



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Developmental Disabilities

Rule Contact Name and Contact Information: Becky.Phillips@dodd.ohio.gov
(614) 644-7393

Regulation/Package Title (a general description of the rules' substantive content):

Major Unusual Incidents and Unusual Incidents

Rule Number(s): 5123-17-02 (Rescind and New)

Date of Submission for CSI Review: November 14, 2024

Public Comment Period End Date: December 2, 2024

Rule Type/Number of Rules:

New/ 1 rule

No Change/ rules (FYR?)

Amended/ rules (FYR?)

Rescinded/ 1 rules (FYR? yes)

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

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

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.

Rule 5123-17-02 (Addressing major unusual incidents and unusual incidents to ensure health, welfare, and continuous quality improvement) establishes processes and requirements for reporting, responding, investigating, and preventing incidents—major unusual incidents (MUIs) and unusual incidents (UIs)—that adversely affect the health or welfare of individuals with developmental disabilities. The processes and requirements delineated in the rule comprise an incident management system that is designed to provide a safety net, lessen trauma, and reduce risk in the lives of individuals served. The rule applies to county boards of developmental disabilities and licensed and certified providers of services to individuals with developmental disabilities.

The rule is due for five-year review. The Department is revising the rule based on a comprehensive review to clarify procedures and timelines, eliminate confusing or redundant provisions, and align wording with newer rules. Revisions include:

- (A): Expand the purpose statement to reflect "[just culture](#)" philosophy.
- (C)(2): Create a streamlined "administrative review" process for major unusual incidents in Category C which is driven by forms included as appendices C, D, and E.
- (C)(16)(a): Replace "accidental or suspicious death" with "unexplained or unanticipated death."
- (C)(16)(a): Replace "verbal abuse" with "emotional abuse."
- (C)(16)(a)(iii): Revise the definition of "failure to report."

- (C)(16)(b)(iv): Revise the definition of "missing individual."
- (C)(16)(b)(v)(e): Remove "verbal act" from list of peer-to-peer incidents.
- (C)(16)(c)(ii): Revise the definition of "unanticipated hospitalization."
- (D)(1): Explicitly state that a developmental disabilities employee must report a major unusual incident.
- (D)(5): Require reasonable measures taken to ensure individuals' health and safety be documented in writing.
- (E): Clarify and consolidate wording regarding removal of a developmental disabilities employee from direct contact with individuals served. Authorize county boards of developmental disabilities to remove an Independent Provider alleged to have been involved in physical abuse or sexual abuse from direct contact with any individual.
- (H)(2): Require staff of an Agency Provider to inform agency management of major unusual incidents of misappropriation, neglect, physical abuse, or sexual abuse.
- Eliminate former paragraph (H)(2)(a) which permitted a county board of developmental disabilities to elect to follow the administrative investigation procedure for Category A major unusual incidents for any category of major unusual incident.
- Eliminate former paragraph (H)(7) that required an Agency Provider to submit the results of its internal review of a major unusual incident to the county board of developmental disabilities within 14 days.
- (I)(10): Require an Investigative Agent who does not reach a preliminary finding regarding an allegation of physical abuse or sexual abuse within 14 working days to notify the individual/guardian and provider of the status of the investigation every 7 working days thereafter.
- (M)(3) and (M)(4): Adjust the lists of major unusual incidents closed by the Department and county boards of developmental disabilities.
- Eliminate former paragraph (N)(1) that required county boards of developmental disabilities to review, on a quarterly basis, a sample of providers' unusual incident logs.
- Eliminate former paragraph (N)(2) that required the Department to review, on a monthly basis, a sample of county board logs.
- Eliminate former paragraph (Q) that authorized the Director of the Department to modify provisions of the rule during the COVID-19 state of emergency.

Due to the volume of revisions, the Department plans to rescind existing rule 5123-17-02 and adopt a new replacement rule of the same number and title. Although the Department plans to rescind the existing rule and adopt a new replacement rule, an amended version is provided so stakeholders can readily see what is changing.

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.

Authorize: 5123.04, 5123.19, 5123.612, 5126.311, 5126.313, 5126.34

Amplify: 2151.421, 5123.04, 5123.093, 5123.19, 5123.31, 5123.61, 5123.611, 5123.612,

5123.613, 5123.614, 5123.62, 5126.044, 5126.221, 5126.30, 5126.311, 5126.313, 5126.333, 5126.34

- 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. The rule implements Ohio's system for responding to incidents involving individuals with developmental disabilities. The federal Centers for Medicare and Medicaid Services (CMS) requires a state to have an incident response and mitigation system in place. CMS requires a level of consistency across the state in implementing and receiving reimbursement for federally-funded programs. Ohio's system of providing services to individuals with developmental disabilities is based on local delivery of services throughout Ohio's 88 counties. Having consistent requirements for incident reporting, notifications, administrative investigations, and prevention measures assures CMS that Ohio has a statewide system. This rule is also part of the specific assurances required to maintain Medicaid Home and Community-Based Services waiver programs in Ohio.

- 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.**

Not applicable.

- 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)?**

The rule establishes a statewide system to ensure the health and welfare of Ohioans with developmental disabilities. Without the rule, there would be no oversight to ensure reporting to law enforcement or public children services agencies, no review of immediate protective actions, administrative investigations, causes and contributing factors, or prevention measures. Data captured in the Department's Ohio Incident Tracking and Monitoring System is used to create Health and Welfare Alerts. The rule also fulfills federal requirements for Medicaid Home and Community-Based Services waiver assurances regarding Ohio's critical incident management system.

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

The rule supports and protects Ohioans with developmental disabilities, whether or not they are involved in an incident. It is difficult to measure overall outcomes. Health and Welfare Alerts issued by the Department are developed based on trends and patterns of reported major unusual incidents and unusual incidents and are disseminated throughout the service

delivery system to prevent incidents from occurring. An increase in incident rates (especially after training regarding the new rule) may be an indicator of better reporting, not necessarily an increase in the number of incidents occurring.

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.

The Department convened a workgroup to conduct a comprehensive review of the rule and recommend revisions. The workgroup included:

- Josh Anderson Ohio Health Care Association
- Lorella Botts Southwest Ohio Developmental Center
- Thom Craig Family Advocate
- Sandy Dirkman Sunshine Communities
- Angela Dunn Belmont County Board of Developmental Disabilities
- Kelli Grisham Hancock County Board of Developmental Disabilities
- Rachel Hayes Ohio Provider Resource Association
- Willie Jones Ohio Association of County Boards of Developmental Disabilities
- Gina Kerman Rose-Mary Center
- Ed Lewis Stark County Board of Developmental Disabilities
- Tim Neville Echoing Hills
- David Nodge Cuyahoga County Board of Developmental Disabilities
- Nicole Powell Clearwater Council of Governments
- Kathy Radar Champaign Residential Services, Inc.
- Tom Rickels X-Excel
- Renee Wood Advocate
- Jessica Wynns Direct Support Professional
- Dalenna Zingalis Independent Provider

Workgroup members were able to participate in meetings virtually and in-person. The workgroup met eight times:

December 1, 2023
January 12, 2024
February 16, 2024
March 22, 2024
April 26, 2024
May 20, 2024
June 17, 2024
October 28, 2024

Throughout the rule review process, workgroup members sought feedback from their colleagues and constituents to broaden the group reviewing the proposed revisions. In April 2024, members of the workgroup submitted approximately 40 questions/suggestions that were reviewed by the workgroup at meetings on April 26 and May 20.

On April 10, 2024, staff of the Department's Major Unusual Incident and Registry Unit met with the Family Advisory Council Core Group. This group of family members leads the Family Advisory Council. Participants in the April 10 discussion included:

- Laura Cifra-Bean Parent and Down Syndrome Association of Northeast Ohio
- George Johnson Parent and Franklin County Board of Developmental Disabilities
- Selina Jones Parent and Lucas County Board of Developmental Disabilities
- Judina Marsh Sibling and Abilities Works
- Alyssa Perna Sibling and Direct Support Professional
- Katie Schwartz Parent

The group discussed the draft rule and provided feedback on the Category C administrative review forms in Appendices C, D, and E of the rule.

Through the Department's rules clearance process, the rule and the Business Impact Analysis form are disseminated to representatives of the following organizations for review and comment:

Advocacy and Protective Services, Inc.
The Arc of Ohio
Autism Society of Central Ohio
Councils of Governments
Disability Rights Ohio
ElevateDD
Family Advisory Council
The League
Ohio Association of County Boards of Developmental Disabilities
Ohio Department of Medicaid
Ohio Developmental Disabilities Council
Ohio Health Care Association

Ohio Provider Resource Association
Ohio Self Determination Association
Ohio SIBS (Special Initiatives by Brothers and Sisters)
Ohio Statewide Independent Living Council
Ohio Superintendents of County Boards of Developmental Disabilities
Ohio Waiver Network
People First of Ohio
Values and Faith Alliance

The rule and the Business Impact Analysis form are posted at the Department's website during the clearance period for feedback from the general public:

<https://dodd.ohio.gov/forms-and-rules/rules-under-development/proposed+rules+for+review>

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

Members of the workgroup provided suggestions and feedback regarding many provisions of the rule. Members shared information about "[just culture](#)" and suggested that incident investigation and review processes should reflect just culture philosophy. A statement of this intent was included in paragraph (A).

Stakeholder discussion and input informed renaming and redefining of "verbal abuse" to "emotional abuse" and renaming of "accidental or suspicious death" to "unexplained or unanticipated death."

Based on workgroup input, major unusual incidents in Category C will be subject to an administrative review process driven by completion of forms included as appendices to the rule. Members of the Family Advisory Council Core Group recommended that use of the forms be mandatory to ensure consistency across the State. Based on feedback from providers of services, the rule and forms were adjusted to make clear that although providers initially submit the forms, responsibility for completing the forms and related processes rests with Investigative Agents employed by county boards of developmental disabilities.

Stakeholders engaged in extensive discussion regarding the definition of "unanticipated hospitalization." Various definitions and suggestions were considered before achieving consensus on the proposed definition in paragraph (C)(16)(c)(ii).

New paragraph (G)(2) was added to clarify the Investigative Agent's role in cases investigated by a public children services agency.

Workgroup members suggested that former paragraph (H)(2)(a), which permitted a county board of developmental disabilities to follow the administrative investigation procedure for Category A major unusual incidents for any major unusual incident might lead to inconsistent procedures across county boards; the paragraph was eliminated.

Additional feedback provided by stakeholders during the clearance period will be considered before the rule is filed.

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?

(C)(16)(c)(ii): Department staff reviewed data regarding causes of Unanticipated Hospitalizations reported as major unusual incidents for calendar year 2023 and consulted with the Department's Medical Director who shared information and data regarding national trends. The data informed the revised definition and selection of the six most critical medical diagnoses included therein.

(I)(11): Department staff reviewed data regarding requests by county boards to extend the timeline for closing major unusual incident investigations in considering whether the requirement for closure within 30 working days was sufficient. Data revealed that approximately 37% of major unusual incidents had one or more extension. The most common reason county boards request an extension is to verify that a prevention plan has been implemented. The Department approves 99% of the requests. Based on further analysis, the timeline for closing major unusual incidents was extended from 30 to 45 days, which is intended to reduce the need for extensions.

(O): Department staff reviewed provider compliance data for unusual incidents which suggested that clarification of requirements was needed to ensure that review of unusual incidents is meaningful and improves outcomes for individuals served.

Appendix B: Based on data regarding the incidence of attempted suicides, incident-specific requirements were added to the investigation procedure.

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.*

The Department considered multiple concepts and suggestions regarding the definition of "unanticipated hospitalization." Various definitions were examined to determine if they achieved the goal of focusing system resources on the most critical incidents where intervention has the greatest impact. Ultimately, after consulting with the Department's Medical Director, a definition was selected that better aligns with hospital operations in that it recognizes stays over 48 hours to be significant and that a re-admission within 30 days for the same diagnosis warrants a closer review. Hospitalizations that do not meet the definition of "unanticipated hospitalization" are reviewed as unusual incidents.

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

Through an interagency agreement with the Ohio Department of Medicaid, the Department is charged with adopting rules governing Medicaid-funded programs administered by the Department. Department staff work with staff of the Ohio Department of Medicaid to ensure the Department's rules align with the federally-approved Home and Community-Based Services waivers and regulations governing Intermediate Care Facilities for Individuals with Intellectual Disabilities.

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.

The Department will disseminate information about the rule through its various publications. The final-filed rule will be posted at the Department's website and directly disseminated to county boards of developmental disabilities and the approximately 6,200 persons who subscribe to the Department's rules notifications.

Staff of the Department's Major Unusual Incident and Registry Unit will work with system stakeholders to develop and provide training throughout the service delivery system prior to implementation of the rule.

Department staff are available to answer questions and provide technical assistance as needed.

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**
- 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 rule applies to all types of providers in Ohio's developmental disabilities service delivery system, including (as of November 4, 2024):

- Independent Providers certified by the Department (11,904);
- Agency Providers certified by the Department (1,839);
- Residential Facilities licensed by the Department (598); and
- Intermediate Care Facilities for Individuals with Intellectual Disabilities licensed by the

Department and certified by the Ohio Department of Health (419).

The rule sets forth processes for compliance with requirements that are already established in the Revised Code:

- 2151.421 (the reporting of abuse and neglect of children)
- 5123.61 (the reporting of abuse and neglect of individuals with developmental disabilities)
- 5123.611, 5123.614, and 5126.31 to 5126.313 (the review and investigation of incidents of abuse and neglect)

and 42 C.F.R. 483.420 for Intermediate Care Facilities for Individuals with Intellectual Disabilities.

The rule coalesces the various requirements into an incident management system for prevention and reduction of risk of harm to individuals with developmental disabilities. This system, created by House Bill 94 of the 124th General Assembly with broad support of stakeholders, including providers of services and county boards of developmental disabilities subject to its requirements, is nationally recognized for its efficacy. Providers of services continue to support this system and worked collaboratively with Department staff to review and improve the rule.

The nature of the adverse impact on providers of services is the time it takes to comply with requirements to report incidents, make notifications regarding incidents, take measures to safeguard individuals, cooperate with investigations of incidents, analyze trends and patterns of incidents, and attend training and/or train staff.

Ensuring the health and welfare of individuals served is the responsibility of each and every provider of services. The cost of compliance with the rule varies by provider and the number and nature of individuals served and incidents that occur. The Department does not have data to quantify providers' costs.

Some changes being made to the rule (e.g., narrowing the definition of "unanticipated hospitalization" and eliminating periodic review of unusual incident logs) are expected to result in efficiencies for providers of services. The Department does not have data to quantify providers' potential cost savings.

16. Are there any proposed changes to the rules that will reduce 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*).

Yes:

- Paragraph (C)(16)(b)(iv) is being amended to simplify the definition of "missing individual."

- Paragraph (C)(16)(c)(ii) is being amended in a manner that is expected to result in reporting fewer major unusual incidents so system resources may be focused on the most serious incidents.
- Paragraphs (N)(1) and (N)(2) are being amended to eliminate the requirement for Independent Providers to review and analyze trends and patterns of major unusual incidents and send an annual report to the Department.

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

The Ohio Revised Code and the federal Centers for Medicare and Medicaid Services require the Department to promulgate rules

Regulatory Flexibility

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

No; the federal Centers for Medicare and Medicaid Services requires Ohio to implement Medicaid-funded programs in a uniform, statewide manner.

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?

It is the policy of the Department to waive penalties for first-time or isolated paperwork or procedural regulatory noncompliance whenever appropriate. The Department believes waiving these penalties is appropriate when:

1. Failure to comply does not result in the misuse of state or federal funds;
2. The regulation being violated, or the penalty being implemented, is not a regulation or penalty required by state or federal law; and
3. The violation does not pose any actual or potential harm to public health or safety.

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

The rule will be posted at the Department's website throughout the rule promulgation process:

<https://dodd.ohio.gov/forms-and-rules/rules-under-development/rules-under-development>

The Department will disseminate information about the rule through its various publications.

Department staff will conduct training regarding changes being made to the rule for Investigative Agents throughout the state. The training will be provided at no cost and made available in a web-based format.

Department staff are available to answer questions and provide technical assistance as needed. Questions and requests for assistance may be submitted at any time to:

Major Unusual Incident and Registry Unit: (614) 995-3810

General questions:

MUIDOC@dodd.ohio.gov

Questions related to the Ohio Incident Tracking and Monitoring System (OITMS):

OhioITMS@dodd.ohio.gov