CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Medicaid

Regulation/Package Title: ODM-administered Waiver Nursing Service Changes

Rule Number(s): 5160-46-04

The following rule is attached for informational purposes only: 5160-46-06

March 20, 2015
Rule Type:

- [ ] New
- [X] Amended
- [ ] 5-Year Review
- [ ] Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   OAC 5160-46-04

   The rule being proposed for amendment sets forth the service specifications and provider requirements for the Ohio Home Care Waiver. The waiver is administered by the Ohio

Department of Medicaid (ODM), and the services described in this rule are waiver nursing, personal care aide, adult day health center, out-of-home respite, supplemental adaptive and assistive device, supplemental transportation, emergency response, home modification and home delivered meal services.

OAC rule 5160-46-04 is being proposed for amendment in order to provide clarification about the waiver nursing service and to update terminology and citations referred to in the rules. Paragraph (A) is being expanded to identify those nursing tasks that shall only be performed by a registered nurse (RN). Further, the paragraph clarifies that waiver nursing does not include visits performed for the purpose of conducting an RN assessment or an RN consultation as those services are described in OAC rule 5160-12-08. Additionally, Ohio Revised Code and OAC cites have been updated, references to the Ohio Department of Job and Family Services have been changed to the Ohio Department of Medicaid, terms of art have been updated (i.e., consumer is now individual, etc.) and Code of Federal Regulation cites have been updated. No substantive changes are being made to the rest of the rule at this time pending a forthcoming five-year review later in 2015.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.**
   Ohio Revised Code Section 5166.02.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.**

Yes. In order for CMS to approve a 1915(c) home and community-based services waiver, a state must meet certain assurances concerning 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 Ohio Home Care 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 rule will assist the State in assuring the health and welfare of waiver participants by among other things, establishing specific qualifications and requirements that providers must meet in order to furnish waiver services.

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

   This rule is consistent with federal requirements. It defines specific processes for meeting waiver program provider eligibility requirements as required by CMS.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   The public purpose of these regulations is to assure the health and welfare of waiver participants as required by 42 C.F.R 441.302(a) through the provision of services by qualified providers. The State is doing so by establishing requirements that providers must meet in order to be ODM-administered waiver service providers.

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

   Successful outcomes are measured through a finding of compliance with 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.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
   If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The changes included in the proposed rule were developed by ODM. The draft rule was shared with ODM's HCBS Rules Workgroup. ODM has been convening this stakeholder

group since May, 2013, for the purpose of crafting and reviewing OAC rules governing ODM-administered waivers including 5160-46-04. The workgroup generally meets every two weeks to four weeks (in-person and by phone) and has been responsible for the development, adoption, rescission and amendment of many rules thus far. It consists of individuals enrolled on ODM-administered waivers, as well as members of the following organizations:

The Ohio Council for Home Care and Hospice
Midwest Care Alliance
CareSource (case management contractor)
CareStar (case management contractor)
Council on Aging (case management contractor)
Public Consulting Group (PCG) (provider oversight contractor)
Ohio Olmstead Task Force
Disability Rights Ohio
Ohio Department of Aging
Ohio Department of Developmental Disabilities

The rule was also shared with ODM's Home Health/Hospice Workgroup, which also meets monthly. Its membership includes but is not limited to many of the same organizations, as well as individual stakeholders.

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

Stakeholders, particularly those with a nursing background, were very helpful in identifying the kinds of skilled nursing tasks that must be performed by a registered nurse as opposed to a licensed practical nurse at the direction of a registered nurse. Reference was also made to Ohio's Nurse Practice Act set forth in Chapter 4723 of the Revised Code and the Medicare Conditions of Participation.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

No scientific data was used to develop the rules or the measurable outcomes of the rules.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

    No alternative regulations were considered as the requirements regarding the types of services that must be provided by a nurse are dictated by Ohio's Nurse Practice Act as set forth in Chapter 4723 of the Ohio Revised Code, and the Medicare Conditions of Participation. Additionally, the language had to meet the federal and state guidelines under which ODM-administered waivers are permitted to operate.

11. **Did the Agency specifically consider a performance-based regulation? Please explain. Performance-based *regulations define the required outcome, but don't dictate the process* the regulated stakeholders must use to achieve compliance.**

    No. Performance-based regulations are not deemed appropriate and are not authorized by statute.

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

    All regulations regarding ODM-administered waivers are promulgated by ODM and implemented by ODM, its designees and providers, as appropriate. The regulations were reviewed by ODM's legal and legislative staff to ensure that there is no duplication within the rules.

13. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    A robust effort will be employed by ODM to notify Ohio Home Care Waiver participants and service providers of the rule changes found in OAC rule5160-46-04. Initial notification of rule changes will occur via a variety of communication methods including, but not limited to ODM's issuance via manual transmittal letter, remittance advice, emails to agency and independent providers, notifications to individuals enrolled on the Ohio Home Care Waiver, electronic communication via the myohiohcp.org website and the provider oversight contractor's (PCG) website.

Implementation of these rule changes will also be predicated on training that will be conducted by ODM and/or its designees.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

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

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) Currently, there are more than 10,600 personal care aides, 2,600 registered nurses (RN)/licensed practical nurses (LPN), and 40 home care attendants enrolled as non-agency home care providers in the Ohio Medicaid Program. There are also more than 770 Medicare-certified home health agencies, 80 otherwise-accredited agencies and 2,800 ancillary service providers.

(b) As a condition of their approval as an Ohio Home Care Waiver service provider,:

- Home health agencies must be Medicare-certified or otherwise accredited by a national accreditation body.
- Waiver nursing providers must be registered nurses or licensed practical nurses who possess a current, valid and unrestricted licensed with the Ohio Board of Nursing.
- 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 from a class that is not solely internet-based and that includes hands-on training by a certified first aid instructor and a successful return demonstration of what was learned in the course. They must also maintain

evidence of completion of 12 hours of in-service continuing education every 12 months and program-specific orientation.

- An adult day health center must provide for replacement coverage due to theft, property damage and/or personal injury. They must also maintain evidence of direct care staff's completion of 12 hours of in-service training within a 12-month period and annually thereafter.

- Home delivered meal providers must furnish meals that are approved by a licensed dietitian who is registered with the Commission on Dietetic Registration. Providers must also possess any applicable, current, valid licenses/certificates from the local health department.

- Home modification providers must maintain licensure, insurance and bonding for general contracting services of applicable jurisdictions. Home modification providers must submit bids for work that include drawings/diagrams of the modification, itemized lists of materials that will be needed, and itemized list of the cost of materials, an itemized list of labor costs, a written statement of all warranties provided and a written attestation that the provider, all employees and/or all subcontractors to be used have the necessary experience and skills.

- Out-of-home respite service providers must 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 eight hours of in-service continuing education every 12 months and program-specific orientation.

- Supplemental transportation service providers 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. Non-agency drivers must possess a valid driver's license, 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.

Providers will incur costs associated with meeting these requirements. They will also incur costs associated with maintaining required documentation pertaining to their particular

service as set forth in the rule. Costs will vary by specific service and associated requirements.

ODM will conduct a training webinar for agency and non-agency providers about the changes to the waiver nursing service when these rules are finalized. Assuming that Ohio Home Care Waiver providers adhere to the provider requirements set forth in the rule, there should be little or no cost of compliance with these changes. However, if the provider does not, and an incident or provider occurrence is reported, they 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.

(c) This rule requires agencies to be Medicare certified and to execute provider agreements as a condition of participation and compliance. The initial Medicare certification process is a lengthy process for a home health agency as it often involves third parties, e.g., an accreditation body and arduous processes (e.g., deeming process). 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 a 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.

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 of 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 to1.5 FTE's at $29 per hour would be $60,000 - $90,000 per year. (This number does not include benefits).

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

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. SOURCE: Ohio Council for Home Care and Hospice and Midwest Care Alliance.

Training and competency testing has 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 Midwest Care Alliance.

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. An independent provider would be responsible for training costs and would not be paid wages while receiving training. SOURCE: Ohio Council for Home Care and Hospice and Midwest Care Alliance.

First aid training is estimated to cost an agency $394 every two years for a group of ten 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 Midwest Care Alliance.

Licensure/registration with the Ohio Board of Dietetics, as is required for the home delivered meal services, is estimated to cost between $65-$180. SOURCE: Ohio Board of Dietetics.

Contractors providing home modification services may incur the following kinds of approximate costs:

- Two (2) percent of the value of work for general liability insurance (e.g., $20,000 cost for $1,000,000 in "sales;"
- $100-$125 for a $10,000 bond for each city;
- $200-$350 fee for city licensure;
- Five (5) percent of the value of work, or a minimum of $250 for drawings;
- Permitting varies from $75 and up to $100s, depending upon the scope of work. (SOURCE: Creative Housing Inc.)

Licensure of nursing facilities will vary by such things as licensure fee, building/fire inspection, bed costs, construction costs, if necessary, and staffing, etc. SOURCE: The Ohio Department of Health.

The cost of a license for an intermediate care facility is $50 for the first year of operation. Then, based on the outcome of their first year licensure review, they can be issued a 1 ($50), 2 ($75) or 3-year ($100) license. SOURCE: Ohio Department of Developmental Disabilities.

Supplemental transportation providers incur $23-$26 in licensure fees. Additionally, 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.

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

    The assurance of waiver participants' health and welfare is integral to the Ohio Home Care Waiver program – 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 include 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 Home Care Waiver service provider.

Regulatory Flexibility

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

    No, not applicable for this program.

17. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

    Not applicable for this program.

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

    Not applicable for this program.