# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

**Agency Name:** Ohio Department of Medicaid

**Regulation/Package Title:** NF-Based LOC Waiver Alignment: Incident Management

**Rule Number(s):** 5160-43-06, 5160-44-05, 5160-45-05, 5160-58-05.3

**Date:** February 21, 2019

**Rule Type:**

- [X] New
- [ ] Amended
- [ ] 5-Year Review
- [X] Rescinded

**The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.**

### Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   ***Please include the key provisions of the regulation as well as any proposed amendments.***

Both the Ohio Department of Medicaid (ODM) and the Ohio Department of Aging (ODA) administer home and community-based services (HCBS) nursing facility level of care waivers, as well as, the HCBS Specialized Recovery Services (SRS) Program. ODM-administered HCBS waivers include the MyCare Ohio and Ohio Home Care waivers. ODA-administered HCBS waivers include the preadmission screening system providing options and resources today (PASSPORT) and Assisted Living waivers. Each waiver and program is described under its own chapter of the OAC and while services and policies across HCBS

programs/waiver may be similar, they are not uniform. Currently ODA does not describe their incident reporting policies in OAC rule.

It is not uncommon for individuals receiving waiver services to move from one waiver to another depending on criteria such as age, Medicare eligibility, service needs or county of residence. Also, often providers deliver services to individuals across all HCBS programs and are made to adhere to different standards and incident reporting policies depending on the enrollment of the individual they are serving. This causes confusion among individuals and providers alike and results in a lack of continuity of care.

To bring consistency to the ODM and ODA administered HCBS programs to benefit individuals and providers, the two agencies have been collaborating to align the OAC rules governing the various waiver programs within a unified OAC chapter, 5160-44. This rule package reflects HCBS waiver alignment collaboration and includes alignment of incident reporting standards and processes.

**5160-44-05 "Nursing facility-based level of care home and community-based services programs and specialized recovery services program: incident management"** is being proposed as new to implement incident reporting requirements in Chapter 5160-44 of the Administrative Code. This rule sets forth the definitions, standards and procedures related to incident reporting for ODM, ODA, their designees, service providers and individuals. It replaces language currently set forth in rules 5160-43-06, 5160-45-05 and 5160-58-05.3 of the Administrative Code.

**5160-43-06 "Specialized recovery services program incident management system"** is being proposed for rescission and will be replaced by rule 5160-44-05 of the Administrative Code. This rule sets forth the definitions, standards and procedures for incident reporting for ODM, its designees, service providers and individuals.

**5160-45-05 "Ohio department of medicaid (ODM)-administered waiver program: incident management system,"** is being proposed for rescission and will be replaced by rule 5160-44-05 of the Administrative Code. This rule sets forth the definitions, standards and procedures for incident reporting for ODM, its designees, service providers and individuals.

**5160-58-05.3 "Mycare Ohio waiver and 1915(i) specialized recovery services program (SRSP): incident management system."** is being proposed for rescission and will be replaced by rule 5160-44-05 of the Administrative Code. This rule sets forth the definitions, standards and procedures for incident reporting for ODM, its desginees (including MyCare Ohio plans), service providers and individuals. This rule is specific to MyCare Ohio and Specialized Recovery Services (SRS) Program managed care members.

## 2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

Ohio Revised Code Sections 5164.02, 5164.91 and 5166.02

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?** ***If yes, please briefly explain the source and substance of the federal requirement.***

Yes, for the Centers for Medicare and Medicaid Services (CMS) to approve a 1915(c) home and community-based services (HCBS) waiver or a 1915(i) State Plan Amendment (SPA), a state must meet certain assurances about the operation of the waiver. These assurances are spelled out in 42 C.F.R. 441.302, and include:

> The State has an established system for reporting, responding to, investigating and remediating all critical incidents. The State has identified and established case management standards for reportable incidents which do not meet the criteria for a critical incident. The State has defined the responsibilities of all incident reporters, case management entities and investigative entities. All investigative entities are required to submit incident data to ODM (or ODA) in a format and frequency determined by ODM (or ODA).
>
> The state uses performance measures to assess compliance with statutory assurances. These performance measures:
> -demonstrate on an ongoing basis that the state identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death; and
> -demonstrate that an incident management system is in place that effectively resolves those incidents and prevents further similar incidents to the extent possible.
>
> The 1915(i) SPA includes a statement that: The state identifies, addresses, and seeks to prevent incidents of abuse, neglect, and exploitation, including the use of restraints.

Accordingly, all HCBS waiver and SRS services providers must report incidents promptly. The proposed new rule will assist the State in assuring the health and welfare of individuals by establishing specific requirements for reporting and investigation of incidents.

4. **If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

These rules are consistent with federal requirements. They define specific processes and procedures for HCBS program providers, individuals, ODM, ODA and their designees as required by CMS.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

HCBS waivers and 1915(i) programs help individuals receive the care they need to remain in the community instead of residing in institutions. The public purpose of these regulations is to assure the health and welfare of individuals enrolled in an ODM or ODA-administered HCBS waiver as required by 42 C.F.R. 44 I. 302(a) and the Specialized Recovery Services program as required by section 1915(i) of the Social Security Act through incident reporting requirements.

6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

Successful outcomes showing that reported incidents are fully and appropriately addressed are measured through review of reports, evidence from findings resulting from structural reviews and investigation of alleged provider occurrences, and review of case records of reported incidents that threaten the health and welfare of individuals participating in an HCBS program.

## Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
***If applicable, please include the date and medium by which the stakeholders were initially contacted.***

October 22, 2018 - The draft proposed rule was shared with the ODA and ODM waiver care management and SRS program entities, and the ODM-contracted investigative entity for review and input. ODM provided a follow up webinar on January 15, 2019. Edits were made to incorporate stakeholder input and to address concerns.

January 18, 2019 - The proposed rule was sent to the HCBS Rules Workgroup described below via email and subsequently reviewed with the group via webinar/in-person meeting on January 23, 2019. There were no concerns expressed by the stakeholders regarding any need to further edit this rule.

ODM has been convening the HCBS Rules Workgroup since May 2013, to draft and review OAC rules governing ODM-administered waivers. The HCBS Rules Workgroup email list includes over 900 members including individuals enrolled on ODM-administered waivers, MyCare Ohio Plans, Area Agencies on Aging (AAAs), agency and independent providers, the investigative entity conducting investigations for ODM waivers, behavioral health provider associations, as well as others.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

   Stakeholders are of critical importance in identifying the requirements for incident reporting and investigation. Throughout the HCBS waiver alignment initiative, stakeholders have provided valuable feedback related to the rule drafts.

   When the draft rule was shared on October 22, 2018 with the ODA and ODM Waiver Care Management (CM) and SRS Program Recovery Management (RM) entities, and the ODM-contracted investigative entity, edits were made, including: the type of incidents that are considered to be critical and those that are reportable; the addition of specific protective agencies included as examples of entities to be notified: aligned timeframe requirements for entering incidents and notifying the State; and adding the CM entities to be included in receipt of the summary of an investigation.

   When the proposed rule was sent to the HCBS Rules Workgroup on January 18, 2019 and reviewed via webinar/in-person meeting on January 23, 2019, there were no concerns expressed by the stakeholders regarding any need to further edit this rule.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

   No scientific data was used to develop the rules or the measurable outcome of the rules.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    Both ODM and ODA policies were considered by the interagency HCBS waiver alignment team. The language must meet the federal and state guidelines under which both ODM and ODA-administered waivers are permitted to operate. The regulation is the result of collaboration between the two agencies and is a blend of the agency policies approved through waiver and state plan authority.

11. **Did the Agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

    No. Performance-based regulations are not deemed appropriate and are not authorized by statute.

12. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

All regulations regarding the ODM and ODA HCBS programs are promulgated by ODM and ODA and implemented by ODM and ODA, their designees and providers, as appropriate. The regulations are reviewed by the interagency legal and legislative staff to ensure there is no duplication within the rules. The HCBS waiver alignment initiative will further ensure the regulation on these providers is not duplicative.

**13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

A robust effort will be executed by ODM and ODA to notify HCBS program participants and service providers of plans regarding the implementation of aligned OAC incident reporting rule. Initial notification of the rule will occur via a variety of communication methods including ODM's issuance of emails to agency and independent providers and electronic communication via the provider oversight contractor's (PCG) website. ODM is considering webinar training for the various entities and has recently conducted a webinar on the topic.

## Adverse Impact to Business

**14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community;**

- All providers of ODA and ODM home and community-based services (HCBS) waivers and Specialized Recovery Services (SRS).
- MyCare Ohio Plans
- ODM and ODA and any designees (including the investigative entity)

**b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**

OAC rules 5160-46-03, 5160-44-05, 5160-45-05 and 5160-58-05.3 require ODM, ODA, or their designees, and all service providers to report all incidents related to individuals enrolled in a home and community-based services (HCBS) waiver or Specialized Recovery Services (SRS) Program. This report of information is a federal requirement and is necessary to ensure the health and safety of individuals enrolled in an HCBS program. Specifically, each rule requires the entities noted above to: take immediate action to ensure the health and welfare of the individual, report the incident immediately upon discovering the incident, and when reporter is a waiver provider who has a supervisor, immediately notify his/her supervisor. The incident report requirements and timeframes are outlined in the rules.

The Care Management (CM) or Recovery Management (RM) entity is required to verify the above actions were taken to protect the health and welfare of the individual, to address the issues impacting the individual, and to report the incident in the incident management system. If it is discovered that a required action was not taken, the CM or RM entity is required to do so.

The investigative entity (an ODM or ODA designee), is required to verify the above actions were taken to protect the health and welfare of the individual. If it is discovered that a required action was not taken, the investigative entity is required to do so. At the conclusion of an investigation, the investigative entity shall provide a summary of the investigative findings, and whether the incident was substantiated, unless such action could jeopardize the health and welfare of the individual. The investigative entity shall submit incident data to ODM/ODA as requested, and in a format and frequency established by ODM/ODA.

**c. Quantify the expected adverse impact from the regulation.**
***The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.***

ODM/ODA, or their designees, and service providers are currently required to report incidents as a condition of doing business with the State. This rule maintains a similar level of reporting and investigative requirements and is not expected to have a significant adverse impact on their current costs of doing business. ODM cannot estimate the cost of compliance as costs will vary depending on the number of incidents that an individual may encounter and that are discovered by ODM/ODA, or their designee, or the service provider.

MyCare Ohio Plans are paid per member per month. ODM must pay MCPs and MCOPs rates that are actuarially sound, as determined by an outside actuary in accordance with 42 C.F.R. 438.6(c) and CMS's "2018/2019 Managed Care Rate Setting Consultation Guide." Ohio Medicaid capitation rates are "actuarially sound" for the period covered by the certification, projected capitation rates and other revenue sources provide for all reasonable, appropriate and attainable costs. Costs include but are not limited to expected health benefits, health benefit settlement expenses, administrative expenses, the cost of capital and government mandated assessments, fees, and taxes.

All rates and actuarial methods can be found on the ODM website in Appendix E of both the Medicaid Managed Care and MyCare Ohio provider agreements. Through the administrative component of the capitation rate paid to the MCPs and MCOPs by ODM, MCPs and MCOPs will be compensated for the cost of the requirements found in these rules. For CY 2018, the

administrative component of the capitation rate varies by program/population and ranges from 3.50% to 8.48% for MCPs and from 2.25% to 10.00% for MCOPs.

The investigative entity and ODM/ODA designees are contracted providers who apply through the request for proposal (RFP) process to become a contracted vendor to perform this work. The providers are aware of the requirements and rate of payment prior to seeking and signing their contracts with the state. The rate of payment to contractors are negotiated according to the work required by the rule. The rule maintains a similar level of reporting and investigative requirements and is not expected to have a significant adverse impact on the contractors' current costs of doing business.

The HCBS service providers are also paid rates that include an administrative component to cover costs such as those incurred when reporting an incident. The rule maintains a similar level of reporting requirements and is not expected to have a significant adverse impact on the providers' current costs of doing business.

**15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The assurance of HCBS program participants' health and welfare is integral to the Ohio HCBS waiver and 1915(i) State Plan Amendment programs – both at the state and federal levels. In order to maintain individuals in the community, all waiver service providers, agencies and contracted case management or recovery management entities have a role in keeping the individual safe. Appropriate notification of incidents that impact the individual's health and safety is necessary and required through federal waiver authority.

Participation in the HCBS programs is optional and at a provider's discretion. Compliance with program requirements is required for providers who choose to participate and may result in administrative costs associated with compliance with the requirements of these rules (e.g., training, monitoring and oversight, etc.). Failure to comply with such requirements may result in a provider's inability to be an Ohio HCBS program service provider.

## Regulatory Flexibility

**16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

No, not applicable for this program.

**17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

Not applicable for this program as ODM/ODA do not fine providers for paperwork violations related to incident reporting.

**18. What resources are available to assist small businesses with compliance of the regulation?**

Providers may contact the Ohio Department of Medicaid (ODM) provider hotline at 1-800-686-1516. Contracted entities may contact their designated contract manager at ODM or ODA.

5160-44-05 **Nursing facility-based level of care home, community-based services programs and specialized recovery services 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 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 on 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(s).

(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.

(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 did not occur.

(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 system, 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 the investigative entity designated by ODM or ODA.

(1) Abuse: the injury, confinement, control, intimidation or punishment of an individual, including self-abuse, 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:

(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, or 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, is lost or wandering.

(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 drug 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, and shall be entered into the incident management system:

(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 the individual's caregiver;

(4) Any of the following prescribed medication issues:

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

(b) individual 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, 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 paragraph (E) or (F) of this rule, and the individual is enrolled in the mycare

Ohio managed care program, he or she 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 contractor 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 shall do so 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 physician.

(3) For waivers administered by ODM and the SRS program, the care management entity or the recovery management contractor 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 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 after discovering the incident.

(c) Enter any reportable incidents identified in paragraph (F) of this rule into the incident management system within three business days after discovering the incident.

(5) For waivers administered by ODM and individuals enrolled in the SRS program, the care management entity or the recovery management contractor 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, 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 and 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 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.

Replaces: 5160-45-05, 5160-58-05.3

Effective:

Five Year Review (FYR) Dates:

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Certification

_____

Date

| | |
|---|---|
| Promulgated Under: | 119.03 |
| Statutory Authority: | 5164.02, 5164.91, 5166.02 |
| Rule Amplifies: | 5164.02, 5164.91, 5166.02, 5166.11, 5167.02 |
| Prior Effective Dates: | 07/07/2004, 09/19/2009, 03/01/2014, 04/01/2014, 08/01/2016 |

TO BE RESCINDED

5160-43-06 **Specialized recovery services program incident management system.**

(A) The Ohio department of medicaid (ODM) or its designee (hereafter referred to as 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 of specialized recovery services (hereafter referred to as providers). ODM may designate other agencies or entities to perform one or more of the incident management functions set forth in this rule.

(B) When the individual is a MyCare Ohio member, this rule is not applicable. Refer to rule 5160-58-05.3 of the Administrative Code for incident management responsibilities.

(C) ODM shall ensure the health and welfare of individuals enrolled in the program. ODM and providers are responsible for ensuring individuals in the specialized recovery services program 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 in the program, must acknowledge in writing they have reviewed this rule and related procedures.

(E) Upon an individual's enrollment in the program, and at the time of each annual reassessment, the recovery manager shall provide the individual and/or the individual's authorized representative or legal guardian with documentation about how to report abuse, neglect, exploitation and other incidents. The recovery manager shall secure from the individual, authorized representative and/or legal guardian written confirmation of receipt of the documentation and it shall be maintained in the individual's 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 in, 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 that meets the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule.

(6) Death of an individual that does not meet the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule.

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

(a) Accident, injury or fall when someone's action or inaction may have caused or contributed to the occurrence, including inadequate oversight of medication or misuse of medication;

(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.

(8) 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.

(9) 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.

(10) Inappropriate service delivery including, but not limited to:

(a) A provider's violation of the requirements set forth in rule 5160-43-04 of the Administrative Code and/or any other Administrative Code rules referenced therein that results in an inability to assure the individual's

health and welfare, or could reasonably be expected to place the individual's health and welfare in jeopardy;

(b) Services provided to the individual that are beyond the provider's scope of practice; and

(c) Medication administration errors involving the individual.

(11) 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) Activities that involve law enforcement;

(b) Misuse of medications;

(c) Use of illegal substances; and

(d) The individual cannot be located.

(G) Incident reporter responsibilities.

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

(2) ODM and all providers are required to report incidents and shall do all of the following:

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

(b) Immediately report any incident(s) set forth in paragraphs (F)(1) to (F)(5) of this rule to the recovery manager and the appropriate authorities set forth in paragraph (G)(4)(a) of this rule.

(c) Report any incidents set forth in paragraphs (F)(6) to (F)(11) of this rule to the recovery manager within twenty-four hours unless bound by federal, state or local law or professional licensure or certification requirements to report sooner.

(d) Report all incidents to his or her supervisor when he or she has a supervisor.

(3) 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 all persons involved and corresponding contact information when available.

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

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

(i) Law enforcement when 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) Coroner's office;

(iii) County board of developmental disabilities;

(iv) Public children services agency; and

(v) Public adult protective services agency.

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

(i) The Ohio long-term care ombudsman;

(ii) Any Ohio, national or federal licensure, certification or accreditation entity when the allegation involves a provider regulated by that entity;

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

(iv) The local probate court when the allegation is suspected to involve the individual's legal guardian.

(H) Recovery management contractor responsibilities.

(1) The recovery 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 individual(s) who may be at-risk;

(b) Notify the appropriate agencies that hold investigative and/or protective authority as set forth in paragraph (G)(4)(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 regulatory, oversight and/or advocacy agencies set forth in paragraph (G)(4)(b) of this rule; and

(d) Notify the individual's primary care provider.

(2) The recovery management contractor shall complete an incident report in the ODM-approved system within twenty-four hours of discovery if the incident was one of those set forth in paragraphs (F)(1) to (F)(11) of this rule.

(3) The recovery 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 recovery management contractor shall notify the individual and/or individual's authorized representative or legal guardian of the incident 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 the ODM-approved assessment and 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 death of an individual when the individual died as a result of criminal or other violent means, by casualty, by suicide, or in any suspicious or unusual manner, or died suddenly when in apparent good health or when the individual had a developmental disability, regardless of the circumstances, and in accordance with section 313.12 of the Revised Code. 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 time frame 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.

(f) Upon substantiating an incident that involves a program provider, the provider oversight contractor shall notify ODM.

(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 which the incident was reported and that may be conducting separate investigations.

(b) Conduct a review of all relevant documents including, but not limited to, assessments, clinical notes, person-centered plans of care, communication notes, coroner's reports, documentation available from other authorities, provider documentation, 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 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 safe and appropriate.

(e) When applicable, make referrals to the 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 the provider oversight contractor discovers an incident that meets the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule, 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 ODM 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.

(4) Incidents set forth in paragraph (F)(6) of this rule 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.

(5) Conducting 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, and excluding the incidents set forth in paragraph (F)(6) of this rule, 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 if it was preventable; and

*(c)* Includes a prevention plan for the individual that identifies steps necessary to mitigate the effects of a substantiated incident, eliminates the causes that resulted in risk to the health and welfare of the individual and helps to prevent future incidents.

(ii) Notify program 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 to mitigate against the causes of and factors contributing to the incident; and

*(d)* The time frame within which the provider must submit a plan of correction to the provider oversight contractor in accordance with rule 5160-43-07 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) Ensure that all such reports issued 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 identification and report submission.

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

(a) A suspicious death that could not reasonably have been expected, and in which at least one of the following circumstances exists:

(i) The circumstances and/or the cause of death are not related to any known medical condition of the individual; or

(ii) Someone's action or inaction may have caused or contributed to the individual's death, including inadequate oversight of medication or misuse of medication.

(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 when someone's action or inaction may have caused or contributed to the occurrence, including inadequate oversight of medication or misuse of medication;

(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 people 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 recovery 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 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 recovery management contractor is or may be responsible for, or contributed to, the abuse, neglect, exploitation or death of an individual, the recovery 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 rule 5160-43-07 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 ensure the health and welfare of the individual and/or failure to comply with all applicable federal, state and local laws and regulations.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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| Promulgated Under: | 119.03 |
| Statutory Authority: | 5164.02 |
| Rule Amplifies: | 5162.03, 5164.02 |
| Prior Effective Dates: | 08/01/2016 |

TO BE RESCINDED

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 authories 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 paragraphs (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.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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|---|---|
| Promulgated Under: | 119.03 |
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TO BE RESCINDED

5160-58-05.3 **MyCare Ohio waiver and 1915(i) specialized recovery services program (SRSP): 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 a member enrolled on the MyCare Ohio waiver or SRSP 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, a member. Incidents include, but are not limited to the events described in paragraph (F) of this rule.

(3) "Provider" means a MyCare Ohio waiver or SRSP 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 members.

(4) "Specialized Recovery Services Program (SRSP)" means Ohio's specialized recovery service program authorized by Section 1915(i) of the Social Security Act, 42 U.S.C. 1396n(i) (July 1, 2016).

(B) ODM or its designee 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 (which, unless otherwise stated, for the purposes of this rule includes, but is not limited to MyCare Ohio plans and their designees), members 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 members enrolled on the MyCare Ohio waiver or SRSP. ODM, its designees and providers are responsible for ensuring members 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 members enrolled on the MyCare Ohio waiver or SRSP, must acknowledge in writing they have reviewed this rule and related procedures.

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

(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 a member.

(3) Exploitation: the unlawful or improper act of using a member or a member'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 a member by any means prohibited by law.

(5) Death of a member that meets the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule.

(6) Death of a member that does not meet the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule.

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

(a) Accident, injury or fall when someone's action or inaction may have caused or contributed to the occurence, including but not limited to, inadequate oversight of medications of misuse of medications;

(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 member's discharge from a hospital.

(8) 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 member.

(9) An unexpected crisis in the member's family or environment that results in an inability to assure the member's health and welfare in his or her primary place of residence.

(10) Inappropriate service delivery including, but not limited to:

(a) A provider's violation of the requirements set forth in rule 5160-58-04 of the Administrative Code and/or any other Administrative Code rules referenced therein that results in an inability to assure the member's health and welfare, or could reasonably be expected to place the member's health and welfare in jeopardy;

(b) Services provided to the member that are beyond the provider's scope of practice;

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

(d) Medication administration errors involving the member.

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

(a) The member 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) Members and/or their authorized representative or legal guardian should report incidents to the member's MyCare Ohio care manager or waiver service coordinator or SRSP recovery 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 member which may include, but is not limited to, seeking or providing medical attention.

(b) Immediately report any incident(s) set forth in paragraphs (F)(1) to (F)(5) of this rule to the MyCare Ohio care manager or waiver service coordinator or SRSP recovery manager and the appropriate authorities set forth in paragraph (G)(6)(a) of this rule.

(c) Report any incidents set forth in paragraphs (F)(6) to (F)(11) of this rule to the MyCare Ohio care manager or waiver service coordinator or SRSP recovery manager within twenty-four hours unless bound by federal, state or local law or professional licensure or certification requirements to report sooner.

(4) Whenever the 1915(i) SRSP recovery manager becomes aware of any incident set forth in paragraph (F) of this rule, he or she must immediately report the incident to the MyCare Ohio care manager or in accordance with processes required by the MyCare Ohio plan.

(5) 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.

(6) 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 member;

(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; and

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

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

(H) MyCare Ohio plan responsibilities.

(1) The MyCare Ohio plan 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 member and any other members who may be at-risk.

(b) Notify the appropriate agencies that hold investigative and/or protective authority as set forth in paragraph (G)(6)(a) of this rule if the incident was one of those set forth in paragraphs (F)(1) to (F)(5) of this rule.

(c) Notify the appropriate additional regulatory, oversight and/or advocacy agencies set forth in paragraph (G)(6)(b) of this rule.

(d) Notify the member's primary care provider.

(2) The MyCare Ohio plan shall complete an incident report in ODM's or its provider oversight contractor's electronic incident management system within twenty-four hours of discovery if the incident was one of those set forth in paragraphs (F)(1) through (F)(5) of this rule.

(3) The MyCare Ohio plan shall complete an incident report in the MyCare Ohio plan's own incident management system within twenty-four hours of discovery if the incident was one of those set forth in paragraphs (F)(6) to (F)(11) of this rule.

(4) The MyCare Ohio plan shall notify ODM or its provider oversight contractor, as appropriate, within twenty-four hours of any incident that meets the criteria of an alert as set forth in paragraph (J) of this rule.

(5) The MyCare Ohio plan shall notify the member and/or the member's authorized representative or legal guardian of the incident as long as such notification will not jeopardize the incident investigation and/or place the health and welfare of the member or reporter at risk.

(6) The MyCare Ohio plan shall submit all incident data resulting from reports filed pursuant to paragraphs (H)(2) and (H)(3) of this rule to ODM or its designee by the close of business on the last business day of the first week following the end of the month.

(I) Incident investigation responsibilities.

(1) As appropriate, ODM or its provider oversight contractor, or the MyCare Ohio plan must review all reported incidents within one business day of notification via ODM's or its designee's electronic incident 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 member and any other members who may be at-risk. If such action was not taken, the MyCare Ohio plan or provider oversight contractor must do so immediately.

(b) Verify that the county coroner was notified in the event of the death of a member when the person died as a result of criminal or other violent means, by casualty, by suicide, or in any suspicious or unusual manner, or died suddenly when in apparent good health, or when the member had a developmental disability regardless of the circumstances, and in accordance with section 313.12 of the Revised Code. If such action was not taken, the MyCare Ohio plan or 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 MyCare Ohio plan or 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.

(f) Upon substantiating an incident that involves a MyCare Ohio waiver or 1915(i) SRSP provider, the investigative entity shall notify the Ohio department of aging (ODA) or Ohio department of medicaid (ODM) or a designee of either agency that certified or approved the provider.

(2) As appropriate, the provider oversight contractor or the MyCare Ohio plan shall initiate an investigation no later than two business days after having been notified of an incident. At a minimum, the provider oversight contractor or MyCare Ohio plan 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, integrated, individualized care 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, members, authorized representatives and/or legal guardians and providers.

(d) Include the member 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 the provider oversight contractor or MyCare Ohio plan discovers an incident that meets the criteria for a suspicious death as described in paragraph (J)(2)(a) of this rule, , the provider oversight contractor or MyCare Ohio plan must notify ODM within twenty-four hours of the contractor's discovery. If ODM agrees the death is suspicious in nature, 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.

(4) Incidents set forth in paragraph (F)(6) of this rule shall be investigated by the MyCare Ohio plan in accordance with the ODM-approved death investigation protocol.

(5) Concluding an incident investigation.

(a) As appropriate, the provider oversight contractor or the MyCare Ohio plan 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, excluding incidents set forth in paragraph (F)(6) of this rule the provider oversight contractor or the MyCare Ohio plan shall:

(i) Submit to ODM and the member, 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 member 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 member and any other persons impacted by the incident and prevent future incidents.

(ii) Notify MyCare Ohio 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 in accordance with rule 5160-45-06 of the Administrative Code, not to exceed fifteen calendar days after the notification date.

(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 member.

(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) As appropriate, the provider oversight contractor or the MyCare Ohio plan 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 that could not reasonably have been expected, and in which at least one of the following circumstances exist: .

(i) The circumstances and/or the cause of death are not related to any known medical condition of the member; or

(ii) Someone's action or inaction may have caused or contributed to the member's death, including but not limited to, inadequate oversight of medications or misuse of medications.

(b) Abuse or neglect that required the member'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 when someone's action or inaction may have caused or contributed to the occurrence, including but not limited to, inadequate oversight of medications or misues of medications;

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

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

(d) Harm to multiple members 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 MyCare Ohio plan 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.

(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 or its designee shall determine when to close incident investigations, and shall be responsible for ensuring that all investigations are properly closed.

(M) If, at any time during the discovery or investigation of an incident, it is determined that an employee of the provider oversight contractor or the MyCare Ohio plan is or may be responsible for, or contributed to, the abuse, neglect, exploitation or death of a member, the provider oversight contractor or MyCare Ohio plan 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, remediation, or corrective action upon the provider in accordance with rules 5160-45-06 and 5160-45-09 of the Administrative Code or rules 173-39-05 to 173-39-08 of the Administrative Code, as appropriate, 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 member and/or failure to comply with all applicable federal, state and local laws and regulations.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

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|---|---|
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