CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: OHIO DEPARTMENT OF AGING

Package Title: ODA PROVIDER CERTIFICATION
STRUCTURAL COMPLIANCE REVIEWS

Rule Numbers: 173-39-04

Date: October 15, 2018

Rule Types:
- ☑ **5-Year Review** 173-39-04
- ☑ **Rescinded** 173-39-04
- ☑ **New** 173-39-04
- ☐ **Amended**
- ☐ **No change**

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 regulations in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

OVERVIEW

173-39-04 implements the requirements for reviewing the compliance of ODA-certified providers (providers) with Chapter 173-39 of the Administrative Code. ODA proposes to rescind this rule and adopt a new rule in its place.

CURRENT VERSION OF RULE *VS.*, NEW RULE

- ODA proposes to remove many unnecessary words and definitions from this rule.
- ODA proposes to require reviews at least once every 365 days instead of "annually."[1]
- ODA proposes to clarify when its designees may conduct desk reviews *vs.* on-site reviews.[2]
- ODA proposes to clarify what comprises a 10% sample of records.[3]
- ODA proposes to require its designee to conduct reviews of participant-directed providers with the individual present and in the individual's home, unless the individual refuses to participate.
- ODA proposes to match the terminology used in the authorizing statute (ORC § 173.391).

[1] See ¶ (B)(1) of the new rule.
[2] See ¶ (C) of the new rule.
[3] See ¶ (D) of the new rule.

2. Please list the Ohio statute authorizing the Agency to adopt these regulations.

ORC §§ 173.01, 173.02, 173.391, 173.52, 173.522, 173.54, and 173.543

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.

In order for the Centers for Medicare and Medicaid Services (CMS) to approve Ohio's application for a Medicaid wavier authorizing the State to launch and maintain the PASSPORT Program, 42 CFR 441.352 requires ODA to assure CMS in the waiver application that ODA established adequate requirements for providers (*i.e.*, Chapter 173-39 of the Administrative Code) and that ODA reviews the providers to ensure they comply with those requirements.

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

The rule exists to comply with the state laws mentioned in ODA's response to #2, which establish the requirements for ODA-certified providers.

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)?

These regulations ensure necessary safeguards are in place to protect the health and safety of individuals receiving services from ODA-certified providers.

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

ODA and its designees conduct structural compliance reviews on providers to ensure compliance for the continued health and safety of individuals receiving services from ODA-certified providers. Likewise, ODA reviews its designees to ensure compliance in conducting structural compliance reviews. The rule is judged as being successful when ODA and its designees find few violations from structural compliance reviews or investigations of alleged incidents.

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.

On Sept. 22, 2017, ODA sent an email to the stakeholders in the table below requesting feedback on ODA's proposals and additional recommendations for improving this rule.

PROVIDERS	PROVIDER ASSOCIATIONS	OTHER ASSOCIATIONS
1. Alzheimer's and Dementia Care Services 2. Home Care by Black Stone 3. National Church Residences (NCR). 4. Senior Resource Connection	5. LeadingAge Ohio 6. Ohio Assisted Living Assn. (OALA). 7. Ohio Assn. of Medical Equipment Services (OAMES). 8. Ohio Health Care Assn. (OHCA) 9. Ohio Council for Home Care and Hospice (OCHCH). 10. Ohio Jewish Communities (OJC).	11. Catholic Social Services of the Miami Valley (a PAA not represented by O4A) 12. The Ohio Association of Area Agencies on Aging (O4A).

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

In response to ODA's Sept. 22, 2017 email, ODA received 4 comments from 2 stakeholders, which are summarized below:

- A provider association asked if this rule should say that federal heightened scrutiny under 42 CFR 441.301(c)(5)(v) is part of structural compliance reviews. *Response:* Structural compliance reviews under this rule pertain to the review of providers already certified by ODA. Whereas, the federal heightened scrutiny rule applies to providers applying to become an ODA-certified provider.

- A non-provider association asked a few questions primarily on the role of individuals when conducting a structural compliance review of a participant-directed provider. *Responses*: Unless individuals refuse to participate, it's reasonable to expect ODA's designee to conduct on-site reviews and to include individuals in those reviews. The individuals are the employers of record for the participant-directed providers. Participant-directed providers are required to store service records in the individuals' homes and in locations accessible to the individuals, the participant-directed providers, ODA, and its designees. ODA's designee should review those records as it would review the records in any other setting. ODA proposes to clarify this matter in the proposed new rule.

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?

ODA is not proposing to amend this rule based upon data.

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?

ODA did not consider any alternative regulations.

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.***

Because 173-39-04 is a rule requiring the review of ODA-certified providers for compliance, it is inherently performance-based. Providers who remain compliant do not need to undergo reviews of expanded sample sizes or incur plans of correction or disciplinary actions.

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

ORC § 173.391 only authorizes ODA to develop requirements for ODA-certified providers.

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.

Before the proposed new rule takes effect, ODA will post it on ODA's website. ODA will also send an email to subscribers of its rule-notification service to feature the rule.

ODA also hosts webinars and in-person meetings with its designees to train them on implementing new rules.

Through its regular monitoring activities, ODA will monitor its designees for compliance with this 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;

Every provider certified by ODA.

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

There are no adverse impacts for providers other than to allow ODA and its designees to regularly conduct structural compliance reviews and have access its records.

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.

There are no adverse impacts for providers other than to allow ODA and its designees to regularly conduct structural compliance reviews and have access to its records. The costs incurred as a result of this rule is likely calculated as part of a provider's operational budget (*i.e.*, the cost of doing business and clerical jobs, such as retaining records).

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

ODA is required to develop rules establishing requirements for ODA-certified providers and to ensure the health and safety of individuals enrolled in ODA-administered waiver programs.

Providers voluntarily apply for ODA certification. Certification is not required to engage in providing a service unless a provider wants paid for providing that service by a program, such as the PASSPORT Program, for which ORC § 173.391 requires providers to be certified. Therefore, compliance with these regulations is only required if a provider voluntarily chooses to participate in an ODA-administered waiver program.

Regulatory Flexibility

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

Because the primary purpose of this rule is to ensure the health and safety of individuals enrolled in ODA-administered waiver programs, the rule treats all providers the same, regardless of their size.

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?

ODA is concerned primarily about protecting the health and safety of individuals receiving services from ODA-certified providers through compliance with this rule. Whenever possible, ODA or its designees will treat administrative violations that do not involve health and safety as opportunities for improvement through warning notices and solicitation of corrective action.

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

ODA and its designees are available to help providers of all sizes with their questions. Any person may contact Tom Simmons, ODA's policy development manager, with questions about this rule.

Additionally, ODA maintains an online rules library to help providers find rules regulating them. Providers may access the online library 24 hours per day, 365 days per year.