



## Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Carrie Kuruc**, Director

### Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

BLTSS HCBS Policy COVID-19 Permanent Filing (BIA)

Rule Number(s): 5160-44-11, 5160-44-12, 5160-44-13, 5160-44-14, 5160-44-16, 5160-44-17, 5160-44-26, 5160-44-27, 5160-44-31, 5160-45-04, 5160-45-06, 5160-46-04

Date of Submission for CSI Review: 8/10/2020

Public Comment Period End Date: 8/17/2020

Rule Type/Number of Rules:

New/\_\_\_ rules

No Change/\_\_\_ rules (FYR? \_\_\_)

Amended/ 12 rules (FYR? None)

Rescinded/\_\_\_ rules (FYR?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.

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### **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.** (OAC 5160-44-11, 5160-44-12, 5160-44-13, 5160-44-14, 5160-44-17, 5160-44-26, 5160-44-27, 5160-44-31, 5160-45-04, and 5160-46-04)
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.** (OAC 5160-45-06)
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.** (OAC 5160-44-12, 5160-44-13, 5160-44-14, 5160-44-17, 5160-44-27, 5160-44-31, 5160-45-04, 5160-45-06, and 5160-46-04)
- d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.** (OAC 5160-45-06)

### **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.***

On March 9, 2020, Ohio Governor Mike DeWine declared a statewide state of emergency to protect the health, safety and well-being of Ohioans from the dangerous effects of COVID-19. All citizens were urged to heed the advice of the Ohio Department of Health (ODH) and other emergency officials regarding this public health emergency. State agencies, including those serving individuals through Ohio Medicaid, were authorized to coordinate the State response to COVID-19, and to develop and implement procedures, including suspending or adopting temporary rules within an agency's authority, consistent with recommendations from ODH designed to prevent or alleviate this public health threat.

To this end, the Ohio Department of Medicaid (ODM) sought and received approval from the Centers for Medicare and Medicaid Services (CMS) of an 1135 waiver on April 22, 2020 good through the end of the public health emergency, and two home and community-based

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services (HCBS) waiver Appendix Ks on May 14, 2020 effective for the period January 27, 2020 to January 26, 2021. Also, Governor DeWine signed Executive Order 2020-23D on June 11, 2020 authorizing related emergency rules affecting administration of the State's HCBS waivers; these emergency rules expire on October 11, 2020. Throughout this time, ODM and the Ohio Department of Aging (ODA) have been issuing joint provider and case management guidance consistent with the agencies' recent waiver alignment efforts.

This business impact analysis (BIA) contains emergency rule provisions requiring CSIO review that ODM is proposing to make permanent due to the ongoing COVID-19 public health emergency. The proposed changes do not affect the adverse impacts, but the rules in which ODM is carrying over the provisions from the emergency rules have pre-existing adverse impact. The service specification rules set forth in OAC Chapter 5160-44 below affect both ODM and ODA.

OAC 5160-44-11 "Nursing facility-based level of care home and community-based services programs: home delivered meals," sets forth the definitions, service description, meal specifications (menu and delivery), limitations and provider qualifications. The proposed amendment permits ODM and ODA to deem any ODM, ODA or Ohio Department of Developmental Disabilities (DODD) waiver provider as having satisfied ODM or ODA requirements for same or similar services.

OAC 5160-44-12 "Nursing facility-based level of care home and community-based services programs: home maintenance and chore services," sets forth the definitions of services, provider requirements and specifications for the delivery of home maintenance and chore services. The proposed amendment permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services.

OAC 5160-44-13 "Nursing facility-based level of care home and community-based services programs: home modification services," sets forth the service description, authorization process and amount, service limitations and provider requirements for home modification services. The proposed amendment permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services.

OAC 5160-44-14 "Nursing facility-based level of care home and community-based services programs: community integration services," sets forth the definitions of services, provider requirements and specifications for the delivery of community integration services. The proposed amendment permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services.

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OAC 5160-44-16 “Nursing facility-based level of care home and community-based services programs: personal emergency response systems,” sets forth the service description, equipment specifications, personal emergency response systems (PERS) limitations, and PERS provider requirements. The proposed amendment permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services. Paragraph (D)(4) is modified to indicate that the initial PERS equipment demonstration can be conducted by telephone or electronically, unless the individual's needs necessitate a face-to-face visit.

OAC 5160-44-17 “Nursing facility-based level of care home and community-based services programs: out-of-home respite services,” sets forth the service description, provider qualifications and clinical record keeping requirements for the nursing facility-based home and community services waiver out-of-home respite service. The proposed amendment permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services.

OAC 5160-44-26, “Nursing facility-based level of care home and community-based services programs: community transition services,” sets forth the definitions of services, provider requirements and specifications for the delivery of community transition services. Paragraph (F)(6) is proposed for amendment to reflect that if individual signature requirement cannot be met at the time of service, the provider may accept an electronic signature or standard signature via regular mail from the individual, or otherwise obtain signature no later than at the next face-to-face visit with the individual. The proposed amendment also permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services.

OAC 5160-44-27, “Nursing facility-based level of care home and community-based services programs: home care attendant services,” sets forth the definitions related to the rule, service description, individual expectations, provider qualifications and requirements, and clinical record keeping requirements. The proposed amendment permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services. Additionally, it is amended to reflect that the face-to-face RN visit may be conducted by telephone or electronically, unless the individual's needs necessitate a face-to-face visit. First aid and CPR certification may be from a class that may be solely internet-based and that does not have to include hands-on training by a certified instructor and a successful return demonstration of what was learned in the course. It is also amended to reflect that if the individual is unable to provide the signature at the time of service, the individual is to submit an electronic signature or standard signature via regular mail, or otherwise provide a signature in no instance any later than at the next face-to-face visit with the provider.

OAC 5160-44-31, “Ohio department of medicaid (ODM)-administered waiver programs: provider conditions of participation,” sets forth the Ohio Department of Medicaid (ODM) provider conditions of participation for services outlined in OAC Chapters 5160-44 and 5160-46. It sets forth what a service provider shall and shall not do while providing services

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to individuals. The proposed amendment clarifies that required provider trainings are limited to on-line and web-based trainings. Additionally, paragraph (B)(14)(c) adds that if the individual is unable to provide the signature required by this paragraph at the time of the service, the individual is to submit an electronic signature or standard signature via regular mail, or otherwise provide a signature in no instance any later than at the next face-to-face visit with the provider.

OAC 5160-45-04, "Ohio department of medicaid (ODM) -administered waiver program: provider enrollment process," sets forth the enrollment process for Ohio Department of Medicaid (ODM) -administered waiver service providers. Paragraph (D) is being amended to reflect that ODM "may" rather than "will" reject a provider application if all requested information is not submitted within the required timeframes.

OAC 5160-45-06, "Ohio department of medicaid (ODM) -administered waiver program: structural reviews of providers and investigation of provider occurrences," sets forth the process and requirements for conducting structural reviews of ODM-administered waiver service providers to ensure providers' compliance with ODM-administered waiver requirements. Paragraph (B)(1) removes the requirement that Medicare-certified and otherwise-accredited agency providers submit a copy of their updated certification and/or accreditation. Paragraph (B)(6) is modified to make in-person structural reviews permissive. They can now also be conducted via desk review. Paragraph (D) (3) permits flexibility with the required timeframes for submission of plans of correction, so long as they are documented in the provider's file.

OAC 5160-46-04, "Ohio home care waiver: definitions of the covered services and provider requirements and specifications," sets forth the definitions of services, provider requirements and specifications for the delivery of Ohio Home Care Waiver services. The rule will permit first aid to be provided by a course that is not solely through the internet and that does not have to include hands-on training by a certified first aid instructor with performance of a successful return demonstration of what was learned in the course. Face-to-face visits referenced in paragraph (A) (personal care aide services) may be conducted by telephone or electronically, unless the individual's needs necessitate a face-to-face visit. Adult day health center service (ADHCS) providers approved to provide services on the effective date of this rule may also furnish ADHCS at the individual's place of residence, telephonically, or electronically. The paid ADHCS direct care staff to individual ratio in Paragraph (B)(4)(f) is increased from 1:6 to 1:10. The proposed amendment permits ODM and ODA to deem any ODM, ODA or DODD waiver provider as having satisfied ODM or ODA requirements for same or similar services.

**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.**

5162.03, 5164.02, 5166.02, 5166.30, 5166.301, 5166.302, 5166.303, 5166.304, 5166.305, 5166.306, 5166.307, 5166.308, 5166.309, 5166.3010

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**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. First, for the Centers for Medicare and Medicaid Services (CMS) to approve a 1915(c) home and community-based services (HCBS) waiver, 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:

*(a) "Health and Welfare -Assurance that necessary safeguards have been taken to protect the health and welfare of the beneficiaries of the services. Those safeguards must include:*

- (1) Adequate standards for all types of providers that provide services under the waiver;*
- (2) Assurance that the standards of any State licensure or certification requirements are met for services or for individuals furnishing services that are provided under the waiver."*

The proposed rule changes reflected herein make permanent those protections put in place as a result of CMS' approval of the aforementioned Appendix Ks, and Executive Order 2020-23D emanating from the current COVID-19 public health emergency. They pertain to the administration of the waivers, directly impacting waiver eligibility, provider enrollment and oversight and case management. Together, the proposed rule changes will assist the State in assuring the health and welfare of waiver participants, and as well as greater availability of and flexibilities for waiver service providers. Thus, providers of HCBS waiver services must be qualified, i.e., only those agencies and persons who meet the state's qualification requirements can provide services to waiver participants. The proposed rules will assist the State in assuring the health and welfare of waiver participants by establishing specific qualifications and requirements that providers must meet to render services.

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

These rules do not exceed federal requirements and are aligned with the CMS-approved waivers. They do not contain provisions not specifically required by the federal government.

**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)?**

The public purpose of these regulations is also to assure the health and welfare of individuals enrolled in an ODM or ODA-administered HCBS waiver as required by 42 C.F.R. 441.302(a) through the provision of services by qualified providers. The State is doing so by

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establishing requirements that individuals, providers and case management agencies must meet.

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

The effectiveness of this regulation will be measured in several ways. First, regarding waiver participants, it will be evident through their continued access to providers and health and welfare during the COVID-19 public health emergency.

Second, success will be measured through provider availability and a provider's compliance with waiver provider standards. The expectation is that flexibility of provider requirements during the public health emergency will result provider availability and a reduced number of incidents that threaten the health and welfare of individuals participating in the waiver program. This is evidenced, in part, by few incidents and no adverse findings resulting from structural reviews and investigation of alleged provider occurrences.

**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.*

ODM has been convening the HCBS Rules Workgroup since May 2013, to draft and review OAC rules governing ODM-administered waivers. This stakeholder group meets in-person and by phone/ webinar and plays a critical role in ODM and ODA HCBS waiver policy development.

The HCBS Rules Workgroup email group includes approximately 900 members. The workgroup consists of individuals enrolled on ODM-administered waivers, agency and independent service providers and members of no less than the following organizations:

Ability Center  
Caresource  
CareStar  
Coalition of Community Living Council on Aging  
Creative Housing/Creative Renovations  
Home Care by Black Stone

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Home Care Network  
LeadingAge Ohio  
LEAP  
Molina Healthcare  
Ohio Academy of Senior Health Sciences, Inc.  
Ohio Assisted Living Association  
Ohio Association of Area Agencies on Aging  
Ohio Association of Senior Centers  
Ohio Council for Home Care and Hospice  
Ohio Department of Aging  
Ohio Department of Developmental Disabilities  
Ohio Health Care Association  
Ohio Long Term Care Ombudsman  
Ohio Olmstead Task Force  
Public Consulting Group (PCG)  
Senior Resource Connection  
United Healthcare

The workgroup was notified of the proposed actions and provided with a summary of the changes via email on July 30, 2020.

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

Stakeholders are of critical importance in updating policy and practice, and in assuring the health and welfare of waiver participants throughout the COVID-19 public health emergency. The proposed rule changes will permanently codify emergency rules and case management and provider protocols developed with stakeholder input. ODM and ODA hosted weekly calls with stakeholders and updated the protocols based on stakeholder feedback received. Most recently, Version 9 of the case management protocols was issued on July 15, 2020. ODA and the Ohio Department of Developmental Disabilities have been ODM's partners throughout this process.

**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 the rules or the measurable outcome 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

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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.

**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.**

HCBS waiver participants and service providers will be notified of plans to implement the rules in this package. Notification will occur via a variety of communication methods including ODM's issuance of emails to case management agencies and agency and independent providers, and electronic communication via the provider oversight contractor's (PCG) website.

**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**

Currently, there are approximately 2,297 non-agency personal care aides, 1,428 registered nurses (RN)/licensed practical nurses (LPN), and 59 home care attendants serving individuals enrolled on an ODM-administered waiver. There are also 700 Medicare-certified home health agencies, 65 otherwise-accredited agencies and approximately 374 ancillary service providers that also furnish services to individuals. Twenty-three agency providers and 380 assisted living providers are currently certified by ODA to provide community transition services.

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

**OAC rule 5160-44-11** requires providers of home delivered meals to obtain a food operations license or other applicable license or certificate. Providers must develop, implement and maintain evidence of a training plan for staff that includes orientation and annual continuing education. Administrative costs may be incurred due to the requirement that delivery instructions are provided to the delivery driver and when notification must be made to individuals that the meal will be delayed.

**OAC rule 5160-44-12** requires that home maintenance and chore service providers be an agency or non-agency provider that has been approved by ODM or certified by ODA as a Medicaid provider of home maintenance and chore services. Home maintenance and chore service providers must submit a fixed cost proposal to perform the services submitted under a referral issued by ODM, ODA or their designee regarding an individual's service needs. The proposal must be good for the term of the proposal and can only be adjusted for good cause if modified in writing, and approved by ODM, ODA or their designee. The provider must also:

- Maintain and upon request, furnish proof of appropriate qualifications to perform services requiring specialized skills such as electrical, heating/ventilation and plumbing work.
- Maintain and upon request, furnish proof of licensure, insurance and bonding for services from applicable jurisdictions.
- Maintain and upon request, furnish a list of the chemicals or substances used for each proposal.
- Furnish to the individual and ODM, ODA or their designee a warranty that covers the workmanship and materials involved in performing the service, as applicable.
- Provide documentation to ODM, ODA or their designee that the service was completed in accordance with the agreed upon specifications using the materials and equipment cited in the proposal.
- Provide documentation to ODM, ODA or their designee that the service was tested, is in proper working order and is usable by the individual, if applicable.

**OAC rule 5160-44-13** requires home modification service providers to submit a fixed cost proposal for services. Prior to beginning a job, the provider shall obtain all permits and pre-job inspections, as well as, post job inspection reports as required by law or any homeowner's association. Home modification providers must provide documentation of service completion in accordance with the agreed upon specifications, that the modification was tested and is in proper working order and that all applicable federal, state and local building codes and accessibility codes are met.

**OAC rule 5160-44-14** requires that community integration service providers comply with the requirements necessary to become an ODM-approved provider or an ODA-

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certified provider. Supervisors shall develop, implement and maintain evidence of a staff training plan that includes initial orientation and annual continuing education.

**OAC rule 5160-44-16** requires PERS providers to do the following:

- Provide individuals with training on how to use PERS equipment.
- Notify the designated responder when activating the individual's PERS equipment and on an annual basis thereafter as part of the monthly service. At a minimum, notification shall include directions on how to respond when an alarm is signaled.
- If the provider cannot assist an individual with an assessed need, the provider shall notify ODM, ODA or their designee, in writing of the service limitations before the provider is included in the individual's person-centered services plan.
- Notify ODM, ODA or their designee of any emergency involving an individual no more than twenty-four hours after the individual sends the alarm signal.
- Notify ODM, ODA or their designee of any emergency involving an individual no more than twenty-four hours after the individual sends the alarm signal.
- Contact emergency service personnel in the event a provider receives an alarm signal, but the station cannot reach a designated responder.

**OAC 5160-44-17** requires out-of-home respite service providers to be a licensed/certified intermediate care facility for individuals with intellectual disabilities, a licensed/certified nursing facility, or another licensed setting approved by ODM or its designee. They must provide for replacement coverage due to theft, property damage and/or personal injury. They must also maintain evidence of completion of twelve hours of in-service continuing education every twelve months and program-specific orientation.

**OAC 5160-44-26** requires that community transition service providers comply with the requirements necessary to become an ODM-approved provider or an ODA-certified provider. Specifically, they must be a waiver agency, non-agency, a transition coordination service provider under contract with ODM that is also an ODM-approved or ODA-certified waiver agency or non-agency provider; or an ODA-certified assisted living waiver service provider.

**OAC 5160-44-27** requires home care attendant providers to submit an ODM-specified form as part of the provider application process. It also requires the provider to submit evidence of the following: successful completion of a competency evaluation and/or training program, certified vocational program and training specific to the services to be provided. The provider must also submit a written attestation of training, instruction and skills testing. Providers must complete first aid certification and CPR certification and must complete at least 12 hours of continuing education annually. Home care attendant

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services providers must maintain clinical documentation in their place of business and within the individual's home. When the home care attendant provider secures an RN, the RN must possess a current valid and unrestricted license with the Ohio board of nursing

Under **OAC 5160-44-31**, providers are required to maintain an active, valid medicaid provider agreement as set forth in rule 5160-1-17.2 of the Administrative Code. ODM-administered waiver service providers are required to notify ODM or its designee within 24 hours when the provider is aware of issues that may affect the individual and/or the provider's ability to render services as directed in their person-centered services plan. Providers may incur costs related to the maintenance and retention of records related to services provided.

Under **OAC 5160-45-06**, Providers may be subject to costs associated with providing information for structural reviews and any corrective action associated with the results of such reviews. If ODM-administered waiver providers and contractors adhere to the ODM-administered waiver provider requirements, there should be little or no cost of compliance with this review. However, if the provider does not, and an incident or provider occurrence is reported, the provider 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.

Under **OAC 5160-46-04**,

- Home health agencies must be Medicare-certified or otherwise accredited by a national accreditation body. Personal care aides must have a certificate of completion of either a competency evaluation program or training and competency evaluation program approved and conducted by the Ohio Department of Health, or the Medicare competency evaluation program for home health aides. They must also obtain and maintain first aid certification.
- Adult day health center must provide for replacement coverage due to theft, property damage and/or personal injury.
- Supplemental transportation service providers must possess a valid driver's license. Additionally, they must maintain collision/liability insurance for each vehicle/driver and obtain and exhibit evidence of valid motor vehicle inspections from the Ohio Highway Patrol for all vehicles used to provide services. Nonagency drivers must possess collision/liability insurance and obtain and exhibit evidence of required motor vehicle inspections. Drivers must also obtain and maintain a certificate of completion of a course in first aid.

**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.*

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A prospective provider can receive home health aide/competency training through adult vocational schools. An informal survey of courses approximates this cost at \$200-\$500 depending on the program and type of instruction. State tested nurse assistant (STNA) programs costs also vary but are generally around \$400.

The cost of 12 hours of continuing education each year for a home care attendant will vary by subject, source and location. Medicaid will not reimburse providers for time spent training.

First aid training costs will also vary by program and geographic region. An informal survey of American Red Cross, American Heart Association and other first aid courses around the state suggests that the average cost is about \$70-75. Tuition can range anywhere from \$50 to over \$110, with lower rates in more rural counties.

5160-46-04 requires agencies to be Medicare-certified and to execute provider agreements as a condition of participation and compliance. The certification process from start to finish can take six to nine months. Administrative staff involved invest as much as 80 or more hours to complete the initial Medicare certification process, and five or more hours per agency administrator to secure the provider agreement from a non-agency provider and/or an accredited agency. The cost of Medicare certification varies by agency and can be more than a \$250,000 endeavor depending on the number of staff hired to support the process. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

Providers must revalidate a provider agreement every 5 years and this includes a \$569 fee. The revalidation may take from one to two hours at a rate of \$29 an hour to complete the revalidation process. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

To maintain Medicare certification, a survey is required to be completed once every three years (or sooner, depending on the number of deficiencies found on the survey). This process is an on-going process for agencies. It is a compliance issue, keeping up with all the new rules and regulations. On average an agency spends a minimum of .5 FTE of a nurse's salary on this compliance piece and if it is a larger agency, it can be 1 to 1.5 FTEs. At \$29 per hour, that could amount to between \$60,000- \$90,000 per year. (This number does not include benefits). SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

"Otherwise accredited agencies" such as those accredited by The Joint Commission may spend approximately \$16,000 every three years for conducting their on-site survey. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

Agencies incur approximately \$190 in costs for RN assignment/oversight/supervision of aides at least every 60 days, or as often as every 14 days. OAC 5160-44-22 requires the RN to conduct a face-to-face visit with the LPN prior to initiating care, at least every

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sixty days, and at least each one hundred and twenty days (with the individual present) to evaluate that the LPN's provision of nursing services are in accordance with the plan of care. The cost of an RN visit, which is not reimbursed by ODM is \$31.50/hour. So, within the first four months the RN visits would equal at least \$126 or more that is not reimbursed by ODM. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

It is a challenge to determine the total cost of maintaining records because the number of documents needed, and time spent gathering these documents would be different for everyone. SOURCE *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

Training and competency testing have been estimated to cost an agency approximately \$2,704 for a group of ten potential personal care aides. More than \$2,200 of these costs are attributable to the cost of instruction (RN/PT instructors) over a 75-hour period. The actual aide handbook is estimated to cost approximately \$30 per person. Agencies also incur additional costs for wages, testing and materials. An independent provider can receive training through adult vocational schools (approximate cost: \$500). Some state tested nurse assistant (STNA) programs are Diversified Health Programs encompassing Aide Training to Medical Assistants. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

Twelve hours of continuing education each year is estimated to cost an agency approximately \$1,821 for a group of ten staff. This estimate includes nearly \$500 for the cost of materials/administrative costs/instruction and the remainder is for payment of wages to staff while they undergo training. Medicaid will not reimburse providers for time spent training. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

First aid training is estimated to cost an agency \$394 every two years for a group of 10 staff. This includes \$174 for the cost of materials/administrative costs/instruction and the remainder is for payment of wages to staff while they undergo training. Again, an independent provider would be responsible for training costs and would not be paid wages while receiving instruction. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

Supplemental transportation as well as other waiver service providers incur \$23-\$26 in licensure fees. Additionally, transportation providers' auto insurance costs will vary by both city and vehicle. According to an analysis of auto insurance rates in Ohio conducted by valuepenguin.com, average minimum coverage premiums range from \$428 to \$1,428 per year.

Costs related to the structural review requirements set forth in OAC 5160-45-06 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

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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 \$1.00 for the letter of certification, or up to and over \$100 depending on the length of reports and plan of correction documents. SOURCE: *Ohio Council for Home Care and Hospice and LeadingAge Ohio*.

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

The assurance of HCBS waiver participants' health and welfare is integral to the Ohio HCBS waiver programs- both at the state and federal levels. Provider participation in this waiver is optional and at the 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 waiver service provider.

**Regulatory Flexibility**

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

No, not applicable to 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 to this program.

**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.