CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: ODM-administered Waiver Provider Rules

Rule Number(s): 5160-45-06 (rescind), 5160-45-06 (new), 5160-45-10 (rescind), and 5160-45-10 (new)

Date: September 12, 2014

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- X Rescinded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.

   OAC 5160-45-06

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The proposed new OAC rule 5160-45-06 sets forth the process and requirements for conducting structural reviews of Ohio Department of Medicaid (ODM) -administered waiver service providers in order to ensure providers' compliance with ODM-administered waiver provider requirements. It also sets forth the process and requirements for investigating provider occurrences. It replaces the current OAC rule 5160-45-06 which is being rescinded pursuant to five year review and as part of this package. Among other things, proposed OAC rule 5160-45-06 sets forth the following:

Structural Reviews

Medicare-certified and/or otherwise accredited agencies are subject to reviews in accordance with their certification and accreditation bodies and are exempt from a regularly scheduled structural review. They shall submit a copy of their updated certification and/or accreditation, and upon request of ODM or its designee, shall make available to ODM all review reports and accepted plans of correction from the certification and/or accreditation bodies.

All other ODM-administered waiver providers are subject to structural reviews during each of the first three years after they begin furnishing waiver services. Thereafter, at ODM's discretion and in accordance with OAC rule 5160-45-06, the provider may be subject to biennial structural reviews.

Structural reviews are conducted in person and use an ODM-approved review tool. Among other things, the review includes an evaluation of the provider's compliance with ODM-administered waiver rules and a unit of service verification to assure that all waiver services are authorized, delivered and reimbursed in accordance with the waiver participant's approved all services plan. Except for unannounced structural reviews, the provider is notified in advance of the impending review in order to arrange a mutually acceptable time, date and location for the review. The provider is expected to ensure the availability of required documents and to maintain the confidentiality of information about the waiver participant. An exit conference is conducted with the provider at the conclusion of the review and is followed by a written report that includes any specific findings of noncompliance as well as a request for a plan of correction.

Provider Occurrences

Provider occurrences are any alleged, suspected or actual performance or operational issues by a provider furnishing ODM-administered waiver services that do not meet the definition

of an incident as set forth in OAC rule 5160-45-05. They include, but are not limited to alleged violations of provider eligibility and/or service specification requirements, billing issues such as overpayments, and Medicaid fraud. ODM or its designee investigates provider occurrences and may request documentation from the provider to do so. If a provider occurrence is substantiated, the provider will be notified in a manner that confirms provider receipt. Notification will specify the provider's action or inaction, the OAC rules that support the findings and any action that must be taken to correct the findings.

Plans of Correction

No later than 45 calendar days after receipt of ODM's or its designee's report following a structural review or investigation of a provider occurrence, providers are required to submit to ODM or its designee a plan of correction for all findings of noncompliance, including individual remediation. ODM or its designee will notify the provider if it finds the plan acceptable. If the plan is not acceptable, the provider shall be notified in writing and be required to submit a new plan within ten calendar days. Overpayments of provider claims must be adjusted by the provider in accordance with OAC rule 5160-1-19 and the provider's plan of correction.

ODM may take action against a provider in accordance with OAC rule 5160-45-09 for failure to comply with any of the requirements set forth in this rule.

OAC 5160-45-10

The proposed new OAC rule 5160-45-10 will establish the core conditions of participation that a provider must meet in order to furnish ODM-administered waiver services. It replaces the current OAC rule 5160-45-10 which is being rescinded pursuant to five year review and as part of this package. Among other things, proposed OAC rule 5160-45-10 sets forth the following:

- ODM-administered waiver service providers shall maintain a professional relationship with the individuals to whom they provide services. Services shall be provided in a person-centered manner that is in accordance with the individual's approved all services plan, is attentive to the individual's needs and maximizes the individual's independence. Providers shall refrain from any behavior that may detract from the goals, objectives and services outlined in the individual's approved all services plan and/or that may jeopardize the individual's health and welfare.

- ODM-administered waiver service providers shall, among other things:
  - Maintain an active, valid Medicaid provider agreement;
  - Comply with all applicable provider requirements set forth in the Administrative Code, and be knowledgeable about and comply with applicable federal and state laws;
  - Deliver services professionally, respectfully and legally;
  - Ensure individuals are protected from abuse, neglect, exploitation and other threats to their health and safety;
  - Work with the individual and case manager to coordinate service delivery;
  - Provide information and documentation to ODM, its designee and the Centers for Medicare and Medicaid Services (CMS) upon request;
  - Participate in mandated provider trainings;
  - Maintain and retain all required documentation;
  - Cooperate during provider monitoring;
  - Notify ODM or its designee of issues that may affect the individual or the provider's ability to furnish services; and
  - Submit written notification to the individual when the provider is terminating service provision.

- ODM-administered waiver service providers shall never:
  - Engage in behavior that causes or may cause abuse or distress or compromise the individual's health and welfare;
  - Engage in advantageous or manipulative behavior, or behavior that may pose a conflict of interest;
  - Falsify the individual's signature, or make fraudulent, deceptive or misleading statements in the advertising, solicitation, administration or billing of services; and
  - Submit claims for waiver services rendered while the individual is hospitalized, institutionalized or incarcerated.

- While rendering services, ODM-administered waiver service providers shall not:
  - Take the individual to the provider's place of residence;
  - Bring children, animals, friends, relatives or other persons to the individual's place of residence;
  - Provide care to persons other than the individual;
  - Smoke without the individual's consent;
  - Sleep;

- Engage in activity that distracts from, or interferes with service delivery;
- Deliver services when the provider is unfit;
- Use or be under the influence of alcohol, illegal drugs, chemical substances and controlled substances that may adversely affect the provider's ability to furnish services; and
- Engage in inappropriate behavior.

- Except as otherwise prescribed in rule, ODM-administered waiver service providers cannot be designated to serve or make decisions for the individual in any capacity involving a declaration for mental health treatment, power of attorney, guardianship, or serve as a representative payee.

- Agency and non-agency providers must pay all applicable federal, state and local income and employment taxes. Additionally, non-agency providers must annually submit an affidavit confirming such payment.

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 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, and include *(a)" necessary safeguards have been taken to protect the health and welfare of the beneficiaries of the services."* CMS cites in its waiver applications that providers of waiver services must be qualified, i.e., only those agencies and workers meeting the state's qualification requirements can provide services to waiver participants. The state must establish qualification requirements for agency and non-agency providers, including licensure/certification standards, training and other requirements. It must also regularly monitor providers' compliance with those requirements. The proposed rules will assist the State in assuring the health and welfare of waiver participants by among other things, requiring the provision of services by qualified ODM-administered waiver service providers who adhere to the programs' provider requirements.

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 federal requirements. They define specific processes for meeting waiver program provider eligibility requirements as required by CMS and conducting regular and periodic structural reviews of providers and investigations of alleged provider occurrences.

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 waiver participants as required by 42 C.F.R 441.302(a) through the provision of services by qualified providers. The State is doing so by establishing core conditions of participation which providers must meet in order to be ODM-administered waiver service providers, and by conducting regular and periodic structural reviews of providers and investigations of alleged provider occurrences.

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 provider standards. The expectation is that adherence to the conditions of participation by providers will result in a reduced number of incidents that threaten the health and welfare of individuals participating in the waiver program. This is evidenced, in part, by no adverse findings resulting from structural reviews and investigation of alleged provider occurrences.

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.
   ODM has been convening an external stakeholder group since May, 2013, for the purpose of reviewing OAC rules governing ODM-administered waivers. The workgroup generally meets every two weeks (in-person and by phone) and has been responsible for the adoption, rescission and amendment of a number of rules thus far. It consists of individuals enrolled on ODM-administered waivers, as well as members of the following organizations:

   The Ohio Council for Home Care and Hospice
   Midwest Care Alliance

CareSource (case management contractor)
CareStar (case management contractor)
Council on Aging (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 also contacted seven non-agency providers (i.e., nurses and personal care aides) for the purpose of soliciting comments regarding the proposed rules. One non-agency personal care aide provided feedback.

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

   The external rules workgroup cited in ODM's response to Question #7 above conducted a thorough review of the existing rules, allowing for ample discussion about such things as consumer choice, control and self-determination, the roles and responsibilities of ODM-administered waiver service providers, structural review and provider occurrences investigatory processes, and the assurance of waiver participants' health and welfare. The result of that work is the proposed rescission of the existing rules and replacement with new rules that reflect a greater understanding of the roles and responsibilities among all stakeholders, particularly waiver participants, service providers and ODM and its designated case management and provider oversight contractors. It is a collaborative effort that is reflective of compromise among all parties.

   The responding non-agency personal care aide provided constructive feedback about both rules that will be addressed following department clearance. She also indicated OAC rule 5160-45-06 is less cumbersome than the current rule and is clear and easy to understand.

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 that was mutually agreed upon and best suited to accomplish the purposes of the rules. 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. Performance-based regulations are not deemed appropriate and are 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 participants and service providers of the rule changes found in OAC rules 5160-45-06 and 5160-45-10. Initial notification of rule changes will occur via a variety of communication methods including, but not limited to ODM's issuance via manual transmittal letter, remittance advice, emails 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.

Implementation of these rule changes will also be predicated on training that will be conducted by ODM and/or its designees. 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.

a) Currently, there are more than 1,600 active agency providers serving individuals enrolled on ODM-administered waivers. Active non-agency providers number nearly 6,500. Provider participation in the ODM-administered waiver program is optional and at the provider's sole discretion. All providers must comply with ODM-administered waiver program requirements.

b) Specific rule requirements include the following:

5160-45-06

Medicare-certified and/or otherwise accredited agencies are subject to reviews in accordance with their certification and accreditation bodies and therefore shall be exempt from a regularly scheduled structural review. They shall submit a copy of their updated certification and/or accreditation, and upon request of ODM or its designee, shall make available to ODM or its designee within ten business days, all review reports and accepted plans of correction from the certification and/or accreditation bodies.

All providers who are subject to a structural review are required to make all requested information available in a manner consistent with paragraph (B)(3) of OAC rule 5160-45-09.

When ODM or its designee is investigating a provider occurrence, it is required to collect from the provider any documentation required for the investigation.

At the conclusion of a structural review or investigation of a provider occurrence, ODM or its designee will issue a written report to the provider. The provider must submit to ODM or its designee a plan of correction for all identified findings of noncompliance,

including any individual remediation, within 45 days after the date on the written report. If ODM or its designee determines that is cannot approve the plan of correction, it shall inform the provider in writing, require that the provider submit a new plan of correction and specify the required actions that must be included in the plan of correction. The new plan of correction is required within ten calendar days.

If ODM or its designee determines through the structural review process or the investigation of a provider occurrence that an overpayment of a provider claim has occurred, the provider shall make all payment adjustments in accordance with rule 5160-1-19 of the Administrative Code and the provider's approved plan of correction.

5160-45-10

Providers may incur administrative expenses associated with provider training that agencies may require for staff regarding provider conditions of participation.

c) 5160-45-06

When queried, the Ohio Council for Home Care and Hospice (OCHCH) and the Midwest Care Alliance indicate that costs associated with this rule may vary due to the length of reports prepared by the Ohio Department of Health for Medicare certification and by other national accreditation bodies. Depending on how many pages that must be copied, agencies would need to consider the following: cost per page, cost of the administrative time, postage and packaging (i.e. certified mail, priority mailing, etc.), tracking to ensure delivery, and any follow up necessary. The amount could be less than a dollar for the letter of certification, or up to and over $100 depending on the length of reports and plan of correction documents.

The non-agency personal care aide service provider indicated that except for potentially losing payment for hours worked in the event a provider is cited for not replying timely during the corrective action planning process following a structural review, she didn't see any financial impact of this rule changing.

5160-45-10

OCHCH and the Midwest Care Alliance together suggested the average cost per Medicare-certified hospice and home health agency to educate direct care employees and implement the incident management requirements set forth in OAC rule 5160-45-05 that are required by OAC rule 5160-45-10 in first year could be approximately $2,397. They do not anticipate the rest of the rule will necessarily have an associated expense for agencies. The non-agency personal care aide who responded to ODM's review request did not see any financial impact as a result of this rule changing.

To mitigate any training costs agency and non-agency providers, ODM has developed a training webinar for agency and non-agency providers about incident management requirements, and will do the same for OAC rules 5160-45-06 and 5160-45-10 when these rules are finalized. Assuming that ODM-administered providers and contractors adhere to the ODM-administered waiver provider requirements, there should be little or no cost of compliance with these rules. However, if the provider or contractor does not, and an incident or provider occurrence 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.

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

The assurance of waiver participants' health and welfare is integral to the ODM-administered waiver program – both at the state and federal levels. Provider participation in this program is optional and at the provider's discretion. 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 (e.g., training, monitoring and oversight, etc.). For example, when queried, the Ohio Council for Home Care and Hospice and the Midwest Care Alliance together suggested the average cost per Medicare-certified hospice and home health agency to educate direct care employees and implement the incident management requirements set forth in OAC rule 5160-45-05 that are required by OAC rule 5160-45-10 in first year could be approximately $2,397. They do not anticipate the rest of the rule would necessarily have an associated expense for agencies.

Failure to comply with such requirements may result in required individual remediation and other sanctions. In this regard, the cost of compliance will vary depending on the number of alleged incidents resulting from failure to comply with the conditions of participation and/or structural review requirements, the nature of alleged provider occurrences, related

investigatory and remediation activities, and any other monitoring and oversight activities that may be required.

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.