

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Developmental Disabilities

Regulation/Package Title: Waiver Nursing Services (to be effective July 1, 2016)

Rule Number(s): 5123:2-9-39

Date: March 17, 2016

Rule Type:

☒ **New**

☐ **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☐ **Rescinded**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.

The Individual Options Waiver is a Medicaid Home and Community-Based Services waiver available to Ohioans with disabilities so they may receive services in their own homes as an alternative to receiving services in an institutional setting. The Medicaid Home and Community-Based Services waiver program is authorized by Section 1915(c) of the Social Security Act. The program permits a state to furnish an array of services that assist Medicaid beneficiaries to live in the community. The state has discretion to design a waiver program to address the needs of the waiver's target population. Waiver services complement and/or supplement the services that are available to participants through the Medicaid State Plan and other federal, state, and local public programs as well as the support that families and communities provide.

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The Ohio Department of Developmental Disabilities administers four Home and Community-Based Services waivers:

- Individual Options,
- Level One,
- Self-Empowered Life Funding, and
- Transitions Developmental Disabilities.

Waiver Nursing Services is currently a service available under the Transitions Developmental Disabilities Waiver governed by existing rule 5123:2-9-59. The Transitions Developmental Disabilities Waiver is being phased-out. Ohio is seeking approval from the federal Centers for Medicare and Medicaid Services (CMS) to add Waiver Nursing Services to the Individual Options Waiver, primarily to support approximately 1,500 individuals enrolled in the Transitions Developmental Disabilities Waiver who are transferring to the Individual Options Waiver and rely upon the service to meet their continuing nursing needs.

The Department is promulgating new rule 5123:2-9-39 to define Waiver Nursing Services under the Individual Options Waiver and set forth provider qualifications, requirements for service delivery and documentation of services, and payment standards for the service.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

5166.21 (In accordance with Section 5166.21 of the Revised Code and an Interagency Agreement with the Ohio Department of Medicaid, the Ohio Department of Developmental Disabilities is responsible for promulgating rules regarding Medicaid waivers it administers.)

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.

The rule sets forth requirements for a service under a Medicaid Home and Community-Based Services Waiver to ensure the service is delivered in accordance with the federally-approved Waiver. The Department has an administrative rule for each service available under a Medicaid waiver.

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

Not applicable; the rule does not exceed federal requirements.

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)?

Rules are required to implement Medicaid waivers approved by CMS. Ohio is seeking approval from CMS to offer Waiver Nursing Services as part of the array of services available to individuals enrolled in the Individual Options Waiver.

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

The Department measures the success of regulations in terms of the number of individuals enrolled in and receiving services through the Individual Options Waiver, the health and welfare of individuals enrolled in the Waiver, individuals' satisfaction with the services they receive, and Ohio's compliance with the Medicaid Home and Community-Based Services program and the approved Waiver.

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.

Department staff gathered input from a Nursing Task Assessment Group, comprised of nurses employed by county boards of developmental disabilities and nurses employed by providers, on April 7, June 1, and July 10, 2015.

Department staff discussed the rule with Transitions Developmental Disabilities Waiver stakeholders on May 26 and October 28, 2015.

On May 27, 2015, Department staff discussed the rule with a stakeholder group convened by The Arc of Ohio.

The rule was shared and discussed at meetings of the Waiver Workgroup on July 27, 2015, August 31, 2015, December 8, 2015, and February 29, 2016. The Waiver Workgroup includes representatives of:

- Advocacy and Protective Services, Inc.
- The Arc of Ohio
- Ohio Association of County Boards Serving People with Developmental Disabilities
- Ohio Department of Medicaid
- Ohio Developmental Disabilities Council
- Ohio Health Care Association/Ohio Centers for Intellectual Disabilities
- Ohio Provider Resource Association
- Ohio Self Determination Association
- Ohio Superintendents of County Boards of Developmental Disabilities
- Ohio Waiver Network

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Values and Faith Alliance

Department staff presented information about the rule at the Ohio Provider Resource Association Fall Conference in November 2015 and at the Ohio Association of County Boards Annual Convention in December 2015.

On December 15, 2015, Department staff conducted an informational session attended by The Arc of Ohio, the Ohio Coalition for Community Living, nurses employed by county boards of developmental disabilities, and nurses employed by providers.

Pursuant to 42 C.F.R. 441.301 and 441.304, the Ohio Department of Medicaid posted notice at its website, from February 1 to March 2, 2016, of the Individual Options Waiver amendment (including addition of Waiver Nursing Services to the benefit package).

Through the Department's rules clearance process, the rule will be disseminated to representatives of the following organizations for review and comment:

- Advocacy and Protective Services, Inc.
- The Arc of Ohio
- Autism Society of Ohio
- Councils of Governments
- Disability Housing Network
- Disability Rights Ohio
- Down Syndrome Association of Central Ohio
- Family Advisory Council
- The League
- Ohio Association of County Boards Serving People with Developmental Disabilities
- Ohio Department of Medicaid
- Ohio Developmental Disabilities Council
- Ohio Health Care Association
- Ohio Provider Resource Association
- Ohio Self Determination Association
- Ohio SIBS (Special Initiatives by Brothers and Sisters)
- Ohio Superintendents of County Boards of Developmental Disabilities
- Ohio Waiver Network
- People First of Ohio
- Values and Faith Alliance

The rule will be posted at the Department's *Rules Under Development* webpage (<http://dodd.ohio.gov/RulesLaws/Pages/Rules-Under-Development.aspx>) during the clearance period.

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

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Stakeholders provided input that Waiver Nursing Services should be added to the Individual Options Waiver benefit package.

Based on stakeholder feedback, the potential provider pool for Waiver Nursing Services under the Individual Options Waiver was expanded by allowing entities other than Home Health Agencies to obtain certification to provide the service.

Based on requests for clarification, paragraph (C)(3) was added to identify tasks and activities that may be performed only by a Registered Nurse.

Stakeholders recommended wording to more accurately describe the assessment of available resources required as part of a service authorization request.

Some requirements initially proposed by the Department for updating an individual's plan of care and Registered Nurse supervisor visits were eliminated based on discussion with stakeholders.

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?

Service utilization data confirmed that Waiver Nursing Services was needed to support approximately 1,500 individuals enrolled in the Transitions Developmental Disabilities Waiver who are transferring to the Individual Options Waiver and rely upon the service to meet their continuing nursing needs.

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?

The Department considered the continuum of health-related supports available such as unlicensed personnel who have appropriate training/oversight in accordance with Chapter 5123:2-6 of the Administrative Code and nursing available through the Medicaid State Plan. To support the phase-out of the Transitions Developmental Disabilities Waiver, as well as community integration initiatives sponsored by the Department, a determination was made to include a nursing service under the Individual Options Waiver. Having a waiver nursing service with a provider pool that includes agencies that provide specialized services to people with developmental disabilities provides greater opportunities for continuity of care and improved outcomes for people served.

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; CMS requires Ohio to implement Medicaid waivers in a uniform, statewide manner.

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

The Ohio Department of Developmental Disabilities is charged with promulgating rules regarding Medicaid waivers (such as the Individual Options Waiver) it administers.

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.

The Department will broadly disseminate information via its listservs and publications about the availability of Waiver Nursing Services throughout Ohio's developmental disabilities service delivery system in advance of the effective date of the rule (projected to be July 1, 2016). Department staff will conduct five regional training sessions during April and May 2016 and produce a recorded webinar which will be accessible via the Department's website. The rule will apply uniformly to all providers of Waiver Nursing Services under the Individual Options Waiver.

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;

The rule will apply to providers of Waiver Nursing Services under the Individual Options Waiver. Approximately 1,400 providers (1,200 Independent Providers and 200 Agency Providers) are currently approved to provide Waiver Nursing Services under the Transitions Developmental Disabilities Waiver; these providers will be deemed certified to provide Waiver Nursing Services under the Individual Options Waiver.

Other persons (Independent Providers) and entities (Agency Providers) may be interested in becoming certified to provide Waiver Nursing Services once the service is available to individuals enrolled in the Individual Options Waiver. The number of others who may be interested in providing Waiver Nursing Services is unknown.

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

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The rule requires interested persons and entities to apply to the Department for certification to provide Waiver Nursing Services and to have a Medicaid Provider Agreement with the Ohio Department of Medicaid. There is an application fee for applying for certification to provide the service. Providers are subject to sanctions if they fail to comply with the rule. The rule requires providers to maintain documentation for the services they provide.

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 application fees for provider certification are set forth in existing rule 5123:2-2-01 (*Provider Certification*) and vary depending on the type of provider (i.e., Independent Provider, Small Agency Provider, or Large Agency Provider). A provider that is already certified to provide one or more services may, for a reduced application fee, apply to add one or more services (such as Waiver Nursing Services) for the remainder of the term of the provider's existing certification.

	Initial or Renewal Certification (3-Year Term)	Adding Waiver Nursing Services to Remainder of Term of Existing Certification
Independent Provider	\$ 125	\$ 25
Small Agency Provider (Serves 50 or Fewer Individuals)	\$ 800	\$ 75
Large Agency Provider (Serves 51 or More Individuals)	\$ 1,600	\$ 150

Certified providers of other services under the Individual Options Waiver are not required to become certified to provide Waiver Nursing Services unless they choose to do so.

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

Waiver Nursing Services is being added to the Individual Options Waiver benefit package in response to stakeholder demand. The rule sets forth provider qualifications, requirements for service delivery and documentation of services, and payment for the service in the same manner as an existing Chapter 5123:2-9 rule for each service available under a Medicaid Home and Community-Based Services waiver administered by the Department.

Regulatory Flexibility

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

No; each provider of Waiver Nursing Services must comply with the requirements set forth in the rule.

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?

It is the policy of the Department to waive penalties for first-time or isolated paperwork or procedural regulatory noncompliance whenever appropriate. The Department believes the waiver of these penalties is appropriate under the following circumstances:

1. When failure to comply does not result in the misuse of state or federal funds;
2. When the regulation being violated, or the penalty being implemented, is not a regulation or penalty required by state or federal law; and
3. When the violation does not pose any actual or potential harm to public health or safety.

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

Staff of the Department's Medicaid Policy, Provider Certification, and Provider Payment and Support units are available to provide technical assistance should any be necessary.