

TO BE RESCINDED

5160-44-05

Nursing facility-based level of care home and community-based services (HCBS) programs, medicaid managed care organizations, the OhioRISE program, and specialized recovery services (SRS) 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 implement a continuous quality improvement process to prevent and reduce the risk of harm to individuals. This rule applies to the Ohio department of aging (ODA), the Ohio department of medicaid (ODM), their designees, and to individuals as defined in this rule. This rule also applies to providers of waiver services, providers of OhioRISE services, providers of services provided through a medicaid managed care organization (MCO), and providers of services under the specialized recovery services (SRS) program. 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 purpose of this rule, the following definitions apply:

- (1) "Care management entity" means an entity delegated or contracted by ODA or ODM to perform care management activities and related functions for individuals enrolled on a waiver, or enrolled concurrently on the MyCare Ohio managed care program and the SRS program.
- (2) "Critical incident" means incidents identified in paragraph (C) of this rule.
- (3) "Health and safety action plan" means a document developed by the care management entity or recovery management entity that identifies situations, circumstances, and behaviors that without intervention may jeopardize the individual's health and welfare and potentially risk his or her program enrollment. It sets forth the interventions to remedy risks to the health and welfare of an individual and to ensure the individual's needs are met.
- (4) "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.
- (5) "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. For the pre-admission screening system providing options and resources today (PASSPORT) waiver, and assisted living waiver, the incident management

system is the system established by ODA. For the Ohio home care waiver, MyCare Ohio waiver, SRS program, OhioRISE program, and individuals enrolled in a MCO, the incident management system is the system established by ODM.

- (6) "Individual" means a person enrolled as a waiver recipient, or in the specialized recovery services (SRS) program, or in the OhioRISE program, or in a MCO.
- (7) "Investigative entity" means ODM, ODA, and their designee.
- (8) "Managed Care Organization" means a health insuring corporation (HIC) licensed in the state of Ohio that enters into a managed care provider agreement with the state of Ohio. As used in this rule, managed care organizations do not include managed care plans defined in rule 5160-58-01 of the Administrative Code which administer the MyCare Ohio managed care program.
- (9) "MyCare Ohio managed care program" means the integrated care delivery system program described in Chapter 5160-58 of the Administrative Code.
- (10) "OhioRISE Plan" means the prepaid inpatient health plan as defined in Chapter 5160-59 of the Administrative Code that is under contract with ODM to manage the OhioRISE program benefits. The OhioRISE plan contracts with local entities to provide care management functions for those individuals enrolled in the OhioRISE program.
- (11) "OhioRISE program" means the Ohio resilience through integrated system and excellence program as described in Chapter 5160-59 of the Administrative Code.
- (12) "Recovery management entity" means an entity delegated or contracted by ODM to perform case management activities via the recovery manager and related functions for individuals enrolled in the SRS program.
- (13) "Reportable incident" means an incident identified in paragraph (D) of this rule.
- (14) "Specialized recovery services program" means Ohio's home and community based services (HCBS) state plan program set forth in Chapter 5160-43 of the Administrative Code.
- (15) "Substantiated" means, there is a preponderance of evidence to indicate the reported incident is more likely to have occurred than not to have occurred.
- (16) "Waiver" means an Ohio medicaid nursing facility-based level of care HCBS waiver program which includes the assisted living waiver set forth in Chapter

173-38 of the Administrative Code, the PASSPORT waiver set forth in Chapter 173-42 of the Administrative Code, the Ohio home care waiver set forth in Chapter 5160-46 of the Administrative Code, and the MyCare Ohio waiver set forth in Chapter 5160-58 of the Administrative Code. 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 PASSPORT program set forth in Chapter 173-40 of the Administrative Code, or the state-funded assisted living program set forth in rule 173-51 of the Administrative Code.

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

(C) Critical incidents. The following alleged or suspected incidents will be reported and investigated or reviewed as described in paragraph (E) or (F) of this rule.

- (1) 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, or 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.
- (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.
- (3) 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.
- (4) Misappropriation: the act of depriving, defrauding, or otherwise obtaining the money, 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.

- (5) Unnatural or accidental death: death 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.
- (6) 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.
- (7) The health and welfare of the individual is at risk due to the individual being lost or missing.
- (8) Any of the following prescribed medication issues:
 - (a) Provider error;
 - (b) Prescribed medication issue resulting in emergency medical services (EMS) response, emergency room visit, or hospitalization.
- (D) Reportable incidents. The following reportable incidents will be addressed and remediated as determined appropriate by the waiver case management agency or recovery management entity as described in paragraphs (E) and (F) of this rule.
 - (1) Natural deaths that are not due to events such as accidents, injuries, homicide, suicide, and overdoses.
 - (2) Individual or family member 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 any of the following:
 - (a) Loss of the individual's paid or unpaid caregiver;
 - (b) Prescribed medication issue not resulting in EMS response, emergency room visit, or hospitalizations; or
 - (c) Eviction or housing crisis
 - (4) Suicide attempt that does not result in emergency room treatment, in-patient observation, or hospital admission.
- (E) Process for individuals enrolled on a waiver or SRS program.
 - (1) Upon an individual's enrollment on a 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.

(2) Incident reporter responsibilities:

- (a) ODM, ODA, and their designees, and all service providers of waiver services, OhioRISE services, services provided through a MCO, or services under the SRS program are required to report all incidents as defined in paragraphs (E) and (F) of this rule, and will do all of the following upon discovering an incident:
 - (i) Take immediate action to ensure the health and welfare of the individual.
 - (ii) For the Ohio home care, MyCare Ohio waivers, and SRS program, report the incident to the waiver case 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.
 - (iii) For the PASSPORT and assisted living waivers, report the incident to the waiver case 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.
 - (iv) If the incident reporter is a waiver provider who has a supervisor, he or she will immediately notify his or her supervisor.
- (b) When the SRS program recovery manager becomes aware of any incident set forth in paragraph (C) or (D) of this rule, and the individual is enrolled in the MyCare Ohio managed care program, the recovery manager must report the incident to the MyCare Ohio case manager within one business day.
- (c) 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.
- (3) Waiver case management agency or recovery management entity responsibilities.
- (a) The waiver case management agency, or the recovery management entity for SRS program recipients who are not also enrolled in the MyCare Ohio managed care program, will do the following upon discovering an incident as deemed appropriate by ODA or ODM:
 - (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, the waiver case management agency or recovery management entity, will take the action immediately, but no later than twenty-four hours after discovering the incident.
 - (ii) 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 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 (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).
 - (L) Referral to ODM for a hospital review to assess alleged issues of improper conduct.
 - (iii) For waivers administered by ODA, the waiver case management agency will notify ODA within one business day of their discovery of any of the following:
 - (A) A public media story about an event directly impacting the health, safety, or welfare of the individual on the waiver; or
 - (B) An employee of the waiver case management agency, recovery management entity, or the investigative entity is the alleged violator.
 - (iv) Enter any critical incident identified in paragraph (C) of this rule into the incident management system within one business day of discovering the incident.
 - (v) Enter any reportable incidents identified in paragraph (D) of this rule into the incident management system within three business days of discovering the incident.
- (4) Investigating critical incidents. The investigative entity will, as deemed appropriate by ODA or ODM, investigate all critical incidents identified in paragraph (C) of this rule, and do the following upon receipt of a reported incident:
 - (a) Within one business day of the date the investigative entity becomes aware of the incident, review the reported incident, and verify the following:

- (i) 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 will do so immediately, but no later than twenty-four hours after discovering the need for such action.
 - (ii) 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 will do so.
- (b) Within two business days of receiving the reported incident, initiate an investigation.
- (c) When an investigation is being conducted by a third-party entity with authority to do so, 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 will determine whether or not further investigation is necessary and either conduct its investigation or close the case.
- (d) 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.
- (e) 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 legal guardians, and providers.
- (f) Identify, to the extent possible, any causes and contributing factors.
- (g) Determine whether the reported incident is substantiated.
- (h) Document all investigative activities in the incident management system.
- (i) Unless a longer timeframe has been prior-approved by ODM or ODA the investigative entity will conclude its incident investigation no later than forty-five days after the investigative entity's initial receipt of the incident report.

- (j) At the conclusion of the investigation, the investigative entity will provide to the waiver case management agency or the recovery management entity, a summary of the investigative findings, and whether or not the incident was substantiated.
- (5) Follow up and close-out responsibilities of the waiver case management agency or recovery management entity.
 - (a) Upon receipt of the findings for a substantiated incident, the waiver case management agency, or recovery management entity for SRS program recipients who are not also enrolled in the MyCare Ohio managed care program, will review the investigation results and include the information when developing a person-centered prevention plan or updating the care plan to assure the health and safety of the individual. A summary of the investigative findings will be communicated 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.
 - (b) The summary will be provided through verbal communication, unless the individual or their authorized representative or legal guardian requests it in writing. Documentation that the summary was provided will be retained by the waiver case management agency or recovery management entity.
 - (c) For each substantiated critical incident, the waiver case management agency or recovery management entity will enter a prevention plan into the incident management system no later than seven business days after being notified that the incident was substantiated.
 - (d) For each reportable incident, the waiver case management agency or recovery management entity will address and remediate the incident as determined appropriate by the waiver case management agency or recovery management entity and close the incident in the incident management system no later than thirty business days after submission of the incident into the incident management system.
- (F) Process for individuals enrolled on the OhioRISE program, or enrolled in a MCO.
 - (1) Incident reporter responsibilities:
 - (a) ODM, its designee, the OhioRISE plan, and entities under contract with the OhioRISE plan to provide care management for the OhioRISE program,

as well as all service providers that serve individuals enrolled in the OhioRISE program or that furnish services under contract with an MCO, will report incidents.

- (b) The incidents that the entities in paragraph (F)(1)(a) of this rule are required to report include those defined in paragraph (E)(3)(a)(ii), of this rule, except that misappropriations are only required to be reported if the estimated value is over five hundred dollars. In addition, all deaths of individuals enrolled on the OhioRISE program will be reported, regardless of whether or not the incident meets the definition of an unnatural or accidental death.
- (c) Upon discovering an incident, the responsible person or entity which discovered it will do all the following:
 - (i) Take immediate action to ensure the health and welfare of the individual.
 - (ii) Report the incident to the OhioRISE plan or its designee, or the MCO 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.
- (2) OhioRISE plan or its designee, or MCO or its designee responsibilities: Upon discovering, or receipt of a reported incident, the OhioRISE plan or its designee, or MCO or its designee will do all the following:
 - (a) 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 OhioRISE plan or MCO, will take the action immediately, but no later than twenty-four hours after discovering the incident;
 - (b) As applicable to the nature of the incident, notify any appropriate entities with investigative, protective, or regulatory authority, such as the examples described in paragraph (E)(3)(a)(ii) of this rule;
 - (c) Enter any incident identified in paragraphs (C)(1) through (C)(6) of this rule into the incident management system within one business day of discovering the incident.
- (3) The OhioRISE plan and the MCO will:

- (a) Work collaboratively with investigative entities as needed to identify potential root causes of the incident, contributing factors, and remediation strategies, enter review notes and results, and develop a prevention plan;
 - (b) Unless a longer timeframe has been prior-approved by ODM, conclude the incident review and enter all relevant information into the incident management system no later than forty-five calendar days after their initial receipt of the incident report.
- (4) Follow up and close-out responsibilities: Except in the case of death, the OhioRISE plan or its designee, or MCO or its designee will enter a prevention plan into the incident management system and close the case no later than seven business days after the conclusion of the review.
- (G) ODA and ODM may request further review of any incident, conduct a separate independent review or investigation of any incident, determine necessary additional action, and assume responsibility for conducting an investigation or review.

Replaces: 5160-44-05

Effective:

Five Year Review (FYR) Dates: 7/22/2024

Certification

Date

Promulgated Under: 119.03

Statutory Authority: 5164.02, 5164.91, 5166.02

Rule Amplifies: 5162.03, 5164.02, 5164.91, 5166.02, 5166.11, 5167.02

Prior Effective Dates: 07/01/2004, 09/19/2009, 03/01/2014, 04/01/2014,
08/01/2016, 07/01/2019, 10/02/2021, 07/01/2022