

### **Business Impact Analysis**

Agency Name:	Ohio Department of Developmental Disabilities	
Regulation/Package Title:	Major Unusual Incidents	
Rule Number(s):	5123:2-17-02	_
Date: December 6,	2012	
Rule Type:		
X New	□ 5-Year Revi	ew
□ Amended	X Rescinded	

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

### **Regulatory Intent**

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

Rule 5123:2-17-02 relates to the health and safety of individuals with developmental disabilities in the State of Ohio. It applies to county boards of developmental disabilities, state-operated developmental centers, and licensed and certified providers. The rule sets forth the processes and requirements for reporting, responding, investigating, and preventing incidents which are named either Major Unusual Incidents (MUIs) or Unusual Incidents (UIs). The processes and requirements comprise an incident management system that is designed to provide a safety net, lessen trauma, and reduce risk in the lives of individuals with developmental disabilities.

While much of the existing rule is being carried forth, there is a different organizational structure and the changes are woven throughout the rule. For this reason, the Department is rescinding the existing rule and bringing forth a new rule of the same number.

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

5123.612

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?

If yes, please briefly explain the source and substance of the federal requirement.

The federal Centers for Medicare and Medicaid Services (CMS) requires a level of consistency across the state in implementing programs and receiving reimbursement. 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 MUI 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 waiver programs in Ohio.

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

The rule protects all Ohioans that receive developmental disabilities services regardless of whether or not they are enrolled in a federal Medicaid waiver.

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

This rule establishes the statewide system to ensure the health and safety of Ohioans with developmental disabilities. Without the rule, there would be no oversight to ensure reporting to law enforcement or children's protective services agencies, no review of immediate protective actions, administrative investigations, cause and contributing factors, or prevention measures. Data captured in the Department's Incident Tracking System is used to create Health and Safety Alerts. This rule also fulfills federal requirements for Medicaid waiver assurances.

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

This rule is designed to protect individuals with developmental disabilities, whether they are involved in an incident or not. Outcomes are geared towards serving and supporting individuals. It is difficult to measure overall outcomes. The Health and Safety Alerts are designed to prevent

incidents from ever occurring. An increase in MUI rates (especially after training on the new rule) could be an indicator of better reporting, not necessarily an increase in the number incidents occurring in individuals' lives.

## **Development of the Regulation**

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

Department staff maintained a list of questions and comments submitted regarding the existing rule since it was implemented in 2007. Many of the changes being incorporated into the new rule are in response to experience implementing the existing rule. The area of peer-to-peer acts was one of the most commented on. For example, law enforcement has commented that they have been called and are required to respond to situations that are not criminal allegations.

Beginning in 2011 and continuing throughout 2012, Department staff met with representatives of the Ohio Association of County Boards Serving People with Developmental Disabilities (OACB) and the Ohio Provider Resource Association (OPRA) to discuss redevelopment of the rule. OACB and OPRA met several times in their own workgroups to develop suggestions. Many of their suggestions were incorporated into the proposed new rule. OACB and OPRA had several common themes in their recommendations, including:

- Maintain clear definitions.
- Focus resources (especially the time of Investigative Agents) on those cases in which the lives of individuals were most affected.
- Change some incidents currently classified as MUIs to UIs.

The draft rule was shared with this group in November 2012 and the group's final suggestions were incorporated in advance of dissemination for official rules clearance.

In 2012, the Department asked the following stakeholders to submit suggestions for improving the existing rule:

- Advocacy and Protective Services, Inc.
- The Arc
- Disability Rights Ohio
- Family Advisory Council
- Investigative Agents of county boards of developmental disabilities
- Ohio Developmental Disabilities Council
- Ohio Self Determination Association
- People First of Ohio
- Superintendents of county boards of developmental disabilities

Many responded that they did not see a need to change anything.

Through the Department's official rules clearance, the draft rule will be sent to the following organizations:

- Advocacy and Protective Services, Inc.
- The Arc
- Autism Society of Ohio
- Councils of Governments
- Disability Housing Network
- Disability Rights Ohio
- Down Syndrome Association of Central Ohio
- The League
- Ohio Association of County Boards Serving People with Developmental Disabilities
- Ohio Developmental Disabilities Council
- Ohio Provider Resource Association
- Ohio Self Determination Association
- Ohio SIBS (Special Initiatives by Brothers and Sisters)
- Ohio Superintendents of County Boards of Developmental Disabilities
- People First of Ohio

When draft rules are disseminated via the official rules clearance process, they are simultaneously posted at the Department's *Rules Under Development* webpage (https://doddportal.dodd.ohio.gov/rules/underdevelopment/Pages/default.aspx).

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

The Department considered all input and incorporated many of the ideas offered by stakeholders. The Department redefined some MUIs and assigned each type of MUI to one of three categories (A, B, or C). Each category has corresponding investigation procedures which are included as appendices to the rule. The Department added clarification suggested by stakeholders regarding investigation of and sharing information about Peer-to-Peer Act MUIs. Roles, responsibilities, and timelines for analyzing and reporting MUI trends and patterns were modified.

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

Data from the Incident Tracking System was used to examine the types and numbers of MUIs.

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

There was, over the course of stakeholder meetings, a give-and-take process with different ideas

being discussed. The proposed rule is the result of building on the alternatives discussed and reaching consensus with stakeholders.

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

No; part of the federal assurances is that there is a mandatory process for the incident management system.

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

Rule 5123:2-17-02 is the only rule relating to an incident management system for individuals with developmental disabilities.

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

Department staff will be making multiple presentations and conducting in-person and web-based training sessions on the prosed new rule prior to implementation; the first presentation is scheduled for the Ohio Association of County Boards Annual Convention on December 7, 2012. The Department provides technical assistance and training to local audiences as necessary. The Department reviews county boards, developmental centers, and licensed and certified providers to ensure their compliance with the rule.

### **Adverse Impact to Business**

- 14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:
  - a. Identify the scope of the impacted business community;
  - b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and
  - 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.

The rule applies to all types of providers in Ohio's developmental disabilities service delivery system, including:

- independent providers certified by the Department (approximately 6,800),
- agency providers certified by the Department (approximately 1,600),
- residential facilities licensed by the Department (approximately 680), and
- Intermediate Care Facilities for Individuals with Intellectual Disabilities certified by the Ohio Department of Health (approximately 420).

The proposed new rule is not expected to result in a net time savings, even though some changes are expected to result in efficiencies. Resources will be devoted to other duties related to individuals' health and safety. Some additions to the rule (e.g., to specify certain information for incident reports, MUI trends and patterns analysis, and UIs) are in most part to clarify what has already been expected and to provide standardization between county boards of developmental disabilities and other providers. Providers that operate in multiple counties can now rely on this rule for what exactly is required, especially in the area of the MUI analysis. The rule does not mandate the method or a particular format for the information in recognition that many providers have their own internal incident management software. Specific details for employee training requirements were added to the rule, but in most cases this training was already being conducted.

The main additions are to the responsibilities of independent providers. An independent provider is a self-employed person who provides services and does not employ or contract with anyone else to provide the services. Under the existing rule, independent providers are responsible for cooperating in MUI and UI investigations, providing documents, and answering questions from the county board Investigative Agent or other county board staff. The proposed new rule requires independent providers to submit written incident reports, conduct UI investigations, and conduct semi-annual MUI analysis. The adverse impact for those independent providers affected will be in additional time required to complete incident reports, conduct investigations, and analyze MUIs. It is anticipated that the impact on any single independent provider will be minimal.

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

The rule is necessary to ensure the health and safety of individuals who receive services. Although the proposed new rule increases requirements for independent providers, independent providers are certified and paid to provide services and supports. It is reasonable that they utilize the universal incident management system established to ensure individuals' health and safety.

### **Regulatory Flexibility**

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

No; the focus and structure of the rule is based on ensuring the health and safety of individuals served, no matter who provides services. The waiver assurances do not provide alternative means of compliance.

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

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 the waiver of these penalties is appropriate under the following circumstances:

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

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

Staff of the Department's Major Unusual Incident Investigation Unit and the Office of Provider Standards and Review answer questions and provide technical assistance and training to entities covered by the proposed rule. Additional resources are available at the Department's website: <a href="http://dodd.ohio.gov/healthandsafety/Pages/default.aspx">http://dodd.ohio.gov/healthandsafety/Pages/default.aspx</a> <a href="http://dodd.ohio.gov/healthandsafety/Pages/Health%20+%20Safety%20Toolkit.aspx">http://dodd.ohio.gov/healthandsafety/Pages/Health%20+%20Safety%20Toolkit.aspx</a>.