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MEMORANDUM

TO: **BRIAN MCCORMICK**
Regulatory and Manual Section Manager
Department of Medical Assistance Services

FROM: **ELIZABETH A. MCDONALD**
Special Counsel to DMAS

DATE: **October 1, 2009**

SUBJECT: **Final Exempt Regulations regarding Nurse Practitioners Authorization of Durable Medical Equipment ("DME")**

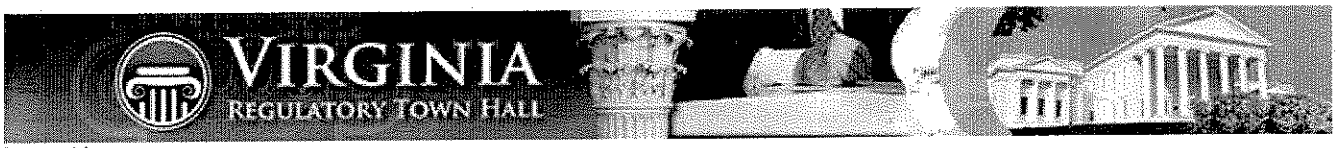
I have reviewed the attached final exempt regulations that will conform the Department of Medical Assistance's ("DMAS") regulations to nurse practitioners' licensing standards, which will permit nurse practitioners to order DME. You have asked the Office of the Attorney General to review and determine if DMAS has the legal authority to promulgate the final exempt regulations and if they comport with state and federal law.

Based on that review, it is my view that the Director, acting on behalf of the Board of Medical Assistance Services pursuant to Virginia Code §32.1-324, has the authority to promulgate these changes to the regulations, subject to compliance with the requirements of Article 2 of the Administrative Process Act and has not exceeded that authority.

The amendments to the regulations incorporate changes required by Chapter 855 of the 2004 Acts of the Assembly. Based on the foregoing, it is my view that the promulgation of these amendments is exempt from the procedures of Article 2 of the Administrative Process Act pursuant to Virginia Code § 2.2-4006(A)(4)(a).

If you have any questions, please contact me at 786-7363.

cc: Kim F. Piner
Senior Assistant Attorney General



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Final Text

Action: Nurse Practitioners Authorization of DME

Stage: Final 9/15/09 3:20 PM [latest]

12VAC30-50-165

12VAC30-50-165. Durable medical equipment (DME) and supplies suitable for use in the home.

A. Definitions. The following word and term when used in these regulations shall have the following meaning unless the context clearly indicates otherwise:

"Practitioner" means a provider of physician services as defined in 42 CFR 440.50 or a provider of nurse practitioner services as defined in 42 CFR 440.166.

B ~~A.~~ General requirements and conditions.

1. All medically necessary supplies and equipment shall be covered. Unusual amounts, types, and duration of usage must be authorized by DMAS in accordance with published policies and procedures. When determined to be cost effective by DMAS, payment may be made for rental of the equipment in lieu of purchase.

2. DME providers shall adhere to all applicable DMAS policies, laws, and regulations for durable medical equipment and supplies. DME providers shall also comply with all other applicable Virginia laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations shall result in denial of coverage for durable medical equipment or supplies that are regulated by such licensing agency or agencies.

3. DME and supplies must be furnished pursuant to a Certificate of Medical Necessity (CMN) (DMAS-352).

4. A CMN shall contain a ~~physician's~~ practitioner's diagnosis of a recipient's medical condition and an order for the durable medical equipment and supplies that are medically necessary to treat the diagnosed condition and the recipient's functional limitation. The order for DME or supplies must be justified in the written documentation either on the CMN or attached thereto. The CMN shall be valid for a maximum period of six months for Medicaid recipients 21 years of age and younger. The maximum valid time period for Medicaid recipients older than 21 years of age is 12 months. The validity of the CMN shall terminate when the recipient's medical need for the prescribed DME or supplies ends.

5. DME must be furnished exactly as ordered by the attending ~~physician~~ practitioner on the CMN. The CMN and any supporting verifiable documentation must be complete (signed and dated by the ~~physician~~ practitioner) and in the provider's possession within 60 days from the time the ordered DME and supplies are initially furnished by the DME provider. Each component of the DME must be specifically ordered on the CMN by the ~~physician~~ practitioner.

6. The CMN shall not be changed, altered, or amended after the attending ~~physician~~ practitioner has signed it. If changes are necessary, as indicated by the recipient's condition, in the ordered DME or supplies, the DME provider must obtain a new CMN. New CMNs must be signed and dated by the attending ~~physician~~ practitioner within 60 days from the time the ordered supplies are furnished by the DME provider.

7. DMAS shall have the authority to determine a different (from those specified above) length of time a CMN may be valid based on medical documentation submitted on the CMN. The CMN may be completed by the DME provider or other health care professionals, but it must be signed and dated by the attending ~~physician~~ practitioner. Supporting documentation may be attached to the CMN but the attending ~~physician's~~ practitioner's entire order must be on the CMN.

8. The DME provider shall retain a copy of the CMN and all supporting verifiable documentation on file for DMAS' post payment audit review purposes. DME providers shall not create or revise CMNs or supporting documentation for this service after the initiation of the post payment review audit process. Attending ~~physicians~~ practitioners shall not complete, or sign and date, CMNs once the post payment audit review has begun.

C ~~B~~. Preauthorization is required for incontinence supplies provided in quantities greater than two cases per month.

D ~~C~~. Supplies, equipment, or appliances that are not covered include, but are not limited to, the following:

1. Space conditioning equipment, such as room humidifiers, air cleaners, and air conditioners;

2. Durable medical equipment and supplies for any hospital or nursing facility resident, except ventilators and associated supplies or specialty beds for the treatment of wounds consistent with DME criteria for nursing facility residents that have been approved by DMAS central office;

3. Furniture or appliances not defined as medical equipment (such as blenders, bedside tables, mattresses other than for a hospital bed, pillows, blankets or other bedding, special reading lamps, chairs with special lift seats, hand-held shower devices, exercise bicycles, and bathroom scales);

4. Items that are only for the recipient's comfort and convenience or for the convenience of those caring for the recipient (e.g., a hospital bed or mattress because the recipient does not have a decent bed; wheelchair trays used as a desk surface); mobility items used in addition to primary assistive mobility aide for caregiver's or recipient's convenience (e.g., electric wheelchair plus a manual chair); cleansing wipes;

5. Prosthesis, except for artificial arms, legs, and their supportive devices, which must be preauthorized by the DMAS central office (effective July 1, 1989);

6. Items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (e.g., dentifrices; toilet articles; shampoos that do not require a ~~physician's~~ practitioner's prescription; dental adhesives; electric toothbrushes; cosmetic items, soaps, and lotions that do not require a ~~physician's~~ practitioner's prescription; sugar and salt substitutes; and support stockings);

7. Orthotics, including braces, splints, and supports;

8. Home or vehicle modifications;

9. Items not suitable for or not used primarily in the home setting (e.g., car seats, equipment to be used while at school, etc.); and

10. Equipment for which the primary function is vocationally or educationally related (e.g., computers, environmental control devices, speech devices, etc.).

E. ~~D~~. For coverage of blood glucose meters for pregnant women, refer to 12VAC30-50-510.

F ~~E~~. Coverage of home infusion therapy. Home infusion therapy shall be defined as the intravenous administration of fluids, drugs, chemical agents, or nutritional substances to recipients in the home setting. DMAS shall reimburse for these services, supplies, and drugs on a service day rate methodology established in 12VAC30-80-30. The therapies to be covered under this policy shall be: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). All the therapies that meet criteria will be covered for three months. If any therapy service is required for longer than the original three months, prior authorization shall be required for the DME component for its continuation. The established service day rate shall reimburse for all services delivered in a single day. There shall be no additional reimbursement for special or extraordinary services. In the event of incompatible drug administration, a separate HCPCS code shall be used to allow for rental of a second infusion pump and purchase of an extra administration tubing. When applicable, this code may be billed in addition to the other service day rate codes. There must be documentation to support the use of this code on the I.V. Implementation Form. Proper documentation shall include the need for pump administration of the medications ordered, frequency of administration to support that they are ordered simultaneously, and indication of incompatibility. The service day rate payment methodology shall be mandatory for reimbursement of all I.V. therapy services except for the recipient who is enrolled in the Technology Assisted waiver program. The following limitations shall apply to this service:

1. This service must be medically necessary to treat a recipient's medical condition. The service must be ordered and provided in accordance with accepted medical practice. The service must not be desired solely for the convenience of the recipient or the recipient's caregiver.

2. In order for Medicaid to reimburse for this service, the recipient must:

a. Reside in either a private home or a domiciliary care facility, such as an adult care residence. Because the reimbursement for DME is already provided under institutional reimbursement, recipients in hospitals, nursing facilities, rehabilitation centers, and other institutional settings shall not be covered for this service;

b. Be under the care of a ~~physician~~ practitioner who prescribes the home infusion therapy and monitors the progress of the therapy;

c. Have body sites available for peripheral intravenous catheter or needle placement or have a central venous access; and

d. Be capable of either self-administering such therapy or have a caregiver who can be adequately trained, is capable of administering the therapy, and is willing to safely and efficiently administer and monitor the home infusion therapy. The caregiver must be willing to and be capable of following appropriate teaching and adequate monitoring. In those cases where the recipient is incapable of administering or monitoring the prescribed therapy and there is no adequate or trained caregiver, it may be appropriate for a home health agency to administer the therapy.

G ~~F~~. The medical equipment and supply vendor must provide the equipment and supplies as prescribed by the ~~physician~~ practitioner on the certificate of medical necessity. Orders shall not be changed unless the vendor obtains a new certificate of medical necessity prior to ordering or providing the equipment or supplies to the patient.

H ~~G.~~ Medicaid shall not provide reimbursement to the medical equipment and supply vendor for services provided prior to the date prescribed by the ~~physician~~ practitioner or prior to the date of the delivery or when services are not provided in accordance with published policies and procedures. If reimbursement is denied for one of these reasons, the medical equipment and supply vendor may not bill the

Medicaid recipient for the service that was provided.

I ~~H.~~ The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to the department. Medically necessary DME and supplies shall be:

1. Ordered by the ~~physician~~ practitioner on the CMN;

2. A reasonable and necessary part of the recipient's treatment plan;

3. Consistent with the recipient's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the recipient;

4. Not furnished solely for the convenience, safety, or restraint of the recipient, the family, attending ~~physician~~ practitioner, or other practitioner or supplier;

5. Consistent with generally accepted professional medical standards (i.e., not experimental or investigational); and

6. Furnished at a safe, effective, and cost-effective level suitable for use in the recipient's home environment.

J ~~I.~~ Coverage of enteral nutrition (EN) which does not include a legend drug shall be limited to when the nutritional supplement is the sole source form of nutrition, is administered orally or through a nasogastric or gastrostomy tube, and is necessary to treat a medical condition. Coverage of EN shall not include the provision of routine infant formula. A nutritional assessment shall be required for all recipients receiving nutritional supplements.

12VAC30-60-75
12VAC30-60-75. Durable medical equipment (DME) and supplies.

A. DME providers as defined in 12VAC30-50-165, shall retain copies of the CMN and all applicable supporting documentation on file for post payment audit reviews. Durable medical equipment and supplies that are not ordered on the CMN for which reimbursement has been made by Medicaid will be retracted. Supporting documentation is allowed to justify the medical need for durable medical equipment and supplies. Supporting documentation does not replace the requirement for a properly completed CMN. The dates of the supporting documentation must coincide with the dates of service on the CMN and the medical practitioner providing the supporting documentation must be identified by name and title. DME providers shall not create or revise CMNs or supporting documentation for durable medical equipment and supplies provided after the post payment audit review has been initiated.

B. Persons needing only DME/supplies may obtain such services directly from the DME provider without having to consult or obtain services from a home health service or home health provider. DME/supplies must be ordered by the ~~physician~~, practitioner (physician or nurse practitioner) be related to the medical treatment of the patient, and the complete order must be on the CMN for persons receiving DME/supplies. Supplies used for treatment during the visit are included in the visit rate of the home health provider. Treatment supplies left in the home to maintain treatment after the visits shall be charged separately.

12VAC30-120-195
12VAC30-120-195. Enteral nutrition products.

A. General requirements and conditions.

1. Enteral nutrition products shall only be provided by enrolled durable medical equipment (DME) providers as defined in 12VAC30-50-165.

2. DME providers shall adhere to all applicable DMAS policies, laws, and

regulations for enteral nutrition products. DME providers shall also comply with all other applicable Virginia laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations shall result in denial of coverage for enteral nutrition that is regulated by such licensing agency or agencies.

B. Service units and service limitations.

1. DME and supplies must be furnished pursuant to the AIDS Waiver Enteral Nutrition Evaluation Form (DMAS-116).

2. A DMAS-116 shall be required for all AIDS waiver recipients receiving enteral nutrition products. Enteral nutrition products that do not contain a legend drug may be obtained for the individual receiving waiver services for conditions of AIDS and HIV-symptomatic when the enteral nutrition product is certified by the ~~physician~~ practitioner as the primary source of nutrition, is administered orally or through a nasogastric or gastrostomy tube, and is necessary for the successful implementation of the individual's health care plan and the individual is not able to purchase enteral nutrition products through other means. Coverage of enteral nutrition products does not include the provision of routine infant formula. The amount of enteral nutrition products that shall be reimbursed by Medicaid shall be limited by medical necessity and cost effectiveness.

3. "Primary source" means that enteral nutrition products are medically indicated for the treatment of the individual's condition if the individual is unable to tolerate other forms of nutrition. The individual may either be unable to take any oral nutrition or the oral intake that can be tolerated is inadequate to sustain life. The focus must be on the maintenance of weight and strength commensurate with the individual's medical condition.

4. The DMAS-116 shall contain a ~~physician's~~ practitioner's order for the enteral nutrition products that are medically necessary to treat the diagnosed condition and the individual's functional limitation. The order for enteral nutrition products must be justified in the written documentation either on the DMAS-116 or attached thereto. The DMAS-116 shall be valid for a maximum period of six months. The validity of the DMAS-116 shall terminate when the individual's medical need for the prescribed enteral nutrition products either ends or when the enteral nutrition products are no longer the primary source of nutrition.

5. A face-to-face nutritional assessment completed by trained clinicians (e.g., physician, physician assistant, nurse practitioner, registered nurse, or a registered dietitian) must be completed as required documentation of the need for enteral nutrition products for both the initial order and every six months. The DMAS-116 is required every six months.

6. The DMAS-116 shall not be changed, altered, or amended after the ~~physician~~ practitioner has signed it. As indicated by the individual's condition, if changes are necessary in the ordered enteral nutrition products, the DME provider must obtain a new DMAS-116. New DMAS-116 must be signed and dated by the ~~physician~~ practitioner within 60 days from the time the ordered enteral nutrition products are furnished by the DME provider. The order cannot be back-dated to cover prior dispensing of enteral nutrition products. If the order is not signed within 60 days of the service initiation, then the date the order is signed becomes the effective date.

7. Preauthorization of enteral nutrition products is not required. The DME provider must assure that there is a valid DMAS-116 completed every six months in accordance with DMAS policy and on file for all Medicaid individuals for whom enteral nutrition products are provided. The DME provider is further responsible for assuring that enteral nutrition products are provided in accordance with DMAS reimbursement criteria. Upon post payment review, DMAS will deny reimbursement for any enteral nutrition products that have not been provided and

billed in accordance with these regulations.

8. DMAS shall have the authority to determine that the DMAS-116 is valid for less than six months based on medical documentation submitted.

C. Provider responsibilities.

1. The DME provider must provide the enteral nutrition products as prescribed by the ~~physician~~ practitioner on the DMAS-116. Orders shall not be changed unless the DME provider obtains a new DMAS-116 prior to ordering or providing the enteral nutrition products to the individual.

2. The ~~physician's~~ practitioner's order (DMAS-116) must state that the enteral nutrition products are the primary source of nutrition for the individual and specify either a brand name of the enteral nutrition product being ordered or the category of enteral nutrition products that must be provided. If a ~~physician~~ practitioner orders a specific brand of enteral nutrition product, the DME provider must supply the brand prescribed. The ~~physician~~ practitioner order must include the daily caloric order and the route of administration for the enteral nutrition product. Supporting documentation may be attached to the DMAS-116 but the entire order must be on the DMAS-116.

3. Enteral nutrition products must be furnished exactly as ordered by the ~~physician~~ practitioner on the DMAS-116. The DMAS-116 and any supporting verifiable documentation must be complete (signed and dated by the ~~physician~~ practitioner) and in the DME provider's possession within 60 days from the time the ordered enteral nutrition product is initially furnished by the DME provider.

4. The DMAS-116 may be completed by the registered nurse, registered dietitian, physician, physician assistant, or nurse practitioner, but it must be signed and dated by the physician.

5. The DMAS-116 must be signed and dated by the assessor and the ~~physician~~ practitioner within 60 days of the DMAS-116 begin service date. If the DMAS-116 is not signed and dated by the assessor and the ~~physician~~ practitioner within 60 days of the DMAS-116 begin service date, the DMAS-116 will not become valid until the date of the ~~physician's~~ practitioner's signature.

6. The DMAS-116 must include all of the following elements:

a. Height (or length for pediatric patients);

b. Weight. For initial assessments, indicate the individual's weight loss over time;

c. Tolerance of enteral nutrition product (e.g., is the individual experiencing diarrhea, vomiting, constipation). This element is only required if the individual is already receiving enteral nutrition products;

d. Indication of whether or not the enteral nutrition product is the primary or sole source of nutrition;

e. Route of administration;

f. The daily caloric order and the number of calories per package, can, etc.;

g. Extent to which the quantity of the enteral nutrition product is available through WIC; and

h. Title, signature, and date of the assessor and the ~~physician~~ practitioner.

7. The DME provider shall retain a copy of the DMAS-116 and all supporting verifiable documentation on file for DMAS' post payment review purposes. DME providers shall not create or revise DMAS-116 or supporting documentation for this service after the initiation of the post payment review process. ~~Physicians~~

Practitioners shall not complete, or sign and date, DMAS-116 once the post payment review has begun.

8. DME providers shall retain copies of the DMAS-116 and all applicable supporting documentation on file for post payment reviews. Enteral nutrition products that are not ordered on the DMAS-116 for which reimbursement has been made by Medicaid will be denied. Supporting documentation is allowed to justify the medical need for enteral nutrition products. Supporting documentation does not replace the requirement of a properly completed DMAS-116. The dates of the supporting documentation must coincide with the dates of service on the DMAS-116 and the medical practitioner providing the supporting documentation must be identified by name and title. DME providers shall not create or revise DMAS-116 or supporting documentation for enteral nutrition products provided after the post payment review has been initiated.

9. To receive reimbursement, the DME provider is expected to:

a. Deliver only the item or items ordered by the ~~physician~~ practitioner and approved by DMAS or the designated preauthorization contractor;

b. Deliver only the quantities ordered by the ~~physician~~ practitioner and approved by DMAS or the designated preauthorization contractor;

c. Deliver only the item or items for the periods of service covered by the ~~physician's~~ practitioner's order and approved by DMAS or the designated preauthorization contractor;

d. Maintain a copy of the ~~physician's~~ practitioner's order and all verifiable supporting documentation for all DME ordered;

e. Document all supplies provided to an individual in accordance with the ~~physician's~~ practitioner's orders. The delivery ticket must document the individual's name and Medicaid number, the date of delivery, what was delivered, and the quantity delivered.

10. DMAS will deny payment to the DME provider if any of the following occur:

a. No presence of a current, fully completed DMAS-116 appropriately signed and dated by the ~~physician~~ practitioner;

b. Documentation does not verify that the item was provided to the individual;

c. Lack of medical documentation, signed by the ~~physician~~ practitioner to justify the enteral nutrition products; or

d. Item is noncovered or does not meet DMAS criteria for reimbursement.

11. The enteral nutrition product vendor must provide the supplies as prescribed by the ~~physician~~ practitioner on the DMAS-116. Orders shall not be changed unless the vendor obtains a new DMAS-116 prior to ordering or providing the enteral nutrition product to the individual.

12. Medicaid shall not provide reimbursement to the vendor for services provided prior to the date prescribed by the ~~physician~~ practitioner or prior to the date of the delivery or when services are not provided in accordance with published policies and procedures. If reimbursement is denied for one of these reasons, the DME provider may not bill the Medicaid recipient for the service that was provided.

13. The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS. Medically necessary DME and supplies shall be:

a. Ordered by the ~~physician~~ practitioner on the DMAS-116.

b. A reasonable and necessary part of the individual's treatment plan;

c. Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual;

d. Not furnished solely for the convenience, safety, or restraint of the individual, the family, attending ~~physician~~ practitioner, or other practitioner or supplier;

e. Consistent with generally accepted professional medical standards (i.e., not experimental or investigational); and

f. Furnished at a safe, efficacious, and cost-effective level suitable for use in the individual's home environment.