

5160-45-05

Ohio department of medicaid (ODM) -administered waiver program: incident management system.

(A) For the purposes of this rule,

(1) "Alert" means an incident that must be reported to the Ohio department of medicaid (ODM) due to the severity and/or impact on an individual enrolled on an ODM-administered waiver or the need for ODM involvement in the incident investigation. Alerts include, but are not limited to the events described in paragraph (J) of this rule.

(2) "Incident" means an alleged, suspected or actual event that is not consistent with the routine care of, and/or service delivery to, an individual. Incidents include, but are not limited to the events described in paragraph (F) of this rule.

(3) "Individual" means a person who is enrolled in an ODM-administered waiver or who participates in any ODM-administered program that is directed to adhere to this rule.

(4) "Provider" means an ODM-administered waiver service provider, any other service provider that is directed to adhere to this rule, and all of their respective staff who have direct contact with individuals.

(B) ODM shall operate an incident management system that includes responsibilities for reporting, responding to, investigating and remediating incidents. This rule sets forth the standards and procedures for operating that system. It applies to ODM, its designees, individuals and providers. ODM may designate other agencies or entities to perform one or more of the incident management functions set forth in this rule.

(C) ODM and its designees shall assure the health and welfare of individuals enrolled on an ODM-administered waiver. ODM, its designees and providers are responsible for ensuring individuals are protected from abuse, neglect, exploitation and other threats to their health, safety and well-being.

(D) Upon entering into a medicaid provider agreement, and annually thereafter, all providers, including all employees who have direct contact with individuals enrolled on an ODM-administered waiver, must acknowledge in writing they have reviewed this rule and related procedures.

(E) Upon an individual's enrollment in an ODM-administered waiver, and at the time of each annual reassessment, ODM or the designated case management contractor shall provide the individual and/or the individual's authorized representative or legal guardian with a waiver handbook that includes information about how to report abuse, neglect, exploitation and other incidents. The case management contractor shall secure from the individual, authorized representative and/or legal guardian written confirmation of receipt of the handbook and it shall be maintained in the individual's case record.

(F) Incidents include, but are not limited to, all of the following:

- (1) Abuse: the injury, confinement, control, intimidation or punishment of an individual by another person that has resulted, or could reasonably be expected to result, in physical harm, pain, fear or mental anguish. Abuse includes, but is not limited to physical, emotional, verbal and/or sexual abuse, and use of 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, the failure to provide goods, services and/or treatment necessary to assure the health and welfare of an individual.
- (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, or real or personal property (including medication) of an individual by any means prohibited by law.
- (5) Death of an individual.
- (6) Hospitalization or emergency department visit (including observation) as a result of:
 - (a) Accident, injury or fall;
 - (b) Injury or illness of an unknown cause or origin; and
 - (c) Reoccurrence of an illness or medical condition within seven calendar days of the individual's discharge from a hospital.
- (7) Unauthorized use of restraint, seclusion and/or restrictive intervention that does not result in, or cannot reasonably be expected to result in, injury to the individual.
- (8) An unexpected crisis in the individual's family or environment that results in an inability to assure the individual's health and welfare in his or her primary place of residence.
- (9) Inappropriate service delivery including, but not limited to:
 - (a) A provider's violation of the conditions of participation set forth in rule 5160-45-10 of the Administrative Code;
 - (b) Services provided to the individual that are beyond the provider's scope of

practice;

(c) Services delivered to the individual without, or not in accordance with, physician's orders; and

(d) Medication administration errors involving the individual.

(10) Actions on the part of the individual that place the health and welfare of the individual or others at risk including, but not limited to:

(a) The individual cannot be located;

(b) Activities that involve law enforcement;

(c) Misuse of medications; and

(d) Use of illegal substances.

(G) Incident reporter responsibilities.

(1) ODM, its designees and all providers are required to report incidents in accordance with the procedures set forth in this rule.

(2) Individuals and/or their authorized representative or legal guardian should report incidents to the individual's case manager and the appropriate authorities.

(3) If a person or an entity identified in paragraph (G)(1) of this rule learns of an incident, the person or entity shall do all of the following:

(a) Take immediate action to assure the health and welfare of the individual which may include, but is not limited to, seeking or providing medical attention.

(b) Immediately report the incident(s) set forth in paragraphs (F)(1) to (F)(5) of this rule to the case manager and the appropriate authorities set forth in paragraph (G)(5)(a) of this rule.

(c) Report any incidents set forth in paragraphs (F)(6) to (F)(10) of this rule to the case manager within twenty-four hours unless bound by federal, state or local law or professional licensure or certification requirements to report sooner.

(4) At a minimum, all incident reports shall include:

(a) The facts that are relevant to the incident;

(b) The incident type; and

(c) The names of, and when available, the contact information for, all persons involved.

(5) The appropriate authority is dependent upon the nature of the incident. Examples of appropriate authorities include, but are not limited to:

(a) The following agencies that hold investigative and/or protective authority:

(i) Local law enforcement if the incident involves conduct that constitutes a possible criminal act including but not limited to, abuse, neglect, exploitation, misappropriation or death of the individual;

(ii) The local coroner's office;

(iii) The local county board of developmental disabilities (CBDD);

(iv) The local public children services agency (PCSA); and

(v) The local public adult protective services agency.

(b) The following regulatory, oversight and/or advocacy agencies:

(i) The Ohio long term care ombudsman;

(ii) The alcohol, drug addiction and mental health service board;

(iii) The Ohio department of health (ODH), or other licensure or certification board or accreditation body when the allegation involves a provider regulated by that entity;

(iv) The Ohio attorney general when the allegation is suspected to involve medicaid fraud by the provider; and

(v) The local probate court when the allegation is suspected to involve the legal guardian.

(6) The incident reporter must also notify his or her supervisor if he or she has one.

(H) Case management contractor responsibilities.

(1) The case management contractor shall do all of the following upon discovery of an incident:

(a) Ensure that immediate action was taken to protect the health and welfare

of the individual and any other individuals who may be at-risk.

(b) Notify the appropriate agencies that hold investigative and/or protective authority as set forth in paragraph (G)(5)(a) of this rule if the incident was one of those set forth in paragraph (F)(1) to (F)(5) of this rule.

(c) Notify the appropriate additional regulatory, oversight and/or advocacy agencies set forth in paragraph (G)(5)(b) of this rule.

(d) Notify the individual's lead physician.

(2) Complete an incident report in ODM's electronic case management system within twenty-four hours of discovery.

(3) The case management contractor shall notify ODM within twenty-four hours of any incident that meets the criteria of an alert as set forth in paragraph (J) of this rule.

(4) The case management contractor shall notify the individual and/or the individual's authorized representative or legal guardian as long as such notification will not jeopardize the incident investigation and/or place the health and welfare of the individual or reporter at risk.

(I) Provider oversight responsibilities.

(1) ODM or its designated provider oversight contractor must review all reported incidents within one business day of notification via ODM's electronic case management system, and shall do all of the following as part of its review:

(a) Verify that immediate action was taken 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 provider oversight contractor must do so immediately.

(b) Verify that the county coroner was notified in the event of the death of an individual. If such action was not taken, the provider oversight contractor must do so immediately.

(c) Verify that the appropriate authorities have been notified as required by this rule. If such action was not taken, the provider oversight contractor must do so immediately.

(d) Verify that the incident was reported within the timeframe required by this rule.

(e) Notify ODM of any incident that meets the criteria of an alert as set forth in paragraph (J) of this rule.

- (2) The provider oversight contractor shall initiate an investigation no later than two business days after having been notified of an incident. At a minimum, the provider oversight contractor shall:
- (a) Contact and work cooperatively with protective agencies and any other entities to whom the incident was reported and that may be conducting a separate investigation.
 - (b) Conduct a review of all relevant documents including, but not limited to, all services plans, assessments, clinical notes, communication notes, coroner's reports, documentation available from other authorities, provider documentation, plans of care, provider billing records, medical reports, police and fire department reports and emergency response system reports.
 - (c) Conduct and document interviews with anyone who may have information relevant to the incident investigation including, but not limited to, the reporter, individuals, authorized representatives and/or legal guardians and providers.
 - (d) Include the individual and the reporter in the incident investigation process, as long as such involvement is both safe and appropriate.
 - (e) When applicable, make referrals to appropriate licensure or certification boards, accreditation bodies, and/or other entities based on the information obtained during the investigation.
 - (f) Document all investigative activities.
 - (g) Document if and why any of the steps set forth in paragraph (I) of this rule were omitted from the incident investigation.
- (3) If, at any time during the investigation of a death, it is determined the incident meets the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule, or the death may have been preventable, the provider oversight contractor must notify ODM within twenty-four hours of the contractor's discovery. If ODM agrees the death is suspicious in nature or was preventable, it shall maintain lead responsibility for the investigation and follow all of the steps set forth in paragraph (I) of this rule and the ODM-approved death investigation protocol. All other deaths shall be investigated by the provider oversight contractor in accordance with the steps set forth in paragraph (I) of this rule and the ODM-approved death investigation protocol.
- (4) Concluding an incident investigation.

- (a) The provider oversight contractor must conclude its incident investigation no later than forty-five days after the provider oversight contractor's initial receipt of the incident report. Extension of this deadline is only permissible upon prior approval by ODM.
- (b) At the conclusion of the investigation, the provider oversight contractor shall:
- (i) Submit to ODM and the individual, authorized representative and/or legal guardian a written report that:
- (a) Summarizes the investigation;
- (b) Identifies if the incident was substantiated and whether it was preventable; and
- (c) Includes a prevention plan for the individual that identifies the steps necessary to mitigate the effects of a substantiated incident, eliminate the causes and contributing factors that resulted in risk to the health and welfare of the individual and any other persons impacted by the incident and prevent future incidents.
- (ii) Notify ODM-administered waiver service providers who are subject to the incident investigation in writing upon substantiation of an incident. The notification shall specify:
- (a) The findings of the investigation that substantiate the occurrence of the incident;
- (b) The Administrative Code rule(s) that support(s) the finding(s) of the investigation;
- (c) What steps the provider must take in order to mitigate against the causes of and factors contributing to the incident; and
- (d) The timeframe within which the provider must submit a plan of correction to the provider oversight contractor in accordance with rule 5160-45-06 of the Administrative Code, not to exceed fifteen calendar days after the date the letter was mailed.
- (iii) Provide a written summary of the investigative findings to the reporter of the incident unless such action could jeopardize the health and welfare of the individual.

(iv) Assure that all such reports issued pursuant to paragraph (I)(4) of this rule shall comply with all applicable state and federal confidentiality and information disclosure laws.

(J) Alerts.

(1) The provider oversight contractor shall ensure that incidents that rise to the level of an alert are reported to ODM within twenty-four hours of the incident's identification and report submission.

(2) The following incidents are cause for an alert:

(a) A suspicious death in which the circumstances and/or the cause of death are not related to any known medical condition, and/or; in which someone's action or inaction may have caused or contributed to the individual's death;

(b) Abuse or neglect that required the individual's removal from his or her place of residence;

(c) Hospitalization or emergency department visit (including observation) as a result of:

(i) Abuse or neglect,

(ii) Accident, injury or fall,

(iii) Injury or illness of an unknown cause or origin, and

(iv) Reoccurrence within seven calendar days of the individual's discharge from a hospital;

(d) Harm to multiple individuals as a result of an incident;

(e) Injury resulting from the authorized or unauthorized use of a restraint, seclusion or restrictive intervention;

(f) Incidents involving an employee of the case management contractor or provider oversight contractor;

(g) Misappropriation that is valued at five hundred dollars or more;

(h) Incidents generated from correspondence received from the Ohio attorney general, office of the governor, the centers for medicare and medicaid services (CMS) or the federal office of civil rights; and

(i) Incidents identified by a public media source.

(K) At its discretion, ODM may request further review of any incident under investigation, and/or conduct a separate, independent review or investigation of any incident.

(L) ODM shall determine when to close incident investigations, and shall be responsible for ensuring that all cases are properly closed.

(M) If, at any time during the discovery or investigation of an incident, it is determined that an employee of the case management contractor or provider oversight contractor is or may be responsible for, or contributed to, the abuse, neglect, exploitation or death of an individual, the case management contractor or provider oversight contractor shall immediately notify ODM. ODM shall assume responsibility for the investigation in accordance with the procedures set forth in this rule.

(N) ODM may impose sanctions upon the provider in accordance with rules 5160-45-06 and 5160-45-09 of the Administrative Code based upon the substantiation of an incident, failure to comply with any of the requirements set forth in this rule, failure to assure the health and welfare of the individual and/or failure to comply with all applicable federal, state and local laws and regulations.

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