

**Proposed New Rule 5123:2-9-39**  
**(Home and Community-Based Services Waivers - Waiver Nursing Services Under the Individual Options Waiver)**  
**Clearance Period: March 17-25, 2016**  
**Comments Received with Department's Responses**

Comment	By Whom	Department's Response
<p>Thank you for the opportunity to provide input on proposed rule 5123:2-9-39, Waiver Nursing Services. We are extremely supportive of the concept, but submit the following comments and questions for your consideration. We had been working under the impression that nursing services were going to be transitioned into the Individual Options (IO) Waiver in two phases. The first phase was going to be the implementation of nursing services for individuals transitioning from the Transitions Developmental Disabilities (TDD) Waiver. The second phase would be the opening up of nursing to all IO Waiver recipients (based on assessed need). The proposed rule does not make any distinction. Therefore, our comments reflect our current understanding that this rule is broader than a TDD Waiver transition and effects all IO recipients.</p>	<p>Anita Allen, Vice President, Ohio Provider Resource Association</p>	<p>When Waiver Nursing Services is added to the IO Waiver, it will be available for all individuals enrolled in the Waiver, not only those transferring from the TDD Waiver. In conversations regarding the scope of the new IO Waiver Nursing Services, Department staff clarified that IO Waiver Nursing Services will be a direct nursing service, similar to the nursing service available under the TDD Waiver. The service is not intended to be a funding source for nursing delegation or for health care coordination. Future work will focus on a funding mechanism for these activities.</p>
<p>We want to thank you for including TDD waiver providers as qualified providers for the purposes of providing this service. Initial discussions included the concept of Medicare Certification, which would have been both cost and time prohibitive for a significant number of agency providers. This change allows agencies to add nursing to their service package via the waiver application process—a much simpler and more cost effective process.</p>	<p>Anita Allen, Vice President, Ohio Provider Resource Association</p>	<p>We appreciate your support.</p>

Comment	By Whom	Department's Response
<p><b>(B)(19):</b> "Waiver nursing services" means services provided to an individual who requires the skills of a registered nurse or a licensed practical nurse working at the direction of a registered nurse. <b>Comment:</b> Paragraph (A)(3)(d) of Ohio Board of Nursing rule 4723-4-08 (<i>Standards for Applying the Nursing Process as a Licensed Practical Nurse</i>) allows for providing basic nursing care as directed by a Registered Nurse, Advance Practice Registered Nurse, or licensed Physician, Dentist, Optometrist, Chiropractor, or Podiatrist. Licensed Practical Nurses can work under the direction of any of the listed practitioners and carry out their orders without the oversight of a Registered Nurse. Why the limitation in scope of practice?</p>	Anita Allen, Vice President, Ohio Provider Resource Association	The definition of Waiver Nursing Services in the proposed new rule aligns with the definition in currently effective rules for the TDD Waiver (5123:2-9-59) and the Ohio Home Care Waiver (5160-46-04).
<p><b>(B)(19)(d):</b> Registered nurse consultations...including but not limited to, those performed by registered nurses for the sole purpose of directing licensed practical nurses in the performance of waiver nursing services or directing personal care aides... <b>Comment:</b> By law, a Registered Nurse must direct a Licensed Practical Nurse in certain situations. This is mandated in law but not funded in this rule. We are opposed to additional unfunded mandates.</p>	Anita Allen, Vice President, Ohio Provider Resource Association	The language in rule is clarifying that Registered Nurse consultation services are not a component of Waiver Nursing Services. The Ohio Board of Nursing does not allow a Licensed Practical Nurse to work without supervision. This rule is not adding new mandates.
<p><b>(C)(3):</b> Nursing tasks and activities that shall be performed only by a registered nurse include, but are not limited to:</p> <ul style="list-style-type: none"> <li>(a) Intravenous insertion, removal or discontinuation;</li> <li>(b) Intravenous medication administration;</li> <li>(c) Programming of a pump to deliver medication including, but not limited to, epidural, subcutaneous, and intravenous (except routine doses of insulin through a programmed pump);</li> <li>(d) Insertion or initiation of infusion therapies;</li> <li>(e) Central line dressing changes; and</li> <li>(f) Blood product administration.</li> </ul> <p><b>Comment:</b> The LPN's scope of practice defines what can be done in regard to IVs. Paragraphs (C)(3)(c), (C)(3)(d), (C)(3)(e), and (C)(3)(f) are redundant as to what is legally restricted. However, an LPN acting within his or her scope of practice (who is licensed M-IV) can discontinue an IV that terminates in a peripheral vein if the catheter is less than 3 inches long, can administer some medications after initiation by an RN, and can start a peripheral IV that is hepllocked. Again, we are questioning why DODD would want limit the scope of LPN practice. There are a few instances in this rule where this occurs, I have limited our comments to 2 examples. We would be happy to discuss this in more detail. In some instances, the use of LPNs would be a more cost effective way to deliver services. Ohio Board of Nursing rule 4723-17-03 (<i>Intravenous Therapy Procedures</i>) outlines what is permissible.</p>	Anita Allen, Vice President, Ohio Provider Resource Association	This rule is not limiting the scope of services that may be provided generally by Licensed Practical Nurses or Registered Nurses; the rule is clarifying those services that are reimbursable through the IO Waiver. This wording mirrors paragraph (A)(1)(b) of rule 5160-46-04 governing the Ohio Home Care Waiver. A group of nurses employed by county boards of developmental disabilities and providers recommended that paragraph (C)(3) be included in the rule as it provides helpful clarification.

Comment	By Whom	Department's Response
<b>(D):</b> We still have concerns about the lack of clarity in the rule on what the actual requirements will be for DODD staff who will be reviewing and either approving or denying this service. DODD includes this type of requirements in other rules (5123:2-8-01 Level of Care and 5123:2-14-01 Preadmission Screening and Resident Review). Although we have been told that services will not be denied without an RN making that decision, the process should be spelled out and the individuals responsible for the decisions defined. A denial would mean that someone is deeming a service ordered by the individual's doctor to be not medically necessary.	Stephen Mould, Communications Director, Ohio Health Care Association/Ohio Centers for Assisted Living/Ohio Centers for Intellectual Disabilities	Authorization for Waiver Nursing Services under the IO Waiver may be denied for reasons other than a lack of medical necessity. An individual who is denied services has an opportunity to request a hearing.
<b>(D)(1)(a):</b> We would suggest that the assessment tool the county boards will be using be included in the rule. Because the assessment is going to be a key part of determining eligibility, it is important that it is standardized, applied uniformly, readily available to service providers, and not subject to arbitrary changes.	Stephen Mould, Communications Director, Ohio Health Care Association/Ohio Centers for Assisted Living/Ohio Centers for Intellectual Disabilities	The assessment is not an assessment of the individual or the individual's needs; it is a way to identify resources available to meet the individual's previously determined needs.
<b>(D)(2):</b> It states that "waiver nursing services shall be authorized only when an individual's needs cannot be met through medication administration and nursing delegation..." So, if the services can be completed under medication administration and delegation, then it cannot be "waiver nursing services." How will this work?	Anita Allen, Vice President, Ohio Provider Resource Association	In accordance with paragraph (D)(3)(d), Waiver Nursing Services would not be authorized because the individual's needs can be met through other available resources.
<b>(D)(2):</b> Who defines what a client's needs are? Most of the DODD people that home health agencies work with in the Service and Support Administrators are social workers and not always able to see a nursing need in clients. Ohio Council for Home Care & Hospice (OCHCH) understands that a medication aide is less costly but will they truly be able to tell if the client is in trouble? The home health agencies deal with medically fragile children. We are concerned that things can go wrong with a nurse on duty much less an aide.	Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care & Hospice	Service and Support Administrators will not conduct a clinical assessment of individuals. Upon receiving a physician's order for nursing services, a representative from the county board of developmental disabilities will be required to assess the resources available to meet this need. Available resources may include unpaid supports, private insurance, Medicare, or Medicaid State Plan services.

<p><b>(D)(3):</b> When reviewing a service authorization request, the department shall determine whether the waiver nursing services for which authorization is requested are medically necessary unless the requested services have been determined by the Ohio Department of Medicaid not to be medically necessary within a twelve-month period immediately preceding the service authorization request, in which case a medical necessity review under this paragraph shall not be required. The department shall determine the services to be medically necessary if the services: ...</p> <p><b>Comment:</b> We had several comments on this provision. No one understands what it means. If the Ohio Department of Medicaid (ODM) found the services not to be necessary, then DODD will stand with ODM's decision and there is no further progress for the individual until 12 months is up? Or, DODD will ignore ODM and proceed with a different process? This provision needs to be clarified.</p> <p><b>Comment:</b> DODD will be determining whether Waiver Nursing Services are medically necessary. This is contrary to any practice conducted by DODD today. Is a physician at DODD going to be making this determination? Additionally, in making the determination of medical necessity, the factors to consider include whether the services are "the most efficient, effective, and lowest cost alternative that, when combined with non-waiver services, ensure the health and welfare of the individual receiving the services" and "are not otherwise available through other resources." See (D)(3)(c) to (D)(3)(d). What other resources -- Medicaid card? Private duty nursing? We have many questions about how this will work. For instance, if the service must first be utilized by the individual's Medicaid card and it is medically necessary under the card, then how would it not be medically necessary under Waiver Nursing Services?</p>	<p>Anita Allen, Vice President, Ohio Provider Resource Association</p>	<p>It means the Department may stand with the decision made by ODM that Medicaid-funded nursing services are not medically necessary. In instances where the Department has more information than was available to ODM, the Department may authorize Waiver Nursing Services. This is the same process we have used for authorization under the TDD Waiver. In response to your comment, however, paragraph (D)(3) has been revised as indicated:</p> <p><del>When reviewing a service authorization request, the department shall determine whether the waiver nursing services for which authorization is requested are medically necessary unless the requested services have been determined by the Ohio Department of Medicaid not to be medically necessary within a twelve-month period immediately preceding the service authorization request, in which case, a medical necessity review under this paragraph shall not be required. The department shall review a service authorization request to determine whether the requested services are medically necessary. When the Ohio department of medicaid has determined within the previous twelve months that the requested services are not medically necessary, the department may without further review accept the Ohio department of medicaid determination.</del> The department shall determine the services to be medically necessary if the services...</p> <p>Medical necessity is a universal requirement for Medicaid-funded services; please see rule 5160-1-01 (<i>Medicaid Medical Necessity: Definitions and Principles</i>).</p>
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<p>The TDD Waiver currently has a 60-day reassessment provision that is a billable service. This appears to be gone. Has it been deleted, or as a separate line service is this to be billed elsewhere?</p>	<p>Anita Allen, Vice President, Ohio Provider Resource Association</p>	<p>Paragraph (D)(4) of currently effective rule 5123:2-9-59 (<i>Waiver Nursing Services Under the Transitions Development Disabilities Waiver</i>) requires the Licensed Practical Nurse to conduct a face-to-face visit:</p> <ul style="list-style-type: none"> <li>• With the individual served and the directing Registered Nurse at least once every 120 days, and</li> <li>• With the directing Registered Nurse at least once every 60 days.</li> </ul> <p>The requirement for the Licensed Practical Nurse to conduct an additional face-to-face visit with the Registered Nurse every 60 days was not included in new rule 5123:2-9-39.</p>
<p>(E)(5): 120 days is too long without supervision.</p>	<p>Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care &amp; Hospice</p>	<p>The Ohio Board of Nursing rules do not appear to establish a requirement regarding the frequency of Registered Nurse supervision. The group of nurses employed by county boards of developmental disabilities and providers that provided input during development of the rule determined not to adopt all standards for Medicare-certified home health agencies. The rule requires supervision at least every 120 days; more frequent supervision may be provided if needed.</p>

Comment	By Whom	Department's Response
<p><b>(E)(6):</b> In all instances, when a treating physician gives verbal orders to the registered nurse or licensed practical nurse working at the direction of a registered nurse, the nurse shall record, in writing, the physician's orders, the date and time the orders were given, and the nurse shall subsequently secure documentation of the verbal orders signed and dated by the treating physician. <b>Comment:</b> What is the expected time frame for getting verbal orders signed?</p>	<p>Anita Allen, Vice President, Ohio Provider Resource Association</p>	<p>In response to your comment, paragraph (E)(6) has been revised as indicated:</p> <p>In all instances, when a treating physician gives verbal orders to the registered nurse or licensed practical nurse working at the direction of a registered nurse, the nurse shall record, in writing <u>within seven calendar days</u>, the physician's orders, the date and time the orders were given, and sign the entry in the service documentation. The nurse shall subsequently secure documentation of the verbal orders signed and dated by the treating physician.</p>
<p><b>(F)(1):</b> Define "Service Documentation" as it implies documentation of services, however, most visit notes do not contain (c), (e), (f), (g), or (k). Claims documentation does contain this information. Can you please explain how the above section seems to be more about billing documentation than actual nursing/home health aide documentation of services?</p>	<p>Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care &amp; Hospice</p>	<p>The rule specifies that the service documentation set forth in paragraph (F)(1) is required to validate payment for Medicaid services.</p>
<p><b>(F)(1)(e):</b> Add "or medical reference number."  Medicaid identification number of individual receiving service <u>or medical reference number</u>.</p>	<p>Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care &amp; Hospice</p>	<p>We do not know what is meant by "medical reference number" and a Medicaid identification number is required to validate payment for Medicaid services.</p>
<p><b>(F)(1)(g):</b> Why require provider identifier/contract number? Agencies bill electronically and it is on the claims.</p>	<p>Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care &amp; Hospice</p>	<p>This requirement is consistent with documentation for all services under Home and Community-Based Services waivers administered by the Department.</p>

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(F)(1)(j): Most of these requirements make sense. However, (F)(1)(j) includes a description and details of the services delivered, including the individual's response to "each medication." A response to each medication seems a bit much, especially for long-standing medications (like cholesterol meds), where you can't really document an immediate response to a medication.	Anita Allen, Vice President, Ohio Provider Resource Association	In response to your comment, paragraph (F)(1)(j) has been revised as indicated:  Description and details of the service delivered that directly relate to the services specified in the approved individual service plan as the services to be provided, including the individual's response to each medication, treatment, or procedure performed <u>in accordance with the physician's orders or plan of care.</u>
(F)(1)(k): Why require the number of units of the delivered service or continuous amount of uninterrupted time during which the service was provided? If agencies have start and end times, the Ohio Council for Home Care & Hospice does not see the need for repetitive information.	Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care & Hospice	The information is not repetitive but should be consistent. Paragraph (F)(1)(l) requires recording the times service begins and ends; paragraph (F)(1)(k) is the sum resulting from the times recorded as required by (F)(1)(l).
(F)(2)(d): Plan of Care initially and then recertified annually by the physician? This is unrealistic.	Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care & Hospice	Paragraph (E)(2)(e) of currently effective rule 5123:2-9-59 governing Waiver Nursing Services under the TDD Waiver requires the Plan of Care to be recertified every 60 days. Based on input from the group of nurses employed by county boards of developmental disabilities and providers, new rule 5123:2-9-39 requires the Plan of Care to be recertified annually.



Comment	By Whom	Department's Response
<b>(G)(2):</b> Paragraph (B)(19) provides that Waiver Nursing Services are services that require the skills of a Registered Nurse or Licensed Practical Nurse working at the direction of a Registered Nurse. Paragraph (B)(13) of current rule 5123:2-9-59 ( <i>Waiver Nursing Services Under the Transitions Developmental Disabilities Waiver</i> ) states this as well, but also provides that "waiver nursing services may include personal care aide services when provided incidental to waiver nursing services performed during the authorized waiver nursing services visit." This language is not present in the proposed rule. However, paragraph (G)(2) of the proposed rule notes that "homemaker personal care may be reimbursed as waiver nursing services when provided incidental to waiver nursing services performed during an authorized waiver nursing services visit." We are not sure if this language is supposed to align with what was removed/not present in the definition of waiver nursing services at (B)(19)? Or does this just include tasks completed by a Registered Nurse or Licensed Practical Nurse?	Anita Allen, Vice President, Ohio Provider Resource Association	New rule 5123:2-9-39 applies to Waiver Nursing Services under the IO Waiver. Personal Care Aide Services is not a service available under the IO Waiver. Paragraph (G)(2) is clarifying that a nurse providing services under the IO Waiver may provide Homemaker/Personal Care incidental to Waiver Nursing Services and bill for Waiver Nursing Services. Future work will focus on a funding mechanism for nursing delegation and health care coordination.
<b>(G)(2):</b> Homemaker/personal care <u>MAY</u> be reimbursed <u>AS</u> waiver nursing services when provided <u>INCIDENTAL</u> to waiver nursing services <u>PERFORMED</u> during an <u>AUTHORIZED WAIVER NURSING SERVICES VISIT</u> . <b>Comment:</b> Implies will be paying waiver nursing visit rate to non-clinicians. Which rate? Independent Provider RN or LPN?	Beth Foster, Director of Regulatory Affairs, Ohio Council for Home Care & Hospice	We believe paragraph (C)(2) of new rule 5123:2-9-39 is clear that only a Registered Nurse or Licensed Practical Nurse with a valid Ohio license may provide and bill for providing Waiver Nursing Services.
What is the process when there is disagreement, for instance when a physician's order is contrary to Ohio Department of Medicaid or Ohio Department of Developmental Disabilities determination or when a physician's order is contrary to Individual Service Plan authorization? What is the responsibility of the provider in these instances?	Anita Allen, Vice President, Ohio Provider Resource Association	The provider is responsible for expressing a dissenting opinion during the person-centered planning process. The existence of a physician's order alone does not make services medically-necessary.
Agencies are having difficulty envisioning what staffing patterns will be for someone who previously had a full day/shift of nursing under the Transitions Developmental Disabilities Waiver. Will they continue to have continual shift nursing support? Or, if some tasks can be completed by certified/delegated staff, will there be a mix of direct service professional and nursing hours in a day since waiver nursing will only be authorized when an individual's needs cannot be met through medication administration and nursing delegation? This could be very complicated and extremely difficult to staff.	Anita Allen, Vice President, Ohio Provider Resource Association	Service authorizations are based upon individual-specific needs identified through the person-centered planning process. This may include a combination of Homemaker/Personal Care, Medicaid State Plan services, and/or Waiver Nursing Services. Individuals who are assessed to require continual shift nursing may have that need addressed through Medicaid State Plan and/or Waiver Nursing Services.

Comment	By Whom	Department's Response
Nurses are required by law to receive/transcribe physician's orders for gastrostomy tubes and insulin. There is no mechanism to bill for this, making it another unfunded mandate.	Anita Allen, Vice President, Ohio Provider Resource Association	Nursing tasks performed while a nurse is working directly with an individual may be billed as Waiver Nursing Services.
There are a lot of moving parts in this model of service. It will take a great deal of time for the provider agencies to track services/supports, manage the paperwork, handle staffing challenges and ensure quality. This is another program that will take time and effort on the part of agencies, without any related reimbursement.	Anita Allen, Vice President, Ohio Provider Resource Association	Administrative costs of agency providers were factored into rate modeling and are reflected in the payment rate.
Home care nurses are often assigned and re-assigned. Therefore, an individual may receive care from many home care nurses, even in a one-month period. There is no reimbursement mechanism for the waiver agency nurse to coordinate services with the home care nurse or to coordinate services within their own agency. The optimum service model would provide for care coordination in which one nurse coordinates and oversees all the medical services that an individual receives. This allows for clear, concise and consistent transfer of information to other health care providers, family members, guardians, and agency staff. This model would reduce duplication of effort, reduce the opportunity for errors, and result in the most cost efficient service delivery system. We welcome the opportunity to discuss how nursing services can be streamlined and provide for the best possible quality of care.	Anita Allen, Vice President, Ohio Provider Resource Association	Future work will focus on a funding mechanism for health care coordination activities.
We need to be sure that Adult Family Living and Adult Foster Care can use nursing while billing. Will they be able to use Medicaid State Plan nursing service to serve the child or adult while the family sleeps, for example? This has been a worry since we started discussing adding nursing to the waiver. I don't know how often this is done. Medically fragile children staying on with their foster parents as part of their adult transition could really be in trouble.	Mary Hall	Individuals receiving shared living services such as Adult Family Living and Adult Foster Care are able to access Medicaid State Plan home health nursing services.
I realize the Department wants to roll the TDD Waiver into their current IO Waiver model and just add the nursing, but the changes it means for private duty nursing clients and their providers and families just seem unrealistic. I am not only worried about the services for my son, but for the entire TDD community that requires nursing services. I feel this move is restrictive and disruptive for many consumers. I have asked numerous questions on a local and state level about how this move is going to be implemented and no one has been able to give me a plan and procedure for this nursing transition and how it fits in with the waiver versus private duty billing, and why it really matters as Medicaid has paid the private duty portion for the most part. I am very worried about how people who have providers now will maintain their services, let alone their familiar providers. I asked about being on a planning or steering committee for this as well and I was told they look for people affiliated with certain organizations. I guess being a DD board member and a parent that has lived this for 18 years, as well as an advisor for Cincinnati Children's Hospital and community leader is not good enough. I am afraid the safety and security of consumers is potentially being compromised. I need to know and understand a lot more about how services are going to be determined and who is going to do it. I would be more than happy to discuss this further with any and all concerned.	Cara Hume	There are other ways to pay for needed nursing services. We expect teams to commence person-centered planning now to ensure sufficient time for smooth transition from the TDD Waiver to the IO Waiver. Authorization for IO Waiver Nursing Services will be based on individual-specific information and not solely on diagnoses and required tasks. Waiver Nursing Services will be authorized for individuals whose needs cannot be addressed by unlicensed personnel or other paid supports, such as those available through the Medicaid State Plan.