



townhall.virginia.gov

Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Dept. of Medical Assistance Services
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 30-50-132; 12 VAC 30-80-30
VAC Chapter title(s)	Amount, Duration, and Scope of Medical and Remedial Care Services and Methods and Standards for Establishing Payment Rate – Other Types of Care
Action title	Private Duty Nursing Services Under EPSDT
Date this document prepared	August 5, 2021

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

This regulatory action updates the Virginia Administrative Code to include the following items related to private duty nursing, in accordance with a mandate from the 2021 General Assembly: services covered, provider qualifications, medical necessity criteria, and rates.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

DMAS = Department of Medical Assistance Services

PDN = Private Duty Nursing

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, either:

- a) Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
- b) Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change

Item 313.MMM (2) of the 2021 Appropriations Act states that DMAS shall "have authority to promulgate any emergency regulations required to implement these necessary changes within 280 days or less from the enactment dated of this act."

There are currently no regulations governing Private Duty Nursing (PDN), and these regulations are required to provide clarity to Medicaid providers and members about what PDN services are, who may provide and be reimbursed for them, as well as who may obtain them.

During 2020 and 2021, DMAS engaged stakeholders to review and adjust the medical necessity criteria used to authorize PDN services. Stakeholders involved in this process included agencies currently providing PDN services, Managed Care Organizations (MCOs), and other State agencies. DMAS held four workgroup meetings to discuss adjustments to medical necessity criteria, as well as numerous subgroup meetings to make corresponding changes to the PDN authorization process. Based on stakeholder engagement, DMAS conducted two pilot tests of a revised PDN service authorization form – one pilot test with MCOs and one with PDN agencies. (The revised PDN service authorization form is attached to the end of this document.)

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts and Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The Code of Virginia § 32.1 325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance and to promulgate

regulations. The Code of Virginia § 32.1-324, grants the Director of the Department of Medical Assistance Services the authority of the Board when it is not in session.

Item 313.MMM(1) of the 2021 Appropriations Act states that DMAS shall make “changes to services covered, provider qualifications, medical necessity criteria, and rates and rate methodologies for private duty nursing.”

Item 313.MMM (2) of the 2021 Appropriations Act states that DMAS shall “have authority to promulgate any emergency regulations required to implement these necessary changes within 280 days or less from the enactment dated of this act.”

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

This regulation is essential to protect the health, safety, and welfare of citizens in that it establishes the regulatory framework for individuals with the need for high-intensity medical care. Having regulations in place (rather than just language in Medicaid manuals) helps ensure that the rules are clear and transparent, are that they are applied equally across providers, and across members. This ensures that quality care is provided to individuals who need it.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of Changes” section below.

The regulatory changes include a service description, a list of service components, provider qualifications, and service limits (which includes references to the documents needed to establish medical necessity).

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

The primary advantages to the public include having transparent rules that can be applied consistently to ensure that high quality private duty nursing care is provided to members who need it. There are no disadvantages to the public, the agency, or the Commonwealth.

Item 313.MMM(2) states that “[t]he adjustments to these services shall meet the needs of members and maintain budget neutrality by not requiring any additional expenditure of general fund beyond the current projected appropriation for such nursing services.”

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There are no alternatives that would satisfy the General Assembly mandate.

Periodic Review and Small Business Impact Review Announcement

If you wish to use this regulatory action to conduct, and this Emergency/NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and Executive Order 14 (as amended, July 16, 2018)), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete the paragraph below and insert “This NOIRA is not being used to announce a periodic review or a small business impact review.”

In addition, pursuant to Executive Order 14 (as amended, July 16, 2018) and § 2.2-4007.1 of the *Code of Virginia*, the agency is conducting a periodic review and small business impact review of this regulation to determine whether this regulation should be terminated, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare; (ii) minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

DMAS is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted by mail, email or fax to Emily McClellan, DMAS, 600 E. Broad Street, Richmond, VA 23219, by phone at (804) 371-4300, or

by email to: Emily.McClellan@dmas.virginia.gov In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the emergency regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
	12 VAC 30-50-132	No regulations currently exist for private duty nursing.	A new regulation is added, including a service description, a list of service components, provider qualifications, and service limits.
12 VAC 30-50 FORMS			The revised DMAS-62 form is added to the forms list and waiver forms that are no longer in existence have been removed.
12 VAC 30-80-30		Current regulations do not describe reimbursement for private duty nursing.	A section has been added to an existing regulation to describe reimbursement for private duty nursing.

The private duty nursing service authorization form is included on the following pages.



**Department of Medical Assistance Services
Medical Necessity Assessment and
Private Duty Nursing Service Authorization Form
(DMAS-62)**

Final eligibility for nursing services will be determined by DMAS, according to medical necessity, as documented in the member's clinical documentation. All points must correspond to actions performed and documented by the nurse.

If you have questions about this form contact DMAS Medical Services Unit at 804-786-8056 or see <https://dmas.kepro.com>.

Please submit this completed referral form and supporting clinical documentation (see additional guidance) through the Atrezzo portal, at <https://atrezzo.kepro.com>

MEMBER INFORMATION	
Member's Name:	Medicaid ID #:
DOB:	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female
Address:	Member phone #:
Parent/Guardian's Name:	Parent Phone #:
Address:	Active Protective Services case? <input type="checkbox"/> Yes <input type="checkbox"/> No
Primary Care Physician:	PCP Phone #:
REFERRAL SOURCE	
Referral Completed by (name):	<input type="checkbox"/> MD/DO <input type="checkbox"/> PA <input type="checkbox"/> NP <input type="checkbox"/> RN/LPN
Phone#:	Address:
Date of last visit to practitioner (PCP or specialist) or of last exam (Note* : Must be <90 days from the request date):	
Date Assessment/Referral Completed:	This is a: <input type="checkbox"/> New Request <input type="checkbox"/> Re-authorization Request <input type="checkbox"/> Request Due to Status Change More information:
NURSING AGENCY INFORMATION	
Phone#:	Person of Contact in Agency:

MEDICAL NEEDS ASSESSMENT		
Summarize daily medical needs to determine eligibility for Private Duty Nursing services.		
<u>All points claimed must correspond with needs both documented and completed by a medical professional.</u>		
<i>Please note the Private Duty Nursing agency can only claim points if the RN/LPN is physically present, documents performing the task.</i>		
<i>The agency cannot claim points for services provided by the primary caregiver of child</i>		
Medical Need	Point Value	Points claimed
<i>Respiratory</i>		
Tracheostomy (do not score if ventilator dependent)	5	
Tracheal suctioning*	Q < 1 hour or more frequently	8
	Q 1-4 hours	6
	Q > 4 hours or less frequently	4
	PRN (cannot score if routine suctioning is required)	2
Tracheostomy Care (Dressing change and change of trach ties; do not score if suctioning required)	1	
Nasal/oral/pharyngeal suctioning	Q < 1 hour-3 hours (not PRN)	6
	Q > 3-7 hours	4
	Q > 7 hours	3
	PRN (must be documented on nursing flow sheet)	2

* See additional guidance in Instructions for completing the Private Duty Nursing Medical Needs Assessment and Referral (DMAS- 62)

Medical Need		Point Value	Points claimed
Ventilator use	22-24 hours per day	25	
	12-21 hours per day	20	
	< 12 hours per day	15	
Oxygen	Via nasal cannula > 2L with titrations based on frequent desaturations (desaturations defined as pulse ox < 92%, sustained to > 1 minute, occurring > 3 times per shift) (At least 8 hours per day)	7	
	Via nasal cannula ≤2L (At least 8 hours per day)	6	
Continuous pulse ox (> 8 hours per day; do not score if also on oxygen)		4	
Oxygen via Heat and Moisture Exchanger (HME)		4	
BiPap or CPAP (no tracheostomy)	≥ 12 hours per day (nurse must be present at least 50% of time child is on BiPAP/CPAP)	12	
	< 12 hours per day (nurse must be present at least 50% of time child is on BiPAP/CPAP)	10	
Chest PT, vest, cough assist and/or nebulizer treatment	≥ Q4 hours	6	
	< Q4 hours	4	
	PRN (Cannot score if scheduled treatments are provided)	1	
Respiratory TOTAL:			
<i>Cardiovascular Access/Medications</i>			
Members who only need education for self-administration of prescribed subcutaneous (SQ), intramuscular (IM), or intravenous (IV) injections do not qualify for PDN services.			
Central Line use (Includes Implanted port, Peripherally inserted central catheter (PICC), triple lumen catheter, non-tunneled and tunneled catheter, hemodialysis)		5	
IV medications	< 4 hours apart	10	
	≥ 4 hours apart	6	
Intravenous Fluids (Continuous ≥ 12 hours)		6	
Total Parenteral Nutrition (TPN) (Nurse must be present at least 50% of time child is on TPN)		15	
Dressing changes/Flushing of lines		2	
Non-IV medications*	> 6 meds NG/PO/G-tube/per rectum medications administered per nursing shift (excluding Oxygen, nebulizer treatments, topical, OTC meds, PRN medications)	4	
	1 to 6 meds NG/PO/G-tube/per rectum medications administered per nursing shift (excluding Oxygen, nebulizer treatments, topical, OTC meds, PRN medications)	3	
Subcutaneous and/or IM injections	≥ 1 time / day	3	
	< 1 time / day (e.g., every other day; once/week)	2	
Continuous Glucose Monitoring (not on insulin pump requiring administration of subcutaneous insulin)		1	
Cardiovascular Access/Medication TOTAL:			
<i>Wound care (not including trach or G/J tube site)</i>			
Ostomy care		5	
Wound vacuum or drain		2	

* See additional guidance in Instructions for completing the Private Duty Nursing Medical Needs Assessment and Referral (DMAS- 62)
DMAS-62- Medical Needs Assessment and Private Duty Nursing Referral

Medical Need		Point Value	Points claimed
		Wound Care TOTAL:	
<i>Feeding</i>			
NG tube	Continuous (12 hours or more per day; nurse must be present during the entire feeding time)	20	
	Bolus	10	
Oral feeds: Documented difficult or prolonged oral feeding(> 30 min per 4 oz; nurse must be present during the entire feeding time; do not score if tube feeding is required)		4	
J/G-tube (score only one)	Continuous tube feeding performed by nurse (≥ 12 hours)	8	
	Tube feeding w/ frequent documented issues (e.g., residual checks, slow feed not to include venting, paced feeds)	6	
	Routine tube feeding by Nurse (< 12 hours)	5	
	Water bolus (via G-tube - requires MD order - ≥100 ml) 10ml/kg	3	
	Flushes	2	
		Feeding TOTAL:	
<i>Central Nervous System</i>			
	Seizures ≥ 3 per day requiring medical intervention*	8	
Seizures* Seizure observation alone does not qualify for skilled nursing care with an RN or LPN	Seizures < 3 per day requiring medical intervention*	6	
	Seizures which do not require medical intervention other than oxygen	4	
	Seizures which do not require medical intervention but require monitoring of heart rate, respiratory rate, pulse ox: ≥ 3 seizures per day	2	
	Seizures which do not require medical intervention but require monitoring of heart rate, respiratory rate, pulse ox: < 3 seizures per day	1	
		Central Nervous System TOTAL:	
<i>Assessments</i>			
Vital signs / neuro / respiratory / special assessments	≥ Q4 hours and recorded	3	
	Per shift and recorded	1	
		Assessments TOTAL:	
<i>Elimination and Toileting</i>			
Incontinence requiring intermittent, indwelling straight catheterization must be performed ≥ Q4 hours		4	
		Elimination and Toileting TOTAL:	
<i>Other. These tasks must be documented in the nursing notes. (These tasks must be documented for individual consideration and can be considered for additional points. These tasks do not meet the requirement for skilled nursing unless one of the above skilled tasks is also required)*</i>			
Uncontrolled incontinence, EITHER bowel (includes ostomy) or ,bladder with bed linen changes required greater than once daily for children ages ≥ 3 years		1	
Splinting removal and replacement	Q4 hours	2	
	Order ≥ Q5 hours	1	
Lifting/transfer required	Weight: > 150lbs	3	

* See additional guidance in Instructions for completing the Private Duty Nursing Medical Needs Assessment and Referral (DMAS- 62)
DMAS-62- Medical Needs Assessment and Private Duty Nursing Referral

Medical Need		Point Value	Points claimed
during shift, non-weight bearing Weight: _____ lbs	Weight: 100-150 lbs	2	
	Weight: < 100 lbs	1	
Combative and exhibits aggressive behaviors toward nurse/caregiver/self *		2	
Disorientation or confusion, or unwilling or unable to cooperate (age >3 years)		2	
Non-verbal/communication deficit (includes age >3 years)		1	
		Other TOTAL:	
EPSDT			
EPSDT	Are additional hours needed to correct or ameliorate the child's condition (ameliorate: to improve a condition or to prevent a condition from getting worse) <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, # of hours needed: Specific condition and additional needs (supporting documentation required):		

MEDICAL NEEDS FINAL SCORE			
Respiratory total		If Member's Total Medical Needs Score is**: = 1 to 4 points = Individual Consideration; Consider Home Health, Skilled Nursing (if ID/DD), Personal Care Services and/or adaptive technologies = 5 to 10 points = Up to 6 hours/day OR 42 hours/week = 11 to 20 points = Up to 8 hours/day OR 56 hours/week = 21 to 35 points = Up to 12 hours/day OR 84 hours/week = 36 to 45 points = Up to 16 hours/day OR 112 hours/week = >45 points = Individual Consideration	
Cardiovascular			
Access/Medications total			
Wound Care total			
Feeding total			
Central Nervous System total			
Assessments total			
Elimination & Toileting total			
Other total			
MEDICAL NEEDS SCORE:		MAX NURSING HOURS AWARDED PER WEEK:	

Note: Total nursing hours (any combination of RN and/or LPN and in any care setting) may not exceed the amount authorized by this form

Is the member receiving school-based nursing (submit IEP)? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many hours per week?	Is the member receiving school-based personal care services (submit IEP)? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, how many hours per week?
---	--

ATTENDING PHYSICIAN ORDER AND ATTESTATION	
The above named patient is in need of Private Duty Nursing services due to his/her current medical condition. Based on the member's medical necessity, I am prescribing: Private Duty Nursing for _____ hours per day, _____ days per week. Shift requested is _____ (am/pm) to _____ (am/pm).	
Attending Physician Signature (no stamps): _____	NPI #: Date:
<i>"I hereby attest that the information contained herein is current, complete and accurate to the best of my knowledge and belief. I understand that my attestation may result in provision of services which are paid for by state and federal funds and I also understand that whoever knowingly and willfully makes or causes to be made a false statement or representation may be prosecuted under the applicable federal and state laws."</i>	

* See additional guidance in Instructions for completing the Private Duty Nursing Medical Needs Assessment and Referral (DMAS- 62)
DMAS-62- Medical Needs Assessment and Private Duty Nursing Referral

Instructions for completing the Private Duty Nursing Medical Needs Assessment and Referral (DMAS-62)

Supporting clinical documentation required to be submitted along with this DMAS-62 includes:

- *The CMS-485, or equivalent*
- *Records of the Department of Education's last Individual Education Plan) IEP, if member is receiving or seeking Personal Care or PDN services delivered in a school setting and paid for by Medicaid; and*
- *Recent clinical documentation.*
 - *If a reauthorization review, include the most recent 2 weeks of nursing notes*
 - *If a new request, examples include: hospital or facility discharge summary, last 3 physician visit notes (primary or specialty care), etc.*

All nursing notes must be legible and easy to read by the reviewers.

All applicants are scored by the DMAS Medical Services Unit (MSU) upon each initial evaluation, renewal request, status change and triggering event.

All individuals are scored upon initial evaluation and reevaluation by a physician. Re-assess individuals upon hospital discharge to determine if care needs have changed. Send all initial assessments and follow up assessments to the DMAS MSU.

Individuals must receive a minimum score of 1 point to receive any level of Private Duty Nursing services.

Assign points in all relevant categories and record the total points under the "Medical Needs Score" at the bottom of the form. All points claimed must correspond to actions to be performed and documented by the nurse. Private Duty Nursing hours awarded will be provided only during the shift/hours which were scored. Private Duty Nursing hours should decrease when there is a decrease in an individual's total points.

Several areas in the Medical Needs Assessment section assign points based on the frequency of the need for the activity (e.g., tracheal suctioning Q 1-4 hours). The individual's nursing record must support the frequency. The agency plan of treatment and the medical needs assessment must document that the individual needs suctioning at this frequency of on an ongoing basis. For example, when an individual has an upper respiratory infection, the need for suctioning may increase, and the frequency determination should not be based on the individual's needs during illness but on the time when an individual is in their normal health status. Document increased need only when a substantial change in their health status has occurred.

ADDITIONAL GUIDANCE

Tracheal suctioning – Defined as suctioning of the trachea requiring a suction machine and flexible catheter. A member is ineligible for points in the suctioning category if he/she is able to suction their own trachea.

Tracheostomy care – Must be performed and documented by the PDN nurse. If a school-aged child has a stable capped tracheostomy and the school requires the presence of a skilled nurse, the PDN agency must document this service is not part of the IEP and/or the school.

Oxygen scores – These scores cannot be added together. Score the points if the member is on oxygen at >2L or if the oxygen needs are titrated based on pulse ox. This can also be used for members who are unstable on oxygen and desaturate often.

CPT/vest/nebulizer – Score points if the member receives CPT/Vest therapy and/or nebulizer treatment (for medications only, NOT saline).

Medications – Medication points relate to the complexity of the individual's medication regimen. Nebulizer treatments, topical, OTC, vitamins and mineral supplements, and PRN medications do not count as medications for the scoring below. Score points only for the number of medications provided per shift, irrespective of the number of doses or frequency of administration per medication.

Tube feeding with frequent documented issues – Score points if the member is receiving tube feedings and the feeding must be stopped > 4 times per week for issues such as documented intolerance to the feeding, requiring documented interventions by nurse. This may include halting the feeding and requiring a re-starting later in the shift, altering the rate of feeding, changing to oral rehydration fluids, or giving an enema/suppository.

Seizures medical intervention – Score points if the member requires the application of oxygen and the administration of medications.