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: 6/13/2024

Public Comment Period End Date: 6/20/2024

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 ___) — **Rescinded/1 rules (FYR?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 programs, medicaid managed care organizations, the OhioRISE program, and specialized recovery services program: incident management" sets forth the definitions, standards, and procedures related to incident reporting for multiple programs administered by the Ohio Department of Medicaid (ODM) and the Ohio Department of Aging (ODA). These programs include nursing facility-based level of care home and community-based services (HCBS) waiver programs, the specialized recovery services (SRS) program, the OhioRISE program, and Medicaid managed care organizations (MCOs). This rule will be proposed as rescind/new due to the volume of amendments being made to the rule.

   Both ODM and ODA administer nursing facility-based level of care HCBS waivers. ODM-administered nursing facility-based level of care HCBS waivers include the MyCare Ohio and Ohio Home Care waivers. ODA-administered nursing facility-based level of care HCBS waivers include the preadmission screening system providing options and resources today (PASSPORT) and Assisted Living waivers. ODM also administers the HCBS SRS program, the OhioRISE program which includes the OhioRISE waiver and the provision of services through psychiatric residential treatment facilities (PRTFs), and Medicaid services through MCOs.

This rule sets forth the requirements for reporting, documenting, and investigating incidents involving individuals enrolled in the waivers, programs, and coverage mentioned above. With multiple populations being covered under the same rule, the verbiage of the rule needs to be as straightforward as possible to support each audience in interpreting the rule and their requirements. The primary purpose of the new rule will be to facilitate interpretation of the rule.

First, all programs listed above will be defined near the beginning of the rule. This way, the high-level requirements will be outlined early on so that the main portion of the rule can focus on the incident management process rather than which person or entity will carry out each step. It will be easier for each audience to locate their requirements and follow the process. Additionally, the reporting requirements for members enrolled in the OhioRISE program will be updated to include youth receiving treatment in a PRTF. The critical incident, "the health and welfare of the individual is at risk due to the individual being lost or missing" will be required to be reported for this population, since it is uniquely relevant to the residential population. The list of appropriate entities with investigative or protective authority that should be notified of an incident will also be shortened. With seven different programs governed under a single rule, it is impossible to formulate a comprehensive list or one that accounts for the intricacies of each program. To avoid confusion and unnecessary outreach, only those entities that are most-applicable will remain within the rule. Other changes will include various updates to timeframe requirements. The requirement for the initial report of an incident will be standardized to one business day for all programs. The timeline for investigating critical incidents will also change from 45 calendar days to 45 business days. This change will allow for alignment across all programs and investigative entities, since most do not have weekend business hours. Finally, the timeline for investigating reportable incidents will match the requirement for critical incidents, to support more thorough investigative efforts and maximize alignment.

A few changes will be made to the rule that do not directly facilitate interpretation. First, PRTFs will be added to the list of programs subject to ~~under administration of~~ the rule. As a new provider type under the OhioRISE program, PRTFs are required to follow the incident management rule. Another change will be the removal of the section of the rule pertaining to uniformity. This section functions to describe what happened until and when ODM and ODA established a single incident management system. The uniformity section is irrelevant now that both agencies are using the incident management system. Finally, the subsection of the rule requiring ODA waiver case management agencies to notify ODA upon discovery of public media stories about an event directly impacting individual health, safety, or welfare or when an employee of the waiver case management agency is the alleged violator in an incident will be removed. Now that ODA uses the incident management system, the appropriate notifications are automatically generated and sent to ODA.

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) 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 implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

This rule is being proposed to meet federal requirements. It will define specific processes and procedures for HCBS program providers, individuals, ODM, ODA, and their designees as required by CMS. The reporting and handling of incidents for Medicaid MCOs and the OhioRISE plan are not a federal requirement, however, they are an expectation established in both the ODM agreement with the MCOs and the ODM agreement with the OhioRISE Plan. The health and welfare of individuals served on Medicaid via the MCOs and the OhioRISE program 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, the OhioRISE program, 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, the OhioRISE program, 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, investigation of alleged provider occurrences, and review of case records of reported incidents that threaten the health and welfare of individuals participating in HCBS programs, the OhioRISE programs, 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.

   December 15, 2023 – The initial justification for the new rule was presented at ODM's Quality Steering Committee meeting, along with the proposed changes.

   January 16-23, 2024 – The draft proposed rule was shared with HCBS policy staff at both ODA and ODM and the front door policy, integrated care policy, OhioRISE, and PRTF teams at ODM. Edits were made to incorporate input.

   January 24, 2024 – The draft proposed rule was presented at ODM's Health, Safety, and Welfare meeting, alongside feedback from various meetings with stakeholders internal to ODM and from ODA.

   January 25, 2024 – The draft proposed rule was shared with the Aetna OhioRISE team for review and input.

February 1, 2024 – The draft proposed rule was sent via email to the HCBS Rules Workgroup email list, which includes 9,002 stakeholders including individuals enrolled on ODM-administered waivers, MyCare Ohio Plans, Area Agencies on Aging, agency and independent providers, Medicaid MCOs, the investigative entity conducting investigations for ODM waiver, 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 timeframe for investigating critical incidents will be changed from 45 calendar days to 45 business days. This will allow the timeframe to be standardized across the board, since some agencies work weekend hours and others work only weekdays. Furthermore, the timeframe for investigating and closing reportable incidents will be changed to align with that for critical incidents. Currently, the timeline for investigating reportable incidents is shorter, but a stakeholder indicated their program prefers to conduct investigations of reportable incidents with the same veracity as critical incidents and feels the current 30-day timeline does not allow for this. At stakeholders' request, verbiage will be removed regarding the inapplicability of the rule to individuals who are enrolled in the SRS Program as well as the MyCare Ohio Managed Care Plan. All other guidance suggests that incidents should be reported and investigated in the incident management system for all individuals enrolled in the SRS program, regardless of whether they are also enrolled in MyCare Ohio. As such, this change will ensure the rule aligns with programmatic expectations. Finally, at the request of the OhioRISE program a requirement will be added for the critical incident, "The health and welfare of the individual is at risk due to the individual being lost or missing," to be reported for members enrolled on OhioRISE who are receiving treatment in a PRTF.

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 the new rule or the measurable outcomes of the new 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?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    No alternative regulations were considered as this regulation needs to be codified to align with state and federal requirements and meet the CMS expectations regarding the approved waivers. ~~There is no regulatory alternative that would have had less of an adverse impact on businesses that would meet CMS approval.~~

13. **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 waivers and 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 waivers and 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 and ORC that covers incident management for programs administered by the two agencies.

14. **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 new rule of the final rule changes via email notification. Additionally, per their provider agreements, the OhioRISE plan and all Medicaid managed care plans are required to subscribe to the appropriate distribution lists for notification of ODM draft rules posted for public comment and notification of when ODM files rules with the Joint Committee of Agency Rule Review.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**
        - MCOs
        - Providers of waiver services
        - Providers of services under the SRS program
        - OhioRISE care management entities
        - Providers serving individuals in the OhioRISE program
        - Providers that furnish services under contract with an MCO

    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
    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.

    The new rule will require all service providers that serve individuals enrolled in an HCBS waiver, OhioRISE, Medicaid MCO, or SRS program to report all incidents related to individuals. 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 the applicable programs. Specifically, the new rule will require the entity that discovers an incident to take immediate action to ensure the health and welfare of the individual involved and report the incident to the relevant waiver case management or recovery management agency or to the OhioRISE plan or MCO immediately upon discovering the incident. The incident report requirements and timeframes will be outlined in the new rule.

16. Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).*

The primary purpose of the new rule ~~current rewrite of the rule~~ is to improve readability and facilitate the correct interpretation of the rule and its requirements. This will reduce the burden on all programs, organizations, and providers that are held to the requirements of the rule. Additionally, the requirement for PASSPORT and Assisted Living waiver case management agencies to notify ODA when there is a story in the media about an event that directly impacts the health, safety, or welfare of an individual on a waiver or when an employee of the waiver case management agency is the alleged violator on an incident is being removed. Since ODA is now using the ODM incident management system, these notifications are automatically generated and sent to ODA, removing administrative burden on the part of the waiver case management agencies. Finally, the incident reporting process is being streamlined for all programs. Currently, incidents impacting individuals enrolled on the Ohio Home Care waiver, the MyCare waiver, the SRS program, the OhioRISE program, the OhioRISE waiver, or receiving services through an MCO have to be reported within 24 hours, while incidents impacting individuals enrolled on the PASSPORT waiver or Assisted Living waiver have to be reported within one business day. The new rule will require all incidents to be reported within one business day. The timeline for investigating incidents is also being streamlined. Currently the rule allows 45 days for critical incident investigation and 30 business days for reportable incident investigation. The new rule will allow 45 business days for incident investigation, regardless of the priority level.

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 MCOs and the OhioRISE Plan. 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 support individuals in the community, all service providers, agencies, and contracted case management or recovery management agencies have a role in keeping the individual safe. Appropriate notification of incidents that have an impact on 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. The assurance of Medicaid program participants' health and welfare is of the utmost importance, regardless of whether services are being provided through an large agency, small agency, or independent provider. **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 or apply any other sanctions for paperwork violations related to incident reporting.

19. 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.

DRAFT - NOT FOR FILING

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

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

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

(1) "Care management entity" (CME) means the agency described in rule 5160-59-03.2 of the Administrative Code.

(2) "Health and safety action plan" or "HSAP" means a document developed by the waiver case management agency or recovery management agency that identifies situations, circumstances, and behaviors that without intervention may jeopardize the individual's health and welfare and potentially risk the individual's program enrollment. The HSAP sets forth the interventions necessary to mitigate risks to the health and welfare of an individual and to ensure the individual's needs are met.

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

(4) "Incident management system" means the system in which reported incidents are entered, including, as applicable, investigative and review notes, findings and results, prevention plans, and any other applicable information.

(5) "Individual" means a person enrolled on a home and community-based services (HCBS) waiver, in the specialized recovery services (SRS) program, in the Ohio resilience through integrated systems and excellence (OhioRISE) program, or in a medicaid managed care organization (MCO).

(6) "Individual crisis and safety plan" means a plan developed through care coordination and the child and family team for an individual enrolled in the OhioRISE program to ensure child and family safety and reduce the risk of harm in the home and community, as defined in Chapter 5160-59 of the Administrative Code.

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

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

(9) "Waiver case management agency" means an entity delegated or contracted by ODA or ODM to perform case management activities and related functions for individuals enrolled on an HCBS waiver program.

(B) Incidents: incidents may be critical or reportable, the definitions of which are as follows:

(1) Critical incidents:

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

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

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

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

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

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

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

(h) Either of the following prescribed medication issues:

(i) Provider error;

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

(2) Reportable incidents:

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

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

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

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

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

(iii) Eviction or housing crisis.

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

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

(1) The nursing facility-based level of care home and community-based services (HCBS) waiver programs administered by ODA and ODM including the assisted living waiver as set forth in Chapter 173-38 of the Administrative Code, the PASSPORT waiver as set forth in Chapter 173-42 of the Administrative Code, the Ohio home care waiver (OHCW) as set forth in Chapter 5160-46 of the Administrative Code, and the MyCare Ohio waiver as set forth in Chapter 5160-58 of the Administrative Code.

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

(b) All critical and reportable incidents are to be reported in accordance with this rule for individuals receiving services through these programs.

(2) The SRS state plan program as set forth in Chapter 5160-43 of the Administrative Code.

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

(b) All critical and reportable incidents are to be reported for individuals receiving services through this program.

(3) The OhioRISE program, including the OhioRISE waiver, as set forth in Chapter 5160-59 of the Administrative Code. Critical incidents in paragraphs (B)(1)(a) through (B)(1)(f) of this rule and reportable incidents in paragraph (B)(2)(a) of this rule are to be reported for all individuals in the OhioRISE program, except that only misappropriations of an estimated value of over five hundred dollars have to be reported. For individuals receiving treatment in psychiatric residential treatment facilities, critical incidents in paragraph (B)(1)(g) of this rule are also to be reported.

(4) Medicaid MCOs operating under ODM's care management system as set forth in Chapter 5160-26 of the Administrative Code. Critical incidents in paragraphs (B)(1)(a) through (B)(1)(f) of this rule are to be reported for all individuals in these organizations, except that only misappropriations of an estimated value of over five hundred dollars have to be reported.

(D) Time frames: The initial report, documentation, investigation, and closure of incidents follow the timeline outlined in paragraph (D) of this rule.

(1) Initial report and documentation.

(a) Upon discovering an incident, ODM, ODA, providers of nursing facility-based level of care HCBS waiver services, waiver case management agencies, providers of services under the SRS program, recovery management agencies, the OhioRISE plan, OhioRISE case management entities, providers of services under the OhioRISE program, MCOs, and providers of services under contract with an MCO will:

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

(ii) Report the incident to the relevant waiver case management agency, recovery management agency, the OhioRISE plan, or MCO, as applicable, immediately upon discovery of the incident, but no later than one business day after discovering the incident, unless bound by federal, state, or local law, or professional licensure or certification to report sooner.

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

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

(ii) The incident type;

(iii) The date of the incident;

(iv) The location of the incident;

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

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

(c) Upon becoming aware of an incident, waiver case management agencies, recovery management agencies, OhioRISE or its designee, and MCOs will:

(i) Enter all critical incidents into the incident management system within one business day of becoming aware of the incident.

(ii) Enter all reportable incidents into the incident management system within three business days of becoming aware of the incident.

(2) Investigation.

(a) Waiver case management agencies for ODA waivers, OhioRISE or its designee, and MCOs will follow the time frames outlined in this rule when investigating or reviewing an incident and documenting the necessary information in the incident management system.

(i) Ensure immediate action was taken, as applicable to the nature of the incident, to protect the health and welfare of the individual. If such action was not taken, take action immediately, but no later than twenty-four hours after the report was received.

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

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

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

(c) The local county board of developmental disabilities;

(d) The local public children services agency;

(e) The local adult protective services agency;

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

(g) The local probate court if the incident may involve the legal guardian of the recipient.

(iii) Within two business days of receiving the incident report, initiate an investigation.

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

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

(vi) Identify, to the extent possible, all causes and contributing factors.

(vii) Determine whether the reported incident is substantiated.

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

(ix) Unless a longer time frame has been prior approved by ODM or ODA, conclude the investigation no later than forty-five business days after the investigative entity's initial receipt of the incident report.

(b) For nursing facility-based level of care HCBS waiver programs administered by ODM and the SRS program, ODM's designee will follow the time frames outlined in paragraph (2)(b) of this rule when investigating an incident and documenting the investigation in the incident management system.

(i) Within one business day of becoming aware of the incident, review the reported incident and verify the following:

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

(b) The appropriate entities have been notified, as applicable to the nature of the incident, with investigative or protective authority, the appropriate additional regulatory, oversight, or advocacy agencies as described in additional program-specific guidance. If such action was not taken, do so as soon as possible.

(ii) Follow steps in paragraphs (D)(3)(a)(i) through (D)(3)(a)(vii) of this rule.

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

(3) Closure.

(a) All waiver case management agencies for nursing facility-based level of care HCBS waiver programs and recovery management agencies will close out investigations as follows:

(i) Upon receipt of the findings for a substantiated incident, review the investigation results and include the information from the results when developing a person-centered prevention plan or updating the care plan to ensure the health and safety of the individual.

(ii) Communicate a summary of the investigative findings with the individual and their authorized representative or legal guardian as applicable to the incident using trauma informed care unless such action could jeopardize the health and welfare of the individual.

(a) The summary will be provided through verbal communication, unless the individual or their authorized representative or legal guardian requests the summary in writing.

(b) The waiver case management agency or recovery management agency documents and retains the documentation that the summary was provided.

(iii) For each substantiated critical incident enter a prevention plan into the incident management system no later than seven business days after being notified that the incident was substantiated.

(iv) For each reportable incident, address and remediate the incident as determined appropriate, and close the incident in the incident management system no later than forty-five business days after submission of the investigative entity's initial receipt of the incident report.

(b) OhioRISE and MCOs will close out incident reviews as follows:

(i) For OhioRISE, except in the case of death, include any relevant information from the investigation when updating the individual crisis and safety plan to ensure the health and safety of the individual.

(ii) Except in the case of death, enter a prevention plan into the incident management system no later than seven business days after the conclusion of the review.

(iii) In all cases, close the incident no later than seven business days after the conclusion of the review.

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