ACTION: Final

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Nursing facility-based level of care home and community-based services programs, medicaid managed care organizations, the OhioRISE program, and specialized recovery services program: incident management.

This rule sets the standards and procedures for managing incidents that may have a negative impact on individuals. The purpose is to establish the procedures for reporting and addressing critical incidents and reportable incidents and to prevent and reduce the risk of harm to individuals. This rule applies to multiple programs administered by the Ohio department of aging (ODA) and the Ohio department of medicaid (ODM). ODA and ODM may designate other entities to perform one or more of the incident management functions set forth in this rule.

- (A) For the purposes of this rule, the following definitions apply:
 - (1) "Care management entity" (CME) means the agency described in rule 5160-59-03.2 of the Administrative Code.
 - (2) "Health and safety action plan" or "HSAP" means a document developed by the waiver case management agency or recovery management agency that identifies situations, circumstances, and behaviors that without intervention may jeopardize the individual's health and welfare and potentially risk the individual's program enrollment. The HSAP sets forth the interventions necessary to mitigate risks to the health and welfare of an individual and to ensure the individual's needs are met.
 - (3) "Incident" means an alleged, suspected, or actual event that is not consistent with the routine care of or service delivery to an individual that may have a negative impact on the health and welfare of the individual.
 - (4) "Incident management system" means the system in which reported incidents are entered, including, as applicable, investigative and review notes, findings and results, prevention plans, and any other applicable information.
 - (5) "Individual" means a person enrolled on a home and community-based services (HCBS) waiver, in the specialized recovery services (SRS) program, in the Ohio resilience through integrated systems and excellence (OhioRISE) program, or in a medicaid managed care organization (MCO).
 - (6) "Individual crisis and safety plan" means a plan developed through care coordination and the child and family team for an individual enrolled in the OhioRISE program to ensure child and family safety and reduce the risk of harm in the home and community, as defined in Chapter 5160-59 of the Administrative Code.

(7) "Recovery management agency" means the agency delegated or contracted by ODM to perform case management activities via the recovery manager and related functions for individuals enrolled in the SRS program.

- (8) "Substantiated" means there is a preponderance of evidence to indicate the reported incident is more likely to have occurred than not to have occurred.
- (9) "Waiver case management agency" means an entity delegated or contracted by ODA or ODM to perform case management activities and related functions for individuals enrolled on an HCBS waiver program.
- (B) Incidents: Incidents may be critical or reportable, the definitions of which are as follows:

(1) Critical incidents:

- (a) Abuse: the injury, confinement, control, intimidation, or punishment of an individual that has resulted in physical harm, pain, fear, or mental anguish. Abuse includes, but is not limited to physical, emotional, verbal, and sexual abuse, or the use of restraint, seclusion, or the use of restrictive intervention implemented without authorization from the waiver case management agency, or the OhioRISE plan or its designee.
- (b) 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.
- (c) Exploitation: the unlawful or improper act of using an individual or an individual's resources through the use of manipulation, intimidation, threats, deceptions, or coercion for monetary or personal benefit, profit, or gain.
- (d) Misappropriation: the act of depriving, defrauding, or otherwise obtaining the money or real or personal property (including prescribed medication) of an individual by any means prohibited by law that could potentially impact the health and welfare of the individual.
- (e) Unnatural or accidental death: death of an individual that could not have reasonably been expected, or the cause of death is not related to any known medical condition of the individual, including inadequate oversight of prescribed medication or misuse of prescribed medication.
- (f) Self-harm or suicide attempt: self-harm or suicide attempt that includes a physical attempt by an individual to harm themselves that results in emergency room treatment, in-patient observation, or hospital admission.

(g) The health and welfare of the individual is at risk due to the individual being lost or missing.

- (h) Either of the following prescribed medication issues:
 - (i) Provider error;
 - (ii) Prescribed medication issue resulting in emergency medical services (EMS) response, emergency room visit, or hospitalization.

(2) Reportable incidents

- (a) Natural deaths that are not due to events such as accidents, injuries, homicide, suicide, and overdoses.
- (b) <u>Individual or family member behavior, action, or inaction resulting in the creation of, or adjustment to, a health and safety action plan.</u>
- (c) The health and welfare of the individual is at risk due to any of the following:
 - (i) Loss of the individual's paid or unpaid caregiver;
 - (ii) <u>Prescribed medication issue not resulting in EMS response, emergency room visit, or hospitalizations; or</u>
 - (iii) Eviction or housing crisis
- (d) Suicide attempt that does not result in emergency room treatment, in-patient observation, or hospital admission.

(C) Programs: this rule applies to the following:

- (1) The nursing facility-based level of care home and community-based services (HCBS) waiver programs administered by ODA and ODM including the assisted living waiver as set forth in Chapter 173-38 of the Administrative Code, the PASSPORT waiver as set forth in Chapter 173-42 of the Administrative Code, the Ohio home care waiver (OHCW) as set forth in Chapter 5160-46 of the Administrative Code, and the MyCare Ohio waiver as set forth in Chapter 5160-58 of the Administrative Code.
 - (a) Upon an individual's enrollment on an HCBS waiver, and at the time of each annual reassessment, the waiver case management agency will 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 will be documented and maintained in the individual's case record.
- (b) All critical and reportable incidents are to be reported in accordance with this rule for individuals receiving services through these programs.
- (2) The SRS state plan program as set forth in Chapter 5160-43 of the Administrative Code.
 - (a) Upon an individual's enrollment on the SRS program, and at the time of each annual reassessment, the recovery case management agency will 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 will be documented and maintained in the individual's case record.
 - (b) All critical and reportable incidents are to be reported for individuals receiving services through this program.
- (3) The OhioRISE program, including the OhioRISE waiver, as set forth in Chapter 5160-59 of the Administrative Code. Critical incidents in paragraphs (B)(1) (a) through (B)(1)(f) of this rule and reportable incidents in paragraph (B)(2) (a) of this rule are to be reported for all individuals in the OhioRISE program, except that only misappropriations of an estimated value of over five hundred dollars have to be reported. For individuals receiving treatment in psychiatric residential treatment facilities, critical incidents in paragraph (B)(1)(g) of this rule are also to be reported.
- (4) Medicaid MCOs operating under ODM's care management system as set forth in Chapter 5160-26 of the Administrative Code. Critical incidents in paragraphs (B)(1)(a) through (B)(1)(f) are to be reported for all individuals in these organizations, except that only misappropriations of an estimated value of over five hundred dollars have to be reported.
- (D) Time frames: The initial report, documentation, investigation, and closure of incidents follow the timeline outlined in paragraph (D) of this rule.
 - (1) Initial report and documentation
 - (a) Upon discovering an incident, ODM, ODA, providers of nursing facility-based level of care HCBS waiver services, waiver case management agencies, providers of services under the SRS program, recovery management agencies, the OhioRISE plan, OhioRISE case management

- entities, providers of services under the OhioRISE program, MCOs, and providers of services under contract with an MCO will:
- (i) Take immediate action to ensure the health and welfare of the individual.
- (ii) Report the incident to the relevant waiver case management agency, recovery management agency, the OhioRISE plan, or MCO, as applicable, immediately upon discovery of the incident, but no later than one business day after discovering the incident, unless bound by federal, state, or local law, or professional licensure or certification to report sooner.
- (b) At a minimum, all incident reports will include the following information when available:
 - (i) The facts relevant to the incident, such as a description of what happened;
 - (ii) The incident type;
 - (iii) The date of the incident:
 - (iv) The location of the incident;
 - (v) The names and contact information of all persons involved; and
 - (vi) Any actions taken to ensure the health and welfare of the individual.
- (c) Upon becoming aware of an incident, waiver case management agencies, recovery management agencies, OhioRISE or its designee, and MCOs will:
 - (i) Enter all critical incidents into the incident management system within one business day of becoming aware of the incident.
 - (ii) Enter all reportable incidents into the incident management system within three business days of becoming aware of the incident.

(2) Investigation

(a) Waiver case management agencies for ODA waivers, OhioRISE or its designee, and MCOs will follow the time frames outlined in this

rule when investigating or reviewing an incident and documenting the necessary information in the incident management system.

- (i) 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, take action immediately, but no later than twenty-four hours after the report was received.
- (ii) As applicable to the nature of the incident, notify all of the appropriate entities with investigative or protective authority, and the appropriate additional regulatory, oversight, or advocacy agencies including as applicable but not limited to:
 - (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:
 - (e) The local adult protective services agency;
 - (f) The Ohio department health, or other licensure or certification board or accreditation body if the incident involves a provider regulated by that entity;
 - (g) The local probate court if the incident may involve the legal guardian of the recipient.
- (iii) Within two business days of receiving the incident report, initiate an investigation.
- (iv) Conduct a review of all relevant documents as appropriate to the reported incident, which include, as applicable, personcentered care plans, service plans, assessments, clinical notes, communication notes, results from an investigation conducted by a third-party entity when available, provider documentation, provider billing records, medical reports, police and fire department reports, and emergency response system reports.

(v) Conduct and document interviews, as appropriate to the reported incident, with everyone who may have information relevant to the incident including, but not limited to, the reporter of the incident, the individual, and the authorized representative, legal guardian, and providers for the individual.

- (vi) Identify, to the extent possible, all causes and contributing factors.
- (vii) Determine whether the reported incident is substantiated.
- (viii) Document all investigative activities in the incident management system.
- (ix) Unless a longer time frame has been prior approved by ODM or ODA, conclude the investigation no later than forty-five business days after the investigative entity's initial receipt of the incident report.
- (b) For nursing facility-based level of care HCBS waiver programs administered by ODM and the SRS program, ODM's designee will follow the time frames outlined in paragraph (2)(b) of this rule when investigating an incident and documenting the investigation in the incident management system.
 - (i) Within one business day of becoming 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 recipients of service who may be at risk. If such action was not taken, the investigative entity will 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 as described in additional programspecific guidance. If such action was not taken, do so as soon as possible.
 - (ii) Follow steps in paragraphs (D)(3)(a)(i) through (D)(3)(a)(iv) of this rule.

(iii) At the conclusion of the investigation, provide a summary of the investigative findings, including an indication to the waiver case management agency or recovery management agency stating whether the incident was substantiated or unsubstantiated.

(3) Closure

- (a) All waiver case management agencies for nursing facility-based level of care HCBS waiver programs and recovery management agencies will close out investigations as follows:
 - (i) Upon receipt of the findings for a substantiated incident, review the investigation results and include the information from the results when developing a person-centered prevention plan or updating the care plan to ensure the health and safety of the individual.
 - (ii) Communicate a summary of the investigative findings with the individual and their authorized representative or legal guardian as applicable to the incident using trauma informed care unless such action could jeopardize the health and welfare of the individual.
 - (a) The summary will be provided through verbal communication, unless the individual or their authorized representative or legal guardian requests the summary in writing.
 - (b) The waiver case management agency or recovery management agency documents and retains the documentation that the summary was provided.
 - (iii) For each substantiated critical incident enter a prevention plan into the incident management system no later than seven business days after being notified that the incident was substantiated.
 - (iv) For each reportable incident, address and remediate the incident as determined appropriate, and close the incident in the incident management system no later than forty-five business days after submission of the investigative entity's initial receipt of the incident report.
- (b) OhioRISE and MCOs will close out incident reviews as follows:
 - (i) For OhioRISE, except in the case of death, include any relevant information from the investigation when updating the individual

- crisis and safety plan to ensure the health and safety of the individual.
- (ii) Except in the case of death, enter a prevention prevention plan into the incident management system no later than seven business days after the conclusion of the review.
- (iii) In all cases, close the incident no later than seven business days after the conclusion of the review.
- (E) ODA and ODM 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 or review.

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