CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: ODM Waivers: Incident Mgt and Provider Oversight

Rule Number(s): 5160-45-05 (rescind), 5160-45-05 (new), 5160-45-09 (rescind) and 5160-45-09 (new)

Date: _____

Rule Type:

X New
☐ Amended
X 5-Year Review
X Rescinded

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

Regulatory Intent

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

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OAC 5160-45-05

The proposed new OAC rule 5160-45-05 will establish an "incident management system" that applies to Ohio Department of Medicaid (ODM), its designees, service providers and individuals who are enrolled on an ODM-administered waiver or who otherwise participate in ODM-administered programs. This incident management system includes responsibilities for reporting, responding to, investigating and remediating incidents involving individuals. It replaces the current OAC rule 5160-45-05 which is being rescinded as part of this package. ODM has the authority to designate other agencies or entities to perform one or more of the incident management functions set forth in the rule. Among other things, proposed OAC rule 5160-45-05 will establish:

- That ODM and its designees must assure the health and welfare of individuals enrolled on an ODM-administered waiver. Further, ODM, its designees and providers are responsible for ensuring that individuals are protected from abuse, neglect, exploitation and other threats to their health, safety and well-being.

- That individuals shall receive a handbook at the time of waiver enrollment and at reassessment that includes information about how to report abuse, neglect, exploitation and other incidents.

- Activities that are considered an incident and/or an alert in the ODM-administered waiver program.

- Incident reporter responsibilities including identification of those incidents that must be reported immediately.

- Case manager responsibilities upon learning of an incident, including ensuring the individual's health and welfare.

- ODM and its designees responsibilities including incident investigation and follow-up.

OAC 5160-45-09

ODM is responsible for the ongoing monitoring and oversight of all ODM-administered waiver service providers and all ODM-administered waiver contractors in order to assure their compliance with ODM-administered waiver program requirements. The new rule is replacing existing OAC rule 5160-45-09 which is being rescinded as part of this rule package. The new proposed OAC rule 5160-45-09 will establish:

- Guidelines for monitoring and oversight to be conducted by ODM and its designees, including the State's provider oversight contractor.
- Requirements with which providers and contractors must comply as part of the monitoring and oversight process.
- ODM sanctioning/enforcement authority.

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

   Ohio Revised Code Section 5166.02.

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

   Yes. In order for the Centers for Medicare and Medicaid Services (CMS) to approve a 1915(c) home and community-based services waiver, a state must make certain assurances concerning the operation of the waiver. These assurances are spelled out in 42 C.F.R 441.302. One of those assurances is health and welfare. The proposed rules will assist ODM in assuring the health and welfare of individuals participating in the Ohio Home Care, Transitions DD, Transitions Carve-Out and Integrated Care Delivery Systems' Waivers.

   Further, according to waiver guidance provided to ODM by CMS,

   - Effective incident management is essential to assuring the health and welfare of waiver participants.

- States are required to describe the operational features of managing incidents at the individual and provider level as well as activities to assure that reports are filed and incidents are investigated in a timely fashion, and to analyze incident data (e.g., about specific types of incidents, providers, individuals' characteristics, results of investigations, the timeliness of reports and investigations) in order to develop strategies to reduce the risk and likelihood of the occurrence of incidents in the future.

- In order to assure individuals' health and welfare and the effective delivery of waiver services, active, continuous monitoring of the implementation of the service plan is an essential component of the waiver. The purpose is to ensure that waiver services are furnished in accordance with the service plan; meet the individual's needs and achieve their intended outcome. Monitoring also is conducted to identify any problems related to the individual's health and welfare that may arise. The State must ensure that there is continuous monitoring of the health and welfare of waiver participants and remediation actions are initiated when appropriate.

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

   These rules are consistent with the federal requirements. They define specific processes for meeting waiver program incident reporting, investigation and remediation, and provider/contractor monitoring and oversight as required by CMS.

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

   The public purpose of these regulations is to assure the health and welfare of participants in ODM-administered home and community-based service waivers as required by 42 C.F.R 441.302(a) by establishing procedures for the reporting, investigation and remediation of incidents, and setting forth the process, procedures and requirements for ongoing monitoring and oversight of waiver service providers and contractors.

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

   Successful outcomes are measured through a finding of compliance with these standards. Additionally, the expectation is that the improvements in monitoring and oversight will result

in a reduced number of incidents that threaten the health and welfare of individuals on the waiver program.

Development of the Regulation

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

   The Ohio Council for Home Care and Hospice
   Midwest Care Alliance
   CareSource (case management contractor)
   CareStar (case management contractor)
   Public Consulting Group (PCG) (provider oversight contractor)
   Ohio Olmstead Task Force
   Disability Rights Ohio
   Ohio Department of Aging
   Ohio Department of Developmental Disabilities
   ODM-administered waiver participants

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

   The workgroup conducted a thorough review of the existing rules, allowing for ample discussion about such things as assuring the health and welfare of waiver participants, understanding when and how to report, investigate and mitigate the occurrence of incidents, and understanding the quality assurance monitoring and oversight process. The result was the creation of new rules that reflect a greater understanding of the roles and responsibilities among all stakeholders, particularly waiver participants, the providers of waiver services and the case management and provider oversight contractors, and that are reflective of compromise among all parties and a truly collaborative effort.

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

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

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

    ODM and the stakeholder workgroup considered alternative rule language as part of the rule development process and settled upon language which was mutually agreed upon and best suited to accomplish the purposes of the rule. Such language had to meet the federal and state guidelines under which ODM-administered waivers are permitted to operate.

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. A performance-based regulation is not deemed appropriate and is not authorized by statute.

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

    All regulations regarding ODM-administered waivers are promulgated by ODM and implemented by ODM, its designees and providers, as appropriate. While other state agencies participated in the rule writing process, they do not impose any requirements that are specific to this program. The regulations were reviewed by Medicaid's legal and legislative staff to ensure that there is no duplication within the rules.

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

    A robust effort will be employed by the department to notify ODM-administered waiver service providers of the rule changes found in OAC rules 5160-45-05 and 5160-45-09. Initial notification of rule changes will occur via a variety of communication methods including, but not limited to ODM's issuance via remittance advice, email blasts to agency and independent providers, notifications to individuals enrolled on ODM-administered waivers, electronic communication via the myohiohcp.org website and the provider oversight contractor's (PCG) website.

    Additionally, implementation of these rule changes will also be predicated on training that will be provided by ODM and/or its designees (i.e., provider oversight contractor and case

management contractors). Additionally, agency providers will be asked to assure that training will be provided at the staff level upon implementation and at least annually thereafter.

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.

Provider participation in the ODM-administered Waiver Program is optional and at the provider's sole discretion. Compliance with program requirements for providers who choose to participate may include administrative costs associated incident reporting, investigation and remediation. They may also include administrative costs associated with ongoing quality assurance monitoring and oversight, as well as any resulting corrective action and/or sanctioning that may be required. ODM cannot estimate the cost of compliance as costs will vary depending upon the circumstances, and providers' respective business models.

5160-45-05

Assuming that ODM-administered providers and contractors adhere to the ODM-administered waiver requirements concerning ensuring individuals' health and welfare, there should be little or no cost of compliance with this rule. However, if the provider or contractor does not, and an incident is reported, they will be subject to investigation and follow-up and could be subject to sanctions that could result in their inability to participate in the Medicaid waiver program.

5160-45-09

ODM-administered waiver providers and contractors must submit to federally and state-required provider monitoring and oversight by ODM and/or ODM's provider

oversight contractor as a condition of participation in the program. This could result in an adverse impact due to the time it takes to gather information for and participate in such reviews. Failure to do so, however, could result in providers' and contractors' termination of their Medicaid provider agreement or contract.

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

Provider participation in this program is optional and at the provider's discretion. However, compliance with program requirements is required for providers who choose to participate and may include administrative costs associated with compliance with the requirements of these rules. ODM cannot estimate the cost of compliance as costs will vary depending on the number of alleged incidents, the nature of each incident, related investigatory and remediation activities, and any specific monitoring and oversight activities that may be undertaken.

Regulatory Flexibility

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

No, not applicable for this program.

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

Not applicable for this program.

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

Not applicable for this program.