primary advance practice registered nurse, as applicable).
- (3) For waivers administered by ODM and the SRS program, the care management entity or the recovery management entity for those not enrolled in the mycare Ohio managed care program, shall notify ODM within twenty-four hours of their discovery of any of the following:
  - (a) A critical incident identified in paragraph (E) of this rule;
  - (b) A public media story about an event directly impacting the health, safety, or welfare of individual on the waiver; or
  - (c) An employee of the care management entity, recovery management entity, or the investigative entity is the alleged violator.
- (4) For waivers administered by ODA, the care management entity shall:
  - (a) Notify ODA within one business day of their discovery of any of the events listed in paragraph (H)(3) of this rule.
  - (b) Enter any critical incident identified in paragraph (E) of this rule into the incident management system within one business day of discovering the incident.
  - (c) Enter any reportable incidents identified in paragraph (F) of this rule into the incident management system within three business days of discovering the incident.
- (5) For waivers administered by ODM and individuals enrolled in the SRS program, the care management entity or the recovery management entity for those not enrolled in the mycare Ohio managed care program, shall enter all incidents (critical and reportable) into the incident management system within twenty-four hours of their discovery.

(I) Responding to critical incidents. The investigative entity shall, as deemed appropriate by ODA or ODM, investigate all critical incidents identified in paragraph (E) of this rule, and shall do the following upon receipt of a reported incident:

(1) Within one business day of the date the investigative entity becomes aware of the incident, review the reported incident, and verify the following:

(a) Immediate action was taken, as applicable to the nature of the incident, to protect the health and welfare of the individual and any other individuals who may be at-risk. If such action was not taken, the investigative entity shall do so immediately, but no later than twenty-four hours after discovering the need for such action.

(b) The appropriate entities have been notified, as applicable to the nature of the incident, with investigative or protective authority, the appropriate additional regulatory, oversight, or advocacy agencies. If such action was not taken, the investigative entity shall do so.

(2) Within two business days of receiving the reported incident, initiate an investigation.

(3) When an investigation is being conducted by a third-party entity with authority to do so (e.g., local law enforcement, fire department, adult protective services, PCSA, the Ohio attorney general, ODH, other licensing boards), the investigative entity may pend its investigation until after receipt of the third party's investigation results if results are available. If the investigation was pended, upon receipt of the results of the investigation, the investigative entity shall determine whether or not further investigation is necessary and either conduct its investigation or close the case.

(J) Investigating critical incidents. The investigative entity shall, as deemed appropriate by ODA or ODM, investigate the incident and do the following:

(1) Conduct a review of all relevant documents as appropriate to the reported incident, which may include, person-centered care plans, service plans, assessments, clinical notes, communication notes, when available results from an investigation conducted by a third-party entity, provider documentation, provider billing records, medical reports, police and fire department reports, and emergency response system reports.

(2) Conduct and document interviews, as appropriate to the reported incident, with anyone who may have information relevant to the incident which may include,

but is not limited to, the reporter, individuals, authorized representatives and/or legal guardians, and providers.

(3) Identify, to the extent possible, any causes and contributing factors.

(4) Determine whether the reported incident is substantiated.

(5) Document all investigative activities in the incident management system.

(K) Concluding a critical incident investigation.

(1) Unless a longer timeframe has been prior-approved by ODM or ODA the investigative entity shall conclude its incident investigation no later than forty-five days after the investigative entity's initial receipt of the incident report.

(2) At the conclusion of the investigation, the investigative entity shall provide to the care management entity or the recovery management entity, and to the individual and/or their authorized representative or legal guardian, a summary of the investigative findings, and whether or not the incident was substantiated, unless such action could jeopardize the health and welfare of the individual.

(3) The summary may be provided through verbal or written communication. Documentation that the summary was provided shall be retained by the investigative entity.

(L) The investigative entity shall submit incident data to ODM or ODA as requested, and in a format and frequency established by ODM or ODA.

(M) ODM or ODA may request further review of any incident, conduct a separate, independent review or investigation of any incident, determine necessary additional action, or assume responsibility for conducting an investigation.



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