

Business Impact Analysis

Agency Name: OHIO DEPARTMENT OF AGING

Package Title: ODA PROVIDER CERTIFICATION
REQUIREMENTS FOR EVERY PROVIDER

Rule Numbers: 173-39-01, 173-39-02

Date: October 19, 2018

Rule Types:

- ☒ **5-Year Review** 173-39-01, 173-39-02
- ☒ **Rescinded** 173-39-01, 173-39-02
- ☒ **New** 173-39-01, 173-39-02
- ☐ **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

173-39-01 introduces Chapter 173-39 and defines terms used in the chapter. ODA proposes to define more terms in this rule to ensure terms are used consistently throughout the chapter. ODA proposes to rescind this rule and adopt a new rule in its place.

173-39-02 contains the requirements for a provider to become and remain an ODA-certified provider. ODA proposes to rescind and replace this rule with a new shorter, reorganized rule that, for the most part, will include the same requirements as the current rule.

PROPOSED AMENDMENTS TO 173-39-01**NEW DEFINITIONS**

Compared to the current rule, ODA proposes for the new rule to define the following terms:

- "ADS"
- "Applicant"
- "Background check"
- "Business site"
- "Change in organizational structure."
- "Change of ownership interest"
- "CMS"
- "COALA program"
- "Complete application"
- "Continuing care retirement communities"

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- "Electronic visit verification"
- "Emergency contact person."
- "Existing owner."
- "HCBS"
- "HHS"
- "IRS"
- "Medicaid provider number"
- "National provider identifier"
- "ODH"
- "Person with an ownership interest" (replaces "ownership or control interest")
- "Provider agreement"
- "Region"
- "Residential care facility"
- "TIN"

PROPOSED AMENDMENTS TO 173-39-02

ORGANIZATION

Many requirements to become or remain certified are the same for each provider type. The new rule's organization results in a significantly-shorter rule because ODA doesn't repeat common requirements for each type of provider.

UPDATES

ODA proposes to update references to the Ohio Revised Code, such as references to Adult Protective Services (APS) and confidentiality statutes.

"NEW" REQUIREMENTS

Business Site:

- ODA proposes to require all providers to maintain a designated, locked storage space for retaining individuals' records that is accessible to ODA and its designees. This is essential for complying with the state and federal requirements for protecting confidential information.
- ODA proposes to require all providers other than participant-directed providers to maintain a business site from which to conduct business. The current rule does not explicitly require this of non-agency or assisted living providers, yet in practice we must know their addresses in order to monitor and pay them.
- ODA proposes to require all providers to meet home and community-based setting requirements. The current rule did not make this requirement of participant-directed providers. Of course, those providers only provide services in individual's homes, so they will naturally comply without any need to take any new action.

Contact Information:

- ODA proposes to require all providers to have a valid email address and to give ODA or its designee any updates to that address. Although this would be a new requirement, most providers have already given ODA their email addresses.
- ODA proposes to require all providers to have a telephone service at its primary business location. The current rule does not explicitly require this for non-agency or assisted living providers, although in practice, it is essential for communicating with providers.

Provider Agreements:

- ODA proposes to explicitly require providers to enter into Medicaid-provider agreements to become certified. The PASSPORT and Assisted Living Programs cannot pay for services to a provider who had not entered into such an agreement, so this is not a new requirement.
- ODA proposes to explicitly require providers to enter into provider agreements with ODA's designee. Although this does not appear in the current rule, it is the current practice. This would not, therefore, impose a new adverse impact upon providers.

EVV: ODA proposes to reference ODM's forthcoming requirement in 5160-1-40 for providers to use an ODM-approved EVV system to verify services are being provided.

Reporting:

- ODA proposes to require all providers to notify ODA or its designee when the provider did not provide an authorized service at the time, or for the period of time, authorized by ODA's designee. Although this is a

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basic requirement for unit-of-service verification, the current rule does not require this for participant-directed or assisted living providers.

- ODA proposes to require all providers to notify ODA or its designee when the individual moves to another address.
- Both the current and proposed new rules require every type of provider, other than an assisted living provider, to notify the individual and ODA's designee in writing at least 30 days before the last day the provider provides the service. To this requirement, ODA proposes to add the following exceptions for every type of provider: (1) The individual has been hospitalized, placed in a long-term care facility, or is deceased, or (2) the individual chooses to no longer receive services from the provider.

Volunteers: ODA proposes to prohibit providers from allowing a volunteer to provide services ODA certified the provider to provide unless the volunteer is supervised by the provider's supervisory staff, if an agency or assisted living provider; unless ODA's designee authorizes the provider to do so, if a non-agency provider; or, unless ODA's designee and the individual authorize the provider to do so, if a participant-directed provider.

Compliance Reviews: ODA proposes to require every provider to participate in compliance reviews. Although the current rule does not require this, the current version of 173-39-04 does. ODA proposes to list the requirement in this rule and to remove it from 173-39-04 in a subsequent rule package.

Revoked Certification: ODA proposes to not recertify a provider if ODA previously revoked the provider's certification. The current rule doesn't address this. Instead, the current version of 173-39-03 does. ODA proposes to list the requirement in this rule and to remove it from 173-39-03 in a subsequent rule package.

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 waiver 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.*, adopted these rules) and that ODA monitors the providers to assure they comply with those requirements (*i.e.*, comply with these rules).

Section 12006 of the 21st-Century Cures Act (P.L. 114-255), amended § 1903 of the Social Security Act (42 USC 1396b) to insert new requirements for states to implement EVV requirements for certain services provided through the state plan or a Medicaid waiver program. ODM proposes to implement the EVV requirements in 5160-1-40. ODA merely proposes to insert a cross-reference to 5160-1-40.

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

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

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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 monitor providers to ensure compliance for the continued health and safety of individuals receiving services from ODA-certified providers. The rules are judged as being successful when ODA and its designees find few violations from structural 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 the rules.

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).

ODA joined ODM and providers in EVV Stakeholder Advisory Group meetings in 2016 on Oct. 14, 25; and Nov. 8, in 2017 on Mar. 1; Apr. 14; Jun. 20; Jul. 19; and Aug. 22; and in 2018 on Feb. 7, Mar. 21, Apr. 18, Jun. 25, Aug. 21, Sept. 19, and Oct. 17. Please review ODM's BIA for 5160-1-40 for information on ODM's plans for EVV and ODM's stakeholder outreach providers who would be affected by ODM's proposed amendments to 5160-1-40.

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. 27, 2017 email, ODA received 20 comments from 6 stakeholders.

- A stakeholder asked if ODA could combine the requirements for the 2 types of participant-directed providers, which is what ODA now proposes to do. As stated in ODA's response to #1, the proposed new rule's organization will result in a significantly-shorter rule because the new rule won't repeat common requirements for each of the 5 provider types. This includes combining common requirements for the 2 types of participant-directed providers.
- A stakeholder asked if ODA would clarify that the requirement for commercial liability insurance is an ongoing requirement. In the proposed new rule, ODA clarifies that maintaining the commercial liability insurance is a requirement to remain certified.
- A stakeholder asked if ODA would increase the number of months agency providers need to have experience from 3 to 12. ODA believes the 3-month requirement is ample for providers to demonstrate experience providing services. This standard is consistent with other programs, and if expanded to require a year of experience, risks making it

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more difficult for providers to become certified and serve individuals enrolled in the PASSPORT or Assisted Living Programs.

- A stakeholder recommended allowing the Assisted Living Program to pay for the assisted living service during "reasonable absences, including cumulative absences." The current rule specifies the Assisted Living program may only pay a provider for authorized services provided in the residential care facility. At this time the state is not supportive of creating a mechanism to reimburse a provider if the individual is not present in the setting.

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.*

173-39-02 establishes the requirements for providers to become and remain certified. The rule generally gives providers flexibility on how to comply with its requirements, which allows providers to innovate on ways to provide high-quality services. Because 42 CFR 431.51 allows individuals enrolled in the PASSPORT and Assisted Living Programs to freely choose to receive services from any ODA-certified provider, it stands to reason that the providers who provide the highest-quality services are more likely to be chosen by individuals.

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 of services to individuals enrolled in ODA-administered programs.

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 rules take effect, ODA will post them on ODA's website. ODA will also send an email to subscribers of our rule-notification service to feature the rule.

Through its regular monitoring activities, ODA and its designees will monitor providers for compliance.

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;

Any provider seeking ODA certification and every provider certified by ODA.

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

ORC § 173.391 requires ODA to adopt rules to establish certification requirements. 173-39-02 establishes the requirements for providers to become, and to remain, certified by ODA.

The requirements for any provider to become certified includes the following:

- Meeting licensure requirements (if applicable).
- Meeting background check requirements.
- Having a place of business that meets the home and community-based setting requirements in 5160-44-01 and has a place to store records in a designated, locked storage space.
- Having valid contact information.
- Having \$1-million in commercial liability insurance and coverage for individuals' losses due to theft or property damage.
- Having a provider agreement with ODM and ODA's designee.
- Having a written procedure for documenting individual's incidents.
- Having an ODM-approved EVV system *if ODM adopts an amendment to rule 5160-1-40 to require the provider to use EVV.*

The requirements for every ODA-certified provider to remain certified are the following:

- Continuing to meet the requirement to become certified.
- Complying with requirements for the specific services the provider provides in OAC Chapter 173-39. For example, if the provider provides home medical equipment and supplies, the provider shall also comply with the requirements for providers of home medical equipment and supplies in 173-39-02.7.
- Reporting abuse, neglect, or exploitation to APS.
- Reporting incidents, significant changes, changes in contact information, and the last day of service to ODA or its designee.
- Complying with federal confidentiality laws.
- Not using legally-responsible family members to provide a service to an individual.
- Not using unsupervised volunteers to provide a service.
- Complying with each individual's person-centered services plan.
- Providing services in an ethical, professional, respectful, and legal manner.
- Participating in ODA's or its designee's mandatory free provider training sessions.
- Using EVV if rule 5160-1-40 requires the provider to use EVV.
- Complying with records-retention and monitoring requirements.
- Complying with the requirements on accepting payments.
- Complying with other federal, state, and local laws *when applicable.*

This rule also makes unique requirements for certain types of providers. The unique requirements include the following:

- Participant-directed providers must be at least 18 years of age and be able to read, write, and understand English at a level enabling the provider to comply with this rule.
- Assisted-living providers must have an RCF license from ODH.

The proposed new version of this rule will make uniform requirements for providers in many areas which should not result in new burdens for providers. (Please review the section on "new" requirements in ODA's response to #1.)

The proposed new version of this rule will make the following new requirements for all providers:

- Provide ODA with a valid email address.
- Notify ODA any time the provider changes its telephone number or email address.

The proposed new version of this rule will require participant-directed providers to meet requirements to which the other provider types are already subject, but which seem reasonable to require:

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- The provider shall notify ODA when: (1) The individual has been hospitalized, placed in a long-term care facility, or is deceased, or (2) the individual chooses to no longer receive services from the provider.
- The provider shall not allow a volunteer to provide services ODA certified the provider to provide unless ODA's designee and the individual authorizes the provider to do so.

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 amount ODA pays providers for services is an all-inclusive rate. It's intended to cover the daily costs incurred in service provision plus costs related to the employees, such as orientation and training. The costs incurred as a result of these rules are likely calculated as part of a provider's operational budgets (e.g., the cost of doing business and clerical jobs, such as retaining records and updating policies and procedures).

Providers set the prices they bill to the PASSPORT Program, so long as those prices do not exceed ODM's maximum-possible payment per unit in the [appendix](#) to OAC 5160-1-06.1 or the [appendix](#) to 5160-1-06.5.

The proposed new requirement in this rule for all providers to provide ODA with a valid email address should not create any significant charge especially since email accounts are readily available for free from Gmail, Yahoo, etc.

The proposed new requirement in this rule for all provider to notify ODA any time the provider changes its telephone number or email address should only create the minimal burden of updating its profile in PIMS/MITS or notifying ODA by another means.

The proposed new requirements for participant-directed providers to notify ODA of hospitalizations, placements in a long-term care facility, deaths, and not wanting to receive services from the provider are essential for maintaining the person-centered requirements in 5160-44-02, for complying with the individual's right to choose a provider in 42 CFR 431.51, and to preserve the integrity of the program (i.e., not paying for home and community-based care after a person is institutionalized, deceased, or no longer wants services).

The prohibition against participant-directed providers using unauthorized volunteers should not create any cost, but also protects the individual, who is the employer of record for the participant-directed provider, from having a volunteer provide services when the individual employed the provider to do so, or if the individual does not want the provider to have assistance from a volunteer in his/her home.

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.

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Regulatory Flexibility

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

Because the primary purpose of these rules is to ensure the health and safety of individuals enrolled in ODA-administered waiver programs, the rules treat 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 these rules. 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 the rules.

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.