Ohio | Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Medicaid

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Regulation/Package Title (a general description of the rules' substantive content): Medicaid Incident Management Rule Revision

Rule Number(s): 5160-44-05

Date of Submission for CSI Review: 3/15/2022

Public Comment Period End Date: 3/22/2022

Rule Type/Number of Rules:

New/ 1 **rules**

No Change/____ **rules (FYR?** ___**)**

Amended/ ___ **rules (FYR?)**

Rescinded/ 1 **rules (FYR?** No**)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

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

   5160-44-05 "Nursing facility-based level of care home and community-based services (HCBS) programs, managed care organizations (MCO), OhioRISE program, and specialized recovery services (SRS) program: incident management" sets forth the definitions, standards and procedures related to incident reporting for the Ohio Department of Medicaid (ODM), the Ohio Department of Aging (ODA), their designees, service providers and individuals. This rule will be proposed as rescind/new due to the volume of amendments being made to the rule.

   Both ODM and ODA administer HCBS nursing facility level of care waivers. ODM-administered HCBS waivers include the MyCare Ohio and the Ohio Home Care waivers. ODA-administered HCBS waivers include the preadmission screening system providing options and resources today (PASSPORT) and Assisted Living waivers. ODM also administers the HCBS Specialized Recovery Services (SRS) Program, the OhioRISE program, and Medicaid services through the Managed Care Organizations (MCO).

This rule sets forth the requirements for reporting and investigating incidents involving individuals enrolled in the waivers and program mentioned above. The primary purpose is to add to the rule the individuals enrolled in the OhioRISE program, and those being served through a Medicaid Managed Care Organization. In doing so, the rule is being reformatted to keep programs together that follow similar processes. This will make it easier to locate and follow the processes that apply to those new populations. Other changes include adding new definitions and revising current definitions for better clarity. Certain incident types are also being revised for better clarity and consistency in application. Another significant revision includes a process change to the conclusion of critical incident investigations so the Investigative Entity will send the results of its investigation to the Case Management Agency (CM agency) or Recovery Management Agency (RM agency) rather than directly to the individual; the CM or RM Agency, in turn, will inform the individual verbally (unless the individual requests it in writing) of the investigation results. This is a more person-centered approach because the sensitive nature of the information will be provided to the individual by a person that they are more familiar with. The addition of timeframes is also being proposed to establish how soon a prevention plan should be entered into the Incident Management System (IMS), and for closing and entering a reportable incident.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   Ohio Revised Code Sections 5164.02, 5164.91 and 5166.02

4. **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 42C.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 Specialized Recovery Services providers must report incidents promptly. The proposed amendment will assist the State in assuring the health and welfare of individuals by establishing specific requirements for reporting and investigation of incidents.

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

   These rules are being proposed in order to meet federal requirements. They define specific processes and procedures for HCBS program providers, individuals, ODM, ODA and their designees as required by CMS. The addition of reporting and handling of incidents for Medicaid MCOs is not a federal requirement, however, it is an expectation established in the ODM agreement with the MCOs. The health and welfare of individuals served on Medicaid via the MCOs is of the utmost importance, and as such, is imperative to include in the rule.

6. **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, 1915(i) programs, and Medicaid services provided through a Medicaid MCO 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 who receive Medicaid services through a Medicaid MCO, or who are 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.

7. **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, evaluation of data, 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 HCBS, OhioRISE, and managed care.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. **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.

   September 9, and October 6, 2021 - The draft proposed rule was shared with the ODA and ODM waiver care management and SRS program administrators for review and input. Edits were made to incorporate input.

   November 9, 2021 – The proposed rule was sent via email to the contracted ODA and ODM waiver case management agencies, SRS recovery management agencies, investigative entity, managed care organizations, and a broader ODM audience. The proposed rule was subsequently reviewed with the group via live, interactive webinar meeting on November 18, 2021.

   December 27, 2021 - The proposed rule was sent to the HCBS Rules Workgroup described below via email, and subsequently reviewed with the group via live, interactive webinar meeting on January 6, 2022. There were no concerns about the proposed rule expressed by the stakeholders requiring the need to further edit. 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 800 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

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

As a result of stakeholder input, the time frames for entering prevention plans into the Incident Management System (IMS) and for closing reportable incidents was changed from 'calendar' days to 'business' days. At stakeholders' request, language that was initially proposed for deletion regarding establishing a single, shared IMS is being retained. An initial proposal to separate self-neglect as a stand-alone incident was retracted because of stakeholder input. As suggested, an example of authorities to notify was added to include making a referral to ODM for a hospital review as applicable to the nature of the incident. Stakeholder input also resulted in revisions to initially proposed language regarding that way individuals are informed of the findings of an investigation.

11. 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 this rule or the measurable outcomes of the rule.

12. 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?

No alternative regulations were considered, as this regulation needs to align with state and federal requirements. There is no regulatory alternative that would have had less of an adverse impact on businesses that would meet CMS approval.

13. 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.***

Ohio has CMS Performance Measures that all states are required to meet. This rule will help us meet those federal measures.

14. 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 waiver programs are promulgated by ODM and ODA and implemented by ODM and ODA, their designees and providers, as appropriate. Likewise, regulations specific to the ODM-administered waiver programs are promulgated by ODM and implemented by ODM, its designees and providers, as appropriate. Where applicable, both agencies have worked together to ensure there's no duplication among their respective regulations. ODM and ODA have verified that the current rule is the only rule in the OAC that covers incident management.

15. 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.

ODM will notify all entities that are required to implement the revised timeframe requirements including all MyCare Managed Care Plans, OhioRISE Plan, and Medicaid Managed Care Organizations of the final rule changes via email notification. Additionally, per the provider agreement, managed care plans are required to subscribe to the appropriate distribution lists for notification of all OAC rule clearances and final published rules including RuleWatch Ohio and the Common Sense Initiative Office eNotification System.

Adverse Impact to Business

16. 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; and

- All providers of ODA and ODM home and community-based services (HCBS) waivers and Specialized Recovery Services (SRS), OhioRISE, and Medicaid Managed Care Organizations (MCO).
- MyCare Ohio Plans
- OhioRISE Plan and any designees
- Medicaid MCOs

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

This rule requires all service providers that serve individuals enrolled in a home and community-based services (HCBS) waiver, OhioRISE, Medicaid MCO, or Specialized Recovery Services (SRS) program to report all incidents related to individual. This report of information for the HCBS waivers and the SRS program is a federal requirement. Reporting this information is necessary to ensure the health and safety of individuals enrolled in an HCBS program. Specifically, the rule requires the the affected entities to take immediate action to ensure the health and welfare of the individual, report the incident immediately upon discovering the incident, and when the reporter is a waiver provider who has a supervisor, immediately notify his or her supervisor, as applicable. The incident report requirements and timeframes are outlined in the rule.

The affected entities are 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 take the required step. At the conclusion of an investigation, the investigative entity shall provide to the CM or RM agency, a summary of the investigative findings, and whether the incident was substantiated, the CM or RM agency in turn, will inform the individual of the findings unless such action could jeopardize the health and welfare of the individual.

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, their designees, and waiver 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.

Medicaid MCOs, the OhioRISE Plan, and 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 2021, the administrative component of the capitation rate varies by program/population and ranges from 4.0% to 6.5% for MCPs and from 3.0% to 6.0% 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.

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

The assurance of Medicaid program participants' health and welfare is of the utmost importance to ODM, and the expectations of reporting and addressing incidents is included in ODM's agreement with the Medicaid MCOs. The assurance of HCBS program participants' health and welfare is also 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 this rule (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

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

No, not applicable for these programs.

19. 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 these programs as ODM and ODA do not fine providers for paperwork violations related to incident reporting.

20. 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.

TO BE RESCINDED

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

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

(1) "Care management entity" means an entity delegated or contracted by the Ohio department of aging (ODA) or the Ohio department of medicaid (ODM) to perform care management activities and related functions for individuals enrolled on a waiver.

(2) "Critical incident" means incidents identified in paragraph (E) of this rule.

(3) "Health and safety action plan" means a document developed by the care management entity that identifies situations, circumstances, and/or behaviors that without intervention may jeopardize the individual's health and welfare and potentially risk his or her enrollment on the waiver. It sets forth the interventions to remedy risks to the health and welfare of an individual on a waiver and to ensure the individual's needs are met through the waiver.

(4) "Incident" means an alleged, suspected or actual event that is not consistent with the routine care of, and/or service delivery to an individual.

(5) "Individual" means a person enrolled on a waiver or in the specialized recovery services (SRS) program as defined in this rule.

(6) "Investigative entity" means ODM, ODA, or their designee.

(7) "Reportable incident" means an incident identified in paragraph (F) of this rule that requires entry into the incident management system, and addressed as determined appropriate by the care management entity or recovery management entity.

(8) "Specialized recovery services (SRS) program" means Ohio's home and community based services (HCBS) state plan program set forth in Chapter 5160-43 of the Administrative Code.

(9) "Substantiated" means, there is a preponderance of evidence to indicate the reported incident is more likely to have occurred than not to have occurred.

(10) "Waiver" means an Ohio medicaid nursing facility-based level of care HCBS waiver program. This rule does not apply to developmental disabilities level of care waivers set forth in Chapter 5123-9 of the Administrative Code, the state-funded pre-admission screening system providing options and resources today (PASSPORT) program set forth in rule 173-39-40 of the Administrative Code, or the state-funded assisted living program set forth in rule 173-39-51 of the Administrative Code.

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

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

(D) Uniformity.

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

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

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

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

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

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

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

(3) Exploitation: the unlawful or improper act of using an individual or an individual's resources for monetary or personal benefit, profit, or gain.

(4) Misappropriation: depriving, defrauding, or otherwise obtaining the money, real or personal property (including prescribed medication) of an individual by any means prohibited by law.

(5) Unexplained death: an unnatural or accidental death, that could not reasonably have been expected, and the circumstances or the cause of death are not related to any known medical condition of the individual, including inadequate oversight of prescribed medication or misuse of prescribed medication.

(6) The health and welfare of the individual is at risk due to any of the following:

(a) Activities involving law enforcement intervention;

(b) The individual's health and welfare is in immediate and serious jeopardy;

(c) An unexpected crisis in the individual's family or environment resulting in an inability to ensure the individual's health and welfare in his or her residence; or

(d) The individual cannot be located.

(7) Any of the following prescribed medication issues:

(a) Provider error;

(b) Individual's misuse resulting in emergency medical services (EMS) response, emergency room visit, or hospitalization; or

(c) Individual's repeated refusal to take a prescribed medication resulting in EMS response, emergency room visit, or hospitalization.

(F) Reportable incidents. The following reportable incidents shall be addressed as determined appropriate by the care management entity or recovery management entity. The outcome shall be documented in accordance with paragraph (D) of this rule.

(1) Death other than unexplained death as described in paragraph (E)(5) of this rule;

(2) Individual or family behavior, action, or inaction resulting in the creation of, or adjustment to, a health and safety action plan;

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

(4) Any of the following prescribed medication issues:

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

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

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

(6) Eviction from place of residence.

(G) Incident reporter responsibilities:

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

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

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

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

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

(2) When the SRS program recovery manager becomes aware of any incident set forth in paragraph (E) or (F) of this rule, and the individual is enrolled in the mycare Ohio managed care program, the recovery manager must immediately report the incident to the mycare Ohio care manager or in accordance with processes required by the mycare Ohio plan.

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

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

(b) The incident type;

(c) The date of the incident;

(d) The location of the incident;

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

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

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

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

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

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

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

(c) The local county board of developmental disabilities;

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

(e) The local adult protective services agency;

(f) The state long-term care ombudsman;

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

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

(i) The Ohio attorney general if the incident may involve medicaid fraud;

(j) The local probate court if the incident may involve the legal guardian;

(k) The individual's primary provider (primary physician or primary advance practice registered nurse, as applicable).

(3) For waivers administered by ODM and the SRS program, the care management entity or the recovery management entity for those not enrolled in the mycare Ohio managed care program, shall notify ODM within one business day of their discovery of any of the following:

(a) A critical incident identified in paragraph (E) of this rule;

(b) A public media story about an event directly impacting the health, safety, or welfare of individual on the waiver; or

(c) An employee of the care management entity, recovery management entity, or the investigative entity is the alleged violator.

(4) For waivers administered by ODA, the care management entity shall notify ODA within one business day of their discovery of any of the events listed in paragraph (H)(3) of this rule.

(5) For all programs identified in this rule, the care management entity, or the recovery management entity for those not enrolled in the mycare Ohio managed care program, will:

(a) Enter any critical incident identified in paragraph (E) of this rule into the incident management system within one business day of discovering the incident.

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

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

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

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

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

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

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

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

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

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

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

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

(4) Determine whether the reported incident is substantiated.

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

(K) Concluding a critical incident investigation.

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

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

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

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

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

Effective:

Five Year Review (FYR) Dates:

_____

Certification

_____

Date

Promulgated Under:	119.03
Statutory Authority:	null
Rule Amplifies:	null

DRAFT - NOT FOR FILING

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

This rule sets the standards and procedures for managing incidents that may have a negative impact on individuals. The purpose is to establish the procedures for reporting and addressing critical incidents and reportable incidents, and to implement a continuous quality improvement process to prevent and reduce the risk of harm to individuals. This rule applies to the Ohio department of aging (ODA), the Ohio department of medicaid (ODM), their designees, and to individuals as defined in this rule. This rule also applies to providers of waiver services, providers of OhioRISE services, providers of services provided through a medicaid managed care organization (MCO), and providers of services under the specialized recovery services (SRS) program. ODA and ODM may designate other entities to perform one or more of the incident management functions set forth in this rule.

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

(1) "Care management entity" means an entity delegated or contracted by ODA or ODM to perform care management activities and related functions for individuals enrolled on a waiver, or enrolled concurrently on the MyCare Ohio managed care program and the SRS program.

(2) "Critical incident" means incidents identified in paragraph (C) of this rule.

(3) "Health and safety action plan" means a document developed by the care management entity or recovery management entity that identifies situations, circumstances, and behaviors that without intervention may jeopardize the individual's health and welfare and potentially risk his or her program enrollment. It sets forth the interventions to remedy risks to the health and welfare of an individual and to ensure the individual's needs are met.

(4) "Incident" means an alleged, suspected or actual event that is not consistent with the routine care of, or service delivery to an individual that may have a negative impact on the health and welfare of the individual.

(5) "Incident management system" means the system in which reported incidents are entered, including, as applicable, investigative and review notes, findings and results, prevention plans, and any other applicable information. For the pre-admission screening system providing options and resources today (PASSPORT) waiver, and assisted living waiver, the incident management system is the system established by ODA. For the Ohio home care waiver, MyCare Ohio waiver, SRS program, OhioRISE program, and individuals enrolled in a MCO, the incident management system is the system established by ODM.

(6) "Individual" means a person enrolled as a waiver recipient, or in the specialized recovery services (SRS) program, or in the OhioRISE program, or in a MCO.

(7) "Investigative entity" means ODM, ODA, and their designee.

(8) "Managed Care Organization" means a health insuring corporation (HIC) licensed in the state of Ohio that enters into a managed care provider agreement with the state of Ohio. As used in this rule, managed care organizations do not include managed care plans defined in rule 5160-58-01 of the Administrative Code which administer the MyCare Ohio managed care program.

(9) "MyCare Ohio managed care program" means the integrated care delivery system program described in Chapter 5160-58 of the Administrative Code.

(10) "OhioRISE Plan" means the prepaid inpatient health plan as defined in Chapter 5160-59 of the Administrative Code that is under contract with ODM to manage the OhioRISE program benefits. The OhioRISE plan contracts with local entities to provide care management functions for those individuals enrolled in the OhioRISE program.

(11) "OhioRISE program" means the Ohio resilience through integrated system and excellence program as described in Chapter 5160-59 of the Administrative Code.

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

(13) "Reportable incident" means an incident identified in paragraph (D) of this rule.

(14) "Specialized recovery services program" means Ohio's home and community based services (HCBS) state plan program set forth in Chapter 5160-43 of the Administrative Code.

(15) "Substantiated" means, there is a preponderance of evidence to indicate the reported incident is more likely to have occurred than not to have occurred.

(16) "Waiver" means an Ohio medicaid nursing facility-based level of care HCBS waiver program which includes the assisted living waiver set forth in Chapter 173-38 of the Administrative Code, the PASSPORT waiver set forth in Chapter 173-42 of the Administrative Code, the Ohio home care waiver set forth in Chapter 5160-46 of the Administrative Code, and the MyCare Ohio waiver set forth in Chapter 5160-58 of the Administrative Code. This rule does not apply to developmental disabilities level of care waivers set forth in Chapter 5123-9 of the Administrative Code, the state-funded PASSPORT program set forth in Chapter 173-40 of the Administrative Code, or the state-funded assisted living program set forth in rule 173-51 of the Administrative Code.

(B) Uniformity.

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

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

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

(1) Abuse: the injury, confinement, control, intimidation, or punishment of an individual that has resulted in physical harm, pain, fear, or mental anguish. Abuse includes, but is not limited to physical, emotional, verbal, or sexual abuse, or the use of restraint, seclusion, or the use of restrictive intervention implemented without authorization from the waiver case management agency, or the OhioRISE plan or its designee.

(2) Neglect: when there is a duty to do so, failing to provide an individual with any treatment, care, goods, or

services necessary to maintain the health or welfare of the individual.

(3) Exploitation: the unlawful or improper act of using an individual or an individual's resources through the use of manipulation, intimidation, threats, deceptions, or coercion for monetary or personal benefit, profit, or gain.

(4) Misappropriation: the act of depriving, defrauding, or otherwise obtaining the money, real or personal property (including prescribed medication) of an individual by any means prohibited by law that could potentially impact the health and welfare of the individual.

(5) Unnatural or accidental death: death that could not have reasonably been expected, or the cause of death is not related to any known medical condition of the individual, including inadequate oversight of prescribed medication or misuse of prescribed medication.

(6) Self-harm or suicide attempt: Self-harm or suicide attempt that includes a physical attempt by an individual to harm themselves that results in emergency room treatment, in-patient observation, or hospital admission.

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

(8) Any of the following prescribed medication issues:

(a) Provider error;

(b) Prescribed medication issue resulting in emergency medical services (EMS) response, emergency room visit, or hospitalization.

(D) Reportable incidents. The following reportable incidents will be addressed and remediated as determined appropriate by the waiver case management agency or recovery management entity as described in paragraphs (E) and (F) of this rule.

(1) Natural deaths that are not due to events such as accidents, injuries, homicide, suicide, and overdoses.

(2) Individual or family member behavior, action, or inaction resulting in the creation of, or adjustment to, a health and safety action plan.

(3) The health and welfare of the individual is at risk due to any of the following:

(a) Loss of the individual's paid or unpaid caregiver;

(b) Prescribed medication issue not resulting in EMS response, emergency room visit, or hospitalizations; or

(c) Eviction or housing crisis

(4) Suicide attempt that does not result in emergency room treatment, in-patient observation, or hospital admission.

(E) Process for individuals enrolled on a waiver or SRS program.

(1) Upon an individual's enrollment on a waiver, and at the time of each annual reassessment, the waiver case management agency will obtain written confirmation that the individual received information about how

to report abuse, neglect, exploitation, and other incidents as defined in this rule. The written confirmation will be documented and maintained in the individual's case record.

(2) Incident reporter responsibilities:

(a) ODM, ODA, and their designees, and all service providers of waiver services, OhioRISE services, services provided through a MCO, or services under the SRS program are required to report all incidents as defined in paragraphs (E) and (F) of this rule, and will do all of the following upon discovering an incident:

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

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

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

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

(b) When the SRS program recovery manager becomes aware of any incident set forth in paragraph (C) or (D) of this rule, and the individual is enrolled in the MyCare Ohio managed care program, the recovery manager must report the incident to the MyCare Ohio case manager within one business day.

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

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

(ii) The incident type;

(iii) The date of the incident;

(iv) The location of the incident;

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

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

(3) Waiver case management agency or recovery management entity responsibilities.

(a) The waiver case management agency, or the recovery management entity for SRS program recipients who are not also enrolled in the MyCare Ohio managed care program, will do the following upon discovering an incident as deemed appropriate by ODA or ODM:

(i) Ensure immediate action was taken, as applicable to the nature of the incident, to protect the

health and welfare of the individual. If such action was not taken, the waiver case management agency or recovery management entity, will take the action immediately, but no later than twenty-four hours after discovering the incident.

(ii) As applicable to the nature of the incident, notify any of the appropriate entities with investigative or protective authority, and the appropriate additional regulatory, oversight, or advocacy agencies including as applicable but not limited to:

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

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

(c) The local county board of developmental disabilities;

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

(e) The local adult protective services agency;

(f) The state long-term care ombudsman;

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

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

(i) The Ohio attorney general if the incident may involve medicaid fraud;

(j) The local probate court if the incident may involve the legal guardian;

(k) The individual's primary provider (primary physician or primary advance practice registered nurse, as applicable).

(l) Referral to ODM for a hospital review to assess alleged issues of improper conduct.

(iii) For waivers administered by ODA, the waiver case management agency will notify ODA within one business day of their discovery of any of the following:

(a) A critical incident identified in paragraph (C) of this rule;

(b) A public media story about an event directly impacting the health, safety, or welfare of the individual on the waiver; or

(c) An employee of the waiver case management agency, recovery management entity, or the investigative entity is the alleged violator.

(iv) Enter any critical incident identified in paragraph (C) of this rule into the incident management system within one business day of discovering the incident.

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

(4) Investigating critical incidents. The investigative entity will, as deemed appropriate by ODA or ODM,

investigate all critical incidents identified in paragraph (C) of this rule, and do the following upon receipt of a reported incident:

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

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

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

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

(c) When an investigation is being conducted by a third-party entity with authority to do so, the investigative entity may pend its investigation until after receipt of the third party's investigation results if results are available. If the investigation was pended, upon receipt of the results of the investigation, the investigative entity will determine whether or not further investigation is necessary and either conduct its investigation or close the case.

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

(e) Conduct and document interviews, as appropriate to the reported incident, with anyone who may have information relevant to the incident which may include, but is not limited to, the reporter, individuals, authorized representatives and legal guardians, and providers.

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

(g) Determine whether the reported incident is substantiated.

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

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

(j) At the conclusion of the investigation, the investigative entity will provide to the waiver case management agency or the recovery management entity, a summary of the investigative findings, and whether or not the incident was substantiated.

(5) Follow up and close-out responsibilities of the waiver case management agency or recovery management entity.

(a) Upon receipt of the findings for a substantiated incident, the waiver case management agency, or

recovery management entity for SRS program recipients who are not also enrolled in the MyCare Ohio managed care program, will review the investigation results and include the information when developing a person-centered prevention plan or updating the care plan to assure the health and safety of the individual. A summary of the investigative findings will be communicated with the individual and their authorized representative or legal guardian as applicable to the incident using trauma informed care, unless such action could jeopardize the health and welfare of the individual.

(b) The summary will be provided through verbal communication, unless the individual or their authorized representative or legal guardian requests it in writing. Documentation that the summary was provided will be retained by the waiver case management agency or recovery management entity.

(c) For each substantiated critical incident, the waiver case management agency or recovery management entity will enter a prevention plan into the incident management system no later than seven business days after being notified that the incident was substantiated.

(d) For each reportable incident, the waiver case management agency or recovery management entity will address and remediate the incident as determined appropriate by the waiver case management agency or recovery management entity and close the incident in the incident management system no later than thirty business days after submission of the incident into the incident management system.

(F) Process for individuals enrolled on the OhioRISE program, or enrolled in a MCO.

(1) Incident reporter responsibilities:

(a) ODM, its designee, the OhioRISE plan, and entities under contract with the OhioRISE plan to provide care management for the OhioRISE program, as well as all service providers that serve individuals enrolled in the OhioRISE program or that furnish services under contract with an MCO, will report incidents.

(b) The incidents that the entities in paragraph (F)(1)(a) of this rule are required to report include those defined in paragraph (E)(3)(a)(ii), of this rule, except that misappropriations are only required to be reported if the estimated value is over $500. In addition, all deaths of individuals enrolled on the OhioRISE program will be reported, regardless of whether or not the incident meets the definition of an unnatural or accidental death.

(c) Upon discovering an incident, the responsible person or entity which discovered it will do all the following:

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

(ii) Report the incident to the OhioRISE plan or its designee, or the MCO immediately upon discovery of the incident, but no later than twenty-four hours after discovering the incident, unless bound by federal, state, or local law, or professional licensure or certification requirements to report sooner.

(2) OhioRISE plan or its designee, or MCO or its designee responsibilities: Upon discovering, or receipt of a reported incident, the OhioRISE plan or its designee, or MCO or its designee will do all the following:

(a) Ensure immediate action was taken, as applicable to the nature of the incident, to protect the health and welfare of the individual. If such action was not taken, the OhioRISE plan or MCO, will take

the action immediately, but no later than twenty-four hours after discovering the incident;

(b) As applicable to the nature of the incident, notify any appropriate entities with investigative, protective, or regulatory authority, such as the examples described in paragraph (E)(3)(a)(ii) of this rule;

(c) Enter any incident identified in paragraphs (C)(1) through (C)(6) of this rule into the incident management system within one business day of discovering the incident.

(3) The OhioRISE plan and the MCO will:

(a) Work collaboratively with investigative entities as needed to identify potential root causes of the incident, contributing factors, and remediation strategies, enter review notes and results, and develop a prevention plan;

(b) Unless a longer timeframe has been prior-approved by ODM, conclude the incident review and enter all relevant information into the incident management system no later than forty-five calendar days after their initial receipt of the incident report.

(4) Follow up and close-out responsibilities: Except in the case of death, the OhioRISE plan or its designee, or MCO or its designee will enter a prevention plan into the incident management system and close the case no later than seven business days after the conclusion of the review.

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