Ohio | Common Sense Initiative

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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):

Home and Community-Based Service (HCBS) Waiver Rules

Rule Number(s):

OAC 5160-44-26; 5160-44-27; 5160-44-31; 5160-45-06; 5160-45-10 (to be rescinded); and 5160-46-04

*For informational purposes, this rule package also includes OAC 5160-45-01, which does not require BIA.

Date of Submission for CSI Review: 10/8/2019

Public Comment Period End Date: 10/15/2019

Rule Type/Number of Rules:

New/___ rules **No Change/____ rules (FYR? ___)**

Amended/_6_rules (FYR? _5_) **Rescinded/__1__ rules (FYR? yes)**

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):

   a. ☒ **Requires 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.

   Both the Ohio Department of Medicaid (ODM) and the Ohio Department of Aging (ODA) administer home and community-based services (HCBS) nursing facility level of care waivers. ODM-administered HCBS waivers include the MyCare Ohio and Ohio Home Care waivers. ODA- administered HCBS waivers include the preadmission screening system providing options and resources today (PASSPORT) and Assisted Living waivers. Each waiver is described under its own chapter of the OAC and while services across waivers may be similar, they are not uniform.

To bring consistency to the ODM and ODA administered waiver programs to benefit individuals and providers, the two agencies have been collaborating to align the OAC rules governing the various waiver programs. This rule package amends two rules (OAC 5160-44-26 and 5160-44-27) that were recently part of phase two of the agencies' HCBS waiver alignment collaboration. The remaining rules are specific to ODM-administered HCBS waiver programs.

OAC 5160-44-26 is being proposed for amendment to update policy relating to the administration of the nursing facility-based level of care home and community-based services waivers. Specifically, it will remove language based on waiver feedback from the Centers for Medicare and Medicaid Services (CMS) that purchase of food cannot be included under community transition services due to the Medicaid room and board exclusion.

OAC 5160-44-27 is being proposed for amendment to correct rule citations.

OAC 5160-44-31 is being proposed for amendment to add the requirement that new Medicaid providers complete "new provider" training no later than 90 days after they receive their Medicaid provider number. The rule also replaces OAC 5160-45-10 for providers of personal care aide services, adult day health center services, supplemental adaptive and assistive device services, and supplemental transportation services in an ODM-administered HCBS waiver. OAC 5160-45-10 is being rescinded as a result of five-year rule review as part of this rule package.

OAC 5160-45-06 is being proposed for amendment as a result of five-year rule review. This rule 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. Among other things, language changes reflect the following:

- Medicare-certified and otherwise-accredited agencies are subject to reviews in accordance with their certification/accreditation bodies and may be exempt from a regularly scheduled structural review as determined by ODM.
- All other agency providers are subject to structural reviews by ODM or its designee every two years after the provider begins furnishing billable services.

- All non-agency ODM-administered waiver providers are subject to structural reviews by ODM or its designee during each of the first three years after a provider begins furnishing billable services. Thereafter, and unless otherwise prescribed in the rule, structural reviews shall be conducted annually.
- ODM or its designee shall examine all substantiated incident reports or provider occurrences related to a provider.
- The provider's compliance with the home and community-based settings requirements set forth in OAC 5160-44-01 will be evaluated as part of the structural review and will include interviews with individuals served in the setting.
- Failure of a provider to successfully complete all plans of correction and/or the existence of repeat violations may lead to additional sanctions, including but not limited to the termination of their provider agreement.
- A final exit interview summarizing the overall outcome of the review will occur between the non-agency provider, or in the case of the agency provider, the agency administrator or his or her designee, and ODM or its designee at the conclusion of the review.
- The exit interview will be followed up with a written report to the provider from ODM or its designee. The report summarizes the overall outcome of the structural review, specifies the OAC rules that are the basis for noncompliance, and outlines the specific findings of noncompliance. When findings are indicated, the provider is to respond in writing to the report in a plan of correction, including any individual remediation.
- Provider occurrences include alleged violations of provider conditions of participation.
- Correcting findings of noncompliance may include acknowledgement of technical assistance and required training.
- When a provider has submitted a plan of correction and it is not accepted by ODM or its designee, the provider is required to submit a new plan of correction within the prescribed timeframes, not to exceed 45 calendar days.
- If the possibility of an overpayment is identified, ODM will conduct a final review, and as appropriate, issue all payment adjustments in accordance with OAC 5160-1-19.

OAC 5160-45-10 is being proposed for rescission as a result of five-year rule review. This rule sets forth the Ohio Department of Medicaid (ODM) provider conditions of participation for services set forth in OAC Chapters 5160-44 and 5160-46. It establishes what a service

provider shall and shall not do while providing services to individuals enrolled on an ODM-administered HCBS waiver. It is being replaced by existing OAC rule 5160-44-31.

OAC 5160-46-04 is being proposed for amendment to update policy relating to the administration of the nursing facility-based level of care home and community-based services waiver. This rule sets forth the definitions of services, provider requirements and specifications for the delivery of Ohio Home Care Waiver services. The rule is being amended to specify that providers will meet provider conditions of participation set forth in OAC rule 5160-44-31. Language is being removed from paragraphs (A), (B), (C) and (D) that is duplicative of requirements in OAC 5160-44-31. Code of Federal Regulations citations and dates are also being updated.

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

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, 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;"*

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.

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 waiver. 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 to assure the health and welfare of individuals enrolled in an ODM or ODA-administered HCBS waiver as required by 42 C.F.R. 44 I. 302(a) through the provision of services by qualified providers. The State is doing so by establishing requirements providers must meet to be waiver service providers, and by conducting regular and periodic structural reviews of providers and investigations of alleged provider occurrences.

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 successful transition from institutional settings into the community using community transition services. Community transition services will permit the purchase of necessary goods and services to help individuals create a safe living environment.

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

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 the ODM and ODA HCBS waiver alignment initiative.

The HCBS Rules Workgroup email group includes almost 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
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 received copies of all the proposed rules (except for OAC 5160-44-27) on July 31, 2019 and it was convened on August 21, 2019, during which time, ODM conducted a review. The workgroup was notified of the proposed changes to OAC 5160-44-27 via email on September 20, 2019.

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 identifying the service specifications and provider requirements for HCBS waiver services, monitoring and oversight. The Ohio Department of Aging has been a partner in rulemaking as a result of nursing facility level of care-related waiver alignment efforts. Other stakeholders provided feedback related to rule drafts during the workgroup review process. The plan of correction timeframe in OAC 5160-45-06 and Medicare conditions of participation citations in OAC 5160-46-04 were modified as a result.

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 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. As part of the ODM/ODA waiver alignment activities and 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 3,750 non-agency personal care aides, 1,680 registered nurses (RN)/licensed practical nurses (LPN), and 56 home care attendants serving individuals enrolled on an ODM-administered waiver. There are also 730 Medicare-certified home health agencies, 63 otherwise-accredited agencies and approximately 493 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.

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

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 that 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. Additionally, this rule 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/or 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 services providers must maintain clinical documentation in their place of business and within the individual's home.

Under **OAC 5160-44-31 and 5160-45-10**, providers may incur costs related to the maintenance and retention of records related to services provided.

Under **OAC 5160-45-06**, ODM may act against a provider in accordance with rule 5160-45-09 of the Administrative Code for failure to comply with any of the requirements set forth in rule 5160-45-06 of the Administrative Code. Additionally,

- Medicare-certified and otherwise-accredited agency providers must submit a copy of their updated certification and/or accreditation, and upon request by ODM or its designee, shall make available within ten business days, all review reports and accepted plans of correction from the certification and/or accreditation bodies.

- Except for unannounced reviews, as part of the structural review process, providers will be notified in advance of the list of the type of documents required for the review. The provider must ensure the availability of the documents.

- When findings are issued by ODM or its designee, the provider must respond in writing within 45 calendar days in a plan of correction. If the plan is not acceptable, the provider will be asked to submit a new plan within prescribed timeframes not to exceed 45 calendar days.

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.

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.

For a home health agency, the Medicare 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.*

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 (12) 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.*

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 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.*

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.

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 waivers 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 for 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?

No. Not applicable for 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.