Ohio | Common Sense Initiative

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Business Impact Analysis

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

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

Rule Number(s): 5160-44-05

Date of Submission for CSI Review: April 28, 2021

Public Comment Period End Date: May 5, 2021

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

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

Rescinded/ rules (FYR?)

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.

   Both the Ohio Department of Medicaid (ODM) and the Ohio Department of Aging (ODA) administer home and community-based services (HCBS) nursing facility level of care waivers, as well as, the HCBS Specialized Recovery Services (SRS) Program. ODM-administered HCBS waivers include the MyCare Ohio and Ohio Home Care waivers. ODA-administered HCBS waivers include the preadmission screening system providing options and resources today (PASSPORT) and Assisted Living waivers.

   This rule sets forth the definitions, standards and procedures related to incident reporting for ODM, ODA, their designees, service providers and individuals involving those enrolled on the waivers and program mentioned above. Changes include: Revising the ODM programs timeframe for entering incidents into the Incident Management System (IMS), and accordingly, for notifying the State of certain incidents to align with current Ohio Department of Aging (ODA) timeframes. This will better allow the Case Management and Recovery Management Entities to focus on ensuring the health and safety of the individual in the first 24 hrs as the more urgent matter of importance.

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

   Ohio Revised Code Sections 5164.02, 5164.91 and 5166.02.

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

Yes, for the Centers for Medicare and Medicaid Services (CMS) to approve a 1915(c) home and community-based services (HCBS) waiver or a 1915(i) State Plan Amendment (SPA), a state must meet certain assurances about the operation of the waiver. These assurances are spelled out in 42 C.F.R. 441.302, and include:

- The State has an established system for reporting, responding to, investigating, and remediating all critical incidents.
- The State has identified and established case management standards for reportable incidents which do not meet the criteria for a critical incident.
- The State has defined the responsibilities of all incident reporters, case management entities and investigative entities.
- All investigative entities are required to submit incident data to ODM (or ODA) in a format and frequency determined by ODM (or ODA).

The state uses performance measures to assess compliance with statutory assurances. These performance measures:

- demonstrate on an ongoing basis that the state identifies, addresses and seeks to prevent instances of abuse, neglect, exploitation and unexplained death; and
- demonstrate that an incident management system is in place that effectively resolves those incidents and prevents further similar incidents to the extent possible.

The 1915(i) SPA includes a statement that: The state identifies, addresses, and seeks to prevent incidents of abuse, neglect, and exploitation, including the use of restraints.

Accordingly, all HCBS waiver and Specialized Recovery Services providers must report incidents promptly. The proposed amendment will assist the State in assuring the health and welfare of individuals by establishing specific requirements for reporting and investigation of incidents.

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

These rules are consistent with federal requirements. They define specific processes and procedures for HCBS program providers, individuals, ODM, ODA and their designees as required by CMS.

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 and 1915(i) programs 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 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, evidence from findings resulting from structural reviews and investigation of alleged provider occurrences, and review of case records of reported incidents that threaten the health and welfare of individuals participating in an HCBS program.

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.

   January 28, 2021 - The draft proposed rule was shared with the ODA and ODM waiver care management and SRS program administrators for review and input. Edits were made to incorporate input.

   March 2, 2021 - The proposed rule was sent to the HCBS Rules Workgroup described below via email and subsequently reviewed with the group via live, interactive webinar meeting on March 10, 2021. There were no concerns expressed by the stakeholders regarding any need to further edit this rule. ODM has been convening the HCBS Rules Workgroup since May 2013, to draft and review OAC rules governing ODM-administered waivers. The HCBS Rules Workgroup email list includes over 900 members including individuals enrolled on ODM-administered waivers, MyCare Ohio Plans, Area Agencies on Aging (AAAs), agency and independent providers, the investigative entity conducting investigations for ODM waivers, behavioral health provider associations, as well as others

March 29, 2021 – The proposed rule was sent to the contracted waiver case management entities and a broader ODM audience. There were no concerns expressed regarding any need to further edit this rule.

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 outreach, no concerns were expressed. Therefore, no changes were made to the rules.

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

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

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

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

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

    No. Performance-based regulations are not deemed appropriate and are not authorized by statute.

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

    All regulations regarding the ODM and ODA HCBS waiver programs are promulgated by ODM and ODA and implemented by ODM and ODA, their designees and providers, as appropriate. Likewise, regulations specific to the ODM-administered waiver programs are promulgated by ODM and implemented by ODM, its designees and providers, as appropriate. Where applicable, both agencies have worked together to ensure there's no duplication among their respective regulations.

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

    ODM will notify all entities that are required to implement the revised timeframe requirements including all MyCare Managed Care Plans of the final rule changes via email notification. Additionally, per the provider agreement, managed care plans are required to subscribe to the

appropriate distribution lists for notification of all OAC rule clearances and final published rules including RuleWatch Ohio and the Regulatory Reform eNotification System.

Adverse Impact to Business

16. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community; and

- All providers of ODA and ODM home and community-based services (HCBS) waivers and Specialized Recovery Services (SRS).
- MyCare Ohio Plans
- ODM and ODA and any designees (including the investigative entity)

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

This rule requires ODM, ODA, or their designees, and all service providers to report all incidents related to individuals enrolled in a home and community-based services (HCBS) waiver or Specialized Recovery Services (SRS) Program. This report of information is a federal requirement and is necessary to ensure the health and safety of individuals enrolled in an HCBS program. Specifically, the rule requires the entities noted above to: take immediate action to ensure the health and welfare of the individual, report the incident immediately upon discovering the incident, and when reporter is a waiver provider who has a supervisor, immediately notify his/her supervisor. The incident report requirements and timeframes are outlined in the rules.

The Care Management (CM) or Recovery Management (RM) entity is required to verify the above actions were taken to protect the health and welfare of the individual, to address the issues impacting the individual, and to report the incident in the incident management system. If it is discovered that a required action was not taken, the CM or RM entity is required to do so.

The investigative entity (an ODM or ODA designee), is required to verify the above actions were taken to protect the health and welfare of the individual. If it is discovered that a required action was not taken, the investigative entity is required to do so. At the conclusion of an investigation, the investigative entity shall provide a summary of the investigative findings, and whether the incident was substantiated, unless such action could jeopardize the health and welfare of the individual. The investigative entity shall submit incident data to ODM/ODA as requested, and in a format and frequency established by ODM/ODA.

c. Quantify the expected adverse impact from the regulation.
The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

ODM/ODA, or their designees, and service providers are currently required to report incidents as a condition of doing business with the State. This rule maintains a similar level of reporting and investigative requirements and is not expected to have a significant adverse impact on their current costs of doing business. ODM cannot estimate the cost of compliance as costs will vary depending on the number of incidents that an individual may encounter and that are discovered by ODM/ODA, or their designee, or the service provider.

MyCare Ohio Plans are paid per member per month. ODM must pay MCPs and MCOPs rates that are actuarially sound, as determined by an outside actuary in accordance with 42 C.F.R. 438.6(c) and CMS's "2018/2019 Managed Care Rate Setting Consultation Guide." Ohio Medicaid capitation rates are "actuarially sound" for the period covered by the certification, projected capitation rates and other revenue sources provide for all reasonable, appropriate and attainable costs. Costs include but are not limited to expected health benefits, health benefit settlement expenses, administrative expenses, the cost of capital and government mandated assessments, fees, and taxes.

All rates and actuarial methods can be found on the ODM website in Appendix E of both the Medicaid Managed Care and MyCare Ohio provider agreements. Through the administrative component of the capitation rate paid to the MCPs and MCOPs by ODM, MCPs and MCOPs will be compensated for the cost of the requirements found in these rules. For CY 2021, the administrative component of the capitation rate varies by program/population and ranges from 4.0% to 6.5% for MCPs and from 3.0% to 6.0% for MCOPs.

The investigative entity and ODM/ODA designees are contracted providers who apply through the request for proposal (RFP) process to become a contracted vendor to perform this work. The providers are aware of the requirements and rate of payment prior to seeking and signing their contracts with the state. The rate of payment to contractors are negotiated according to the work required by the rule. The rule maintains a similar level of reporting and investigative requirements and is not expected to have a significant adverse impact on the contractors' current costs of doing business.

The HCBS service providers are also paid rates that include an administrative component to cover costs such as those incurred when reporting an incident. The rule maintains a similar level of reporting requirements and is not expected to have a significant adverse impact on the providers' current costs of doing business.

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

The assurance of HCBS program participants' health and welfare is integral to the Ohio HCBS waiver and 1915(i) State Plan Amendment programs- both at the state and federal levels. In order to maintain individuals in the community, all waiver service providers, agencies and contracted case

management or recovery management entities have a role in keeping the individual safe. Appropriate notification of incidents that impact the individual's health and safety is necessary and required through federal waiver authority.

Participation in the HCBS programs is optional and at a provider's discretion. Compliance with program requirements is required for providers who choose to participate and may result in administrative costs associated with compliance with the requirements of these rules (e.g., training, monitoring and oversight, etc.). Failure to comply with such requirements may result in a provider's inability to be an Ohio HCBS program service provider

Regulatory Flexibility

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

No, not applicable for this program.

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

Not applicable for this program as ODM/ODA do not fine providers for paperwork violations related to incident reporting.

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

Providers may contact the Ohio Department of Medicaid (ODM) provider hotline at 1-800-686-1516. Contracted entities may contact their designated contract manager at ODM or ODA.