ACTION: Revised



Carrie Kuruc, Director

Mike DeWine, Governor Jon Husted, Lt. Governor

Initiative

Business Impact Analysis

Agency, Board, or Commission Name: OHIO DEPT. OF AGING

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Regulation/Package Title (a general description of the rules' substantive content): ODA PROVIDER CERTIFICATION

These rules establish the requirements to become, and to remain, ODA certified providers.

Rule Number(s): 173-39-01, 173-39-02.1, 173-39-02.4, 173-39-02.7, 173-39-02.8, 173-39-02.10, 173-39-02.11, 173-39-03, 173-39-03.2, 173-39-03.3, 173-39-03.4

Date of Submission for CSI Review: September 28, 2020

Public Comment Period End Date: October 11, 2020 at 11:59PM.

<u>Rule Type/Number of Rules</u>:

□ New/0 rules ☑ Amended/11 rules (FYR? ☑) □ No Change/ 0 rules (FYR? □) □ Rescinded/ 0 rule (FYR?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):

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- \Box a. Require 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.

There is no requirement for a provider to obtain ODA's certification in order to provide services in this state. These rules are not a gateway to doing business in Ohio. Instead, a provider who wants to add the PASSPORT Program or Assisted Living Program to its lines of business must become certified by ODA in order for those programs to pay the provider for services the provider wants to provide to individuals enrolled in those programs. Thus, these rules are a gateway to being paid for business conducted through these ODA-administered programs. Specifically, the rules in this package establish requirements related to certification by ODA.

- Rule **173-39-01** of the Administrative Code introduces Chapter 173-39 of the Administrative Code and defines terms used throughout that chapter. ODA proposes to amend this rule to define "unique identifier."
- Rules 173-39-02.1, 173-39-02.7, and 173-39-02.8 of the Administrative Code establish requirements applying only to the certification of providers of adult day services, home medical equipment and supplies, and homemaker (respectively). On June 11, 2020, ODA adopted one or more emergency amendment(s) into each of these rules to temporarily allow providers to decide whether to collect a unique identifier of the individual (*e.g.*, a handwritten signature) to verify that an activity or unit of service was provided. This has been allowing the provider and individual to maintain social distancing. Through this rule package ODA proposes to amend the verification requirements to allow providers to decide whether, during any state of emergency declared by the governor, to collect a unique identifier of the individual to verify that an activity or unit of service was provided.
- In rule **173-39-02.1** of the Administrative Code, ODA also proposes to do the following:
 - On June 11, 2020, ODA also adopted an emergency amendment to the definition of "adult day service." The amendment temporarily gave ADS providers flexibility to provide ADS activities in individual's homes. Through this rule package, ODA proposes to adopt this amendment on an ongoing basis.
 - Move the text that defines the levels and activities of ADS from a paragraph under paragraph (B) of the rule, which should be reserved for requirements for certified providers, to under paragraph (A) of the rule, which is the paragraph that defines "adult day service." In doing so, ODA proposes to no longer include the long-form text that itemizes what Table 1 to the rule conveys with much less text.

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- Add Table 2 to the rule to define which individuals are eligible to receive ADS activities in their homes, which ADS activities are allowable in their homes, and the allowable duration or frequency of allowable ADS activities in their homes.
- Replace a reference to requirements for therapeutic diets in rule 173-39-02.14 of the Administrative Code, to requirements for therapeutic diets in rule 5160-44-11 of the Administrative Code, since the requirements for therapeutic diets are no longer in rule 173-39-02.14 of the Administrative Code. Similarly, ODA also proposes to add rule 5160-44-11 of the Administrative Code to a reference to requirements for home-delivered meals in rule 173-39-02.14 of the Administrative Code.
- Transform the requirement in paragraph (B)(3)(a) of the rule from a list of requirements for a provider's adult day center to a list of specifications an adult day center must meet to qualify to be a center where an ODA-certified provider may be paid to provide ADS.
- Replace "paid personal care staff member" in paragraph (B)(4)(a) of the rule with "paid staff member who provides hands-on activities."
- Replace "on sit at the ADS center" in paragraph (B)(4)(c) of the rule with "available," which would make it
 possible to provide ADS in an individual's home without having an RN, or LPN under the direction of a
 RN, on site at the ADS center.
- Change the staffing ratios in paragraph (B)(4)(b) of the rule from 1:6 to 1:10.
- Add "based on the needs of the individual and" to paragraph (B)(4)(c) of the rule.
- Replace "acting as a personal care staff member" from paragraph (B)(5)(b)(i) of the rule with "planning to practice in the adult day center." This will align the wording with a similar paragraph in rule 173-3-06.1 of the Administrative Code. It would also remove language that appears to require licensure when a licensed professional practices personal care, which is not a service that requires licensure.
- Delete "to verify each ADS session" form paragraph (B)(6)(a) of the rule because it duplicates language in paragraph (B)(6) of the rule.
- o Require providers to complete form ODA1200 when providing ADS activities in individuals' homes.
- Rule **173-39-02.4** of the Administrative Code establishes requirements applying only to the certification of providers of the choices home care attendant service. To this rule, ODA proposes to make the following amendments:
 - Replace "may not" in paragraph (A)(5) of the rule with "does not" because a definition describes what is, not what may or may not be done.
 - Replace the requirement to "furnish the service as agreed upon with the individual and as authorized in the individual's service plan" in paragraph (B)(1)(a) of the rule with a requirement in [renumbered] paragraph (B)(2) of the rule to "maintain availability to provide this service as agreed upon with the individual and as authorized in the individual's person-centered service plan."
 - Replace "Only a...that ODA certifies shall furnish the service" in paragraph (B)(2)(a)(i) of the rule with "Only a...that ODA certifies qualifies to provide this service" in [renumbered] paragraph (B)(4)(a)(i) of the rule.

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- Add a clarification to paragraph (B)(3)(a) of the rule [renumbered as paragraph (B)(4)(e)(i) of the rule] that verifying continuing education includes documenting evidence of successful completion of training on required on the form.
- Delete paragraphs (B)(4) and (C)(4) of this rule as redundancies of rule 173-39-02 of the Administrative Code.
- Make other non-substantive amendments such as updating terminology, moving paragraphs, renumbering paragraphs, and updating cross-references.
- In rule 173-39-02.7 of the Administrative Code, ODA also proposes to do the following:
 - On June 11, 2020, ODA adopted an emergency amendment to temporarily replace the requirement for a provider using a common carrier to replace any home medical equipment that was lost or stolen between the time of delivery and receipt by the individual to a requirement or every provider to do the same. Through this rule package, ODA proposes to adopt this amendment on an ongoing basis.
 - On June 11, 2020, ODA also adopted an emergency amendment to temporarily require providers to contact the individua by telephone at least once per month to alert the individual to any delivery left outside the door to their home. Through this rule package, ODA proposes to adopt this amendment on an ongoing basis.
- Rule **173-39-02.8** and **173-39-02.11** of the Administrative Code establish requirements applying only to the certification of providers of homemaker and personal care (respectively). On June 11, 2020, ODA also adopted emergency amendments to the definition of "homemaker" and "personal care" (respectively) in those rules. The amendments temporarily gave providers flexibility to consider errands outside the presence of the individual (*e.g.*, picking up a prescription) as part of "homemaker" or "personal care." Through this rule package, ODA proposes to adopt these amendments on an ongoing basis.
- In rule **173-39-02.8** of the Administrative Code, ODA also proposes to do the following:

On June 11, 2020, ODA temporarily amended the supervisory requirements to allow subsequent supervisor visits to occur by telephone, video conference, or in person, rather than only in person. Through this rule package ODA proposes to adopt this amendment on an ongoing basis.

Insert ", when authorized in a person-centered services plan" after "Homemaker activities include the following" in paragraph (A) of the rule, ODA proposes to insert. ODA also proposes to delete "as authorized by their case manager" from the same paragraph. This amendment brings the definition into alignment with the person-centered planning requirements in rule 5160-44-02 of the Administrative Code.

- Rule **173-39-02.10** of the Administrative Code establishes the requirements applying only to the certification of providers of nutritional consultations. To this rule, ODA proposes to do the following:
 - Move paragraphs (B)(3)(b) and (B)(3)(e) of the rule to the definition of "nutritional consultation" in paragraph (A) of the rule and to modify the limitation when the individual receives a similar services under Chapter 173-39 of the Administrative Code to a limitation when the individual receives a similar service paid (in full or in part) by Medicare, state plan Medicaid, or anther third-party payer.
 - Replace occurrences of "nutrition assessment" with "nutritional assessment" to align the terminology with rule 4759-2-01 of the Administrative Code.

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- Delete paragraph (B)(3)(c) of this rule because paragraph (B)(11)(d) of rule 173-39-02 of the Administrative Code already requires the same.
- Delete paragraph (B)(3)(d) of this rule because paragraphs (B)(11)(c) and (B)(11)(d) of rule173-39-02 of the Administrative Code already require the same.
- Replace "face-to-face" in paragraph (B)(4) of the rule with "in person" and to replace "telecommunications system" with "telephone" and "video conference." This will align the terminology with other rules in Chapter 173-39 of the Administrative Code.
- Allow providers, in paragraph (B)(4) of the rule, to provide an initial consultation by telephone or video conference during a state of emergency declared by the governor. This will allow for social distancing during the state of emergency.
- Replace the language in paragraph (B)(8)(b) of the rule on a handwritten signature with language on a unique identifier.
- o Indicate in paragraph (C)(1) of the rule that a unit of service is 15 minutes of session time.
- In rule 173-39-02.11 of the Administrative Code, ODA also proposes to do the following:
 - Insert "when authorized in a person-centered services plan" after "Personal care activities include the following" in paragraph (A)(1) of the rule. This amendment brings the definition into alignment with the person-centered planning requirements in rule 5160-44-02 of the Administrative Code.
 - Delete the definition of "PCA," because ODA is simultaneously proposing to add a definition of "PCA" to rule 173-39-01 of the Administrative Code that will apply to the entire chapter.
 - Replace occurrences of "continuing education and "in-service continuing education" with "in-service training."
 - Replace "training dates; training locations; training hours successfully completed; instruction materials used; subjects covered; and to verify the accuracy of the record, the name, qualifications, and signature of each trainer and of each tester: in paragraph (B)(3)(e)(i) of the rule with "name of the school or training organization, name of the course, training dates, and training hours successfully completed.
 - Add "expired" as a valid option in paragraph (B)(3)(e)(ii) of the rule.
 - Delete the need to verify a person's name in paragraph (B)(3)(e)(iii) of the rule.
 - Add paragraph (B)(3)(f) of the rule to establish standards that remote training is acceptable, but skills testing by return demonstration is only acceptable if conducted in person.
 - Delete from paragraph (B)(5)(d) of the rule an obsolete paragraph citation from a reference to rule 173-39-02 of the Administrative Code.
- Rule **173-39-03** of the Administrative Code establishes the process for the initial application process for a provider to be certified by ODA. In this rule, ODA proposes to do the following:
 - Add an introductory statement to indicate that ODA will be unable to process applications during a period in which it works with ODM to implement a new application system.

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- On June 11, 2020, ODA adopted an emergency amendment to temporarily allow its designees to conduct a desk review of a provider's business site for a pre-certification review. Through this rule package ODA proposes to give its designees flexibility to determine when to visit or conduct a desk review of the provider's business site for a pre-certification review.
- On June 11, 2020, ODA adopted an emergency amendment to temporarily allow ODA to approve an extended deadline for its designees to complete pre-certification reviews. Through this rule package, ODA proposes to adopt the amendment on an ongoing basis.
- On June 11, 2020, ODA adopted an emergency amendment to temporarily allow its designees to decide whether to conduct a pre-certification of a participant-directed provider with or without the individual who directs the participant-directed provider. Through this rule package, ODA proposes to adopt the amendment on an ongoing basis.
- On June 11, 2020, ODA adopted an emergency amendment to temporarily deem any provider certified by ODM or ODODD to provide one or more services through a Medicaid-waiver program as having satisfied the requirements for certification by ODA for the same or similar services under Chapter 173-39 of the Administrative Code. Through this rule package, ODA proposes to adopt the amendment on an ongoing basis.
- Rule 173-39-03.2 of the Administrative Code establishes the process for reporting changes of ownership interest or
 organizational structure to ODA. ODA proposes to amend this rule to add a statement that ODA will be unable to
 process a change of ownership interest or organizational structure.
- Rule **173-39-03.3** of the Administrative Code establishes the process for an already-certified provider to apply for certification to provide additional services. On June 11, 2020, ODA adopted an emergency amendment to temporarily allow its designees to decide whether to conduct a visit or desk review of a provider's business site during pre-certification review. Through this rule package ODA proposes to adopt the amendment on an ongoing basis.
- Rule **173-39-03.4** of the Administrative Code establishes the process for an already-certified provider to apply for certification to provide services in additional regions. On June 11, 2020, ODA adopted an emergency amendment to temporarily allow its designees to decide whether to conduct a visit or desk review of a provider's business site during pre-certification review. Through this rule package ODA proposes to adopt the amendment on an ongoing basis.
- Throughout all of the rules in this package, ODA also proposes to make non-substantive amendments to correct cross-references, eliminate unnecessary words, use uniform terminology, and comply with the Legislative Service Commission's requirements in the 5th edition of *Rule Drafting Manual* (June, 2020).

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

173-39-02.1, **173-39-02.7**, **173-39-02.8**, **173-39-02.11**, and **173-39-03.4**: R.C. §§ <u>121.07</u>, <u>173.01</u>, <u>173.02</u>, <u>173.391</u>, <u>173.52</u>, and <u>173.522</u>.

173-39-01, 173-39-03, and 173-39-03.3: R.C. §§ 121.07, 173.01, 173.02, 173.391, 173.52, 173.522., 173.54, and 173.543.

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.

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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).

5. 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 require ODA to establish the standards for ODA-certified providers.

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)?

These rules exist to comply with the state laws mentioned in ODA's response to #2, which require ODA to establish standards for ODA-certified providers and the PASSPORT Program.

7. 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. ODA will judge the proposed amendments to these rules to be a success when ODA and its designees find few violations against these rules during structural compliance reviews or investigations of alleged incidents.

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.

ODA's guide <u>Participating in ODA's Rule Development</u> and <u>this webpage</u> on ODA's website encourage stakeholders and the general public to give input on improving ODA's rules and provide contact information for doing so. Since ODA adopted the emergency amendments to the rules now in this package on June 11, 2020, ODA's policy development manager has received no input from stakeholders or the general public on those amendments.

On August 21, 2020, ODA presented its 4th webinar to providers, PASSPORT administrative agencies (PAAs), and others concerning matters relating to the COVID-19 state of emergency. During the meeting, ODA announced that was considering adopting many of the emergency amendments on an ongoing basis. ODA, then fielded questions from providers, AAAs, *et al.*

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

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During the August 21, 2020 webinar, ODA received questions on whether ODA would propose to adopt all, or only some, of the emergency amendments on an ongoing basis. ODA explained that it only planned to adopt some and was open to input. ODA did not receive any such input during the question and answer portion of the webinar and has not since received any such input.

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?

Many of ODA's proposals in this rule package are based upon CDC guidelines for social distancing to reduce exposure to COVID-19.

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?

R.C. §<u>173.391</u> requires ODA to adopt rules to establish requirements for ODA-certified providers. Additionally, federal rules require ODA to establish adequate requirements for providers to assure the health and safety of individuals enrolled in ODA-administered programs.

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.

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 rules.

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

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

R.C. §<u>173.391</u> authorizes only ODA to develop standards for ODA-certified providers of services to individuals enrolled in ODA-administered programs.

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.

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

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

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173-39-01, **173-39-02.1**, **173-39-02.4**, **173-39-02.7**, **173-39-02.8**, **173-39-02.10**, **173-39-02.11**, **173-39-03**, **173-39-03.2**, **173-39-03.3**, and **173-39-03.4** regulate provider certification for providers operating in the PASSPORT Program.

173-39-01, **173-39-03**, **173-39-03.2**, and **173-39-03.3** regulate provider certification for providers operating in the PASSPORT Program and the Assisted Living Program.

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

Rule **173-39-01** of the Administrative Code merely introduces Chapter 173-39 of the Administrative Code and, therefore, creates no adverse impact.

The adverse impact of rules 173-39-02.1, 173-39-02.4, 173-39-02.7, 173-39-02.8, 173-39-02.10, and 173-39-02.11 of the Administrative Code is the requirement for every ODA-certified provider to comply with the requirements for every ODA-certified provider in rule 173-39-02 of the Administrative Code plus specific requirements for each service listed in rules 173-39-02.1, 173-39-02.4, 173-39-02.7, 173-39-02.8, 173-39-02.10, and 173-39-02.11 of the Administrative Code.

Rules **173-39-03**, **173-39-03.2**, **173-39-03.3**, and **173-39-03.4** of the Administrative Code establish requirements for ODA' designees when processing applications for certification from providers. The only requirement upon a provider in these rules is the requirement to apply for certification if the provider wants to add the PASSPORT Program or Assisted Living Program to its lines of business or to notify ODA of a change of ownership interest or organizational structure.

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 a provider for a service is an all-inclusive rate. It's intended to cover the daily costs incurred in providing the service plus costs related to the employees. The costs incurred as a result of the rules in this package are likely calculated as part of a provider's operational budget—the cost of doing business and clerical jobs, such as retaining records and updating policies and procedures.

The rules in this package do not determine the amount ODA pays a provider. Instead, a provider sets the price it bills to the PASSPORT Program or Assisted Living Program. In turn, the program pays the provider the amount the provider bills, so long as the price billed does not exceed the maximum that the Ohio Dept. of Medicaid (ODM) allows per unit per unit {*i.e.*, per job (*e.g.*, a home modification), per unit (*e.g.*, a home-delivered meal), or per a period of time (*e.g.*, personal care)}. In the appendix to rule <u>5160-1-06.1</u> of the Administrative Code, ODM establishes the maximum-allowed payment of Medicaid funds for these services provided through the PASSPORT Program. In the appendix to rule <u>5160-1-06.4</u> of the Administrative Code, ODM establishes the maximum-allowed payment of Medicaid funds for these services provided through the PASSPORT Program.

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

R.C. §<u>173.391</u> requires ODA to develop rules establishing standards for ODA-certified providers and R.C. §<u>173.01</u> requires ODA to represent the interests older Ohioans. Establishing standards for ODA-certified providers in the rules of this package ensures the health and safety of the older Ohioans enrolled in the PASSPORT Program and Assisted Living Program, which fulfills both statutes.

Most of ODA's proposed amendments in this package will give providers flexibility to maintain social distancing during the COVID-19 state of emergency. Specifically, these amendments will allow providers to (1) conduct supervisory visits (for

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personal care and homemaker) by telephone or video conference instead of only in person, and (2) verify that they provided services without making unnecessary physical contact with the individual (*e.g.*, to collect a unique identifier, such as a handwritten signature, from the individual).

There is no requirement for a provider to obtain ODA's certification in order to provide services in this state. Certification by ODA not a gateway to doing business in Ohio. Instead, a provider who wants to add the PASSPORT Program or Assisted Living Program to its lines of business must become certified by ODA in order for those programs to pay the provider for the services the provider wants to provide to individuals enrolled in those programs. Thus, certification by ODA is a gateway to being paid for services a provider wants to provide to individuals enrolled in those programs.

Additionally, providers voluntarily apply for certification from ODA. A provider is only required to comply with the rules in this package if the provider applies for certification from ODA.

Regulatory Flexibility

18. 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 programs, the rules treat all providers the same, regardless of their size.

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?

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.

20. 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 <u>Tom Simmons</u>, 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.

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