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Final Regulation
Agency Background Document

Agency name	DEPT. OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation(s)	12VAC30-50-165
Regulation title(s)	Durable Medical Equipment (DME) and Supplies Suitable for Use in the Home
Action title	Clarifications for Durable Medical Equipment and Supplies
Date this document prepared	July 26, 2019

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 (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) 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. If applicable, generally describe the existing regulation.

The Virginia Department of Medical Assistance Services (DMAS) proposes to amend 12VAC30-50-165, Durable Medical Equipment (DME) and Supplies Suitable for Use in the Home. The changes for this regulatory section are intended to update coverage and documentation requirements to better align them with best practices and Centers for Medicare and Medicaid (CMS) guidance, and to eliminate unnecessary elements that create confusion among DME providers. Specifically, these proposed changes include elements around: enteral nutrition, implantable pumps, delivery ticket components, and replacement DME after a disaster.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

DMAS = Department of Medical Assistance Services
DME = Durable Medical Equipment and Supplies
CMS = Centers for Medicare and Medicaid

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

I hereby approve the foregoing Regulatory Review Summary entitled "Clarifications for Durable Medical Equipment and Supplies" and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012, of the Administrative Process Act.

7/26/2019
Date

/Jennifer S. Lee, M.D./
Jennifer S. Lee, M.D., Director

Dept. of Medical Assistance Services

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no changes to the previously-reported information.

Legal Basis

Please identify (1) the agency or other promulgating entity, 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 of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Section 32.1-325 of the Code of Virginia authorizes the Board of Medical Assistance Services to administer and amend the State Plan for Medical Assistance and to promulgate regulations. Section 32.1-324 of the Code of Virginia authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the State Plan for Medical Assistance and to promulgate regulations according to the Board's requirements. The Medicaid authority as established by § 1902 (a) of the Social Security Act (42 USC § 1396a) provides governing authority for payments for services.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

As practices evolve and coverage is provided under the State Medicaid Plan, there are times when it becomes necessary to amend regulations to conform them to best practices and new guidance from CMS, and to eliminate areas of confusion moving forward. It is expected that these changes will clarify coverage of DME and supplies for DME providers and Medicaid beneficiaries, and reduce unnecessary documentation elements for DME providers. Further, the changes will improve coverage by permitting newer and better forms of service delivery that have evolved in recent years and align Virginia's coverage with recent guidance from CMS for enteral nutrition.

These regulatory changes will improve the health, safety, and welfare of the affected Medicaid individuals by providing care coordination and well-person preventive services.

Substance

Please 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.

1. **Enteral Nutrition**

   Current Coverage Requires:

   Current coverage in Virginia requires that enteral nutrition be the primary or sole source of nutrition (defined) in order to qualify for coverage. In addition, DME providers must indicate on the Certificate of Medical Necessity (CMN) if the enteral nutrition is covered through Women, Infants, and Children (WIC), a program of the U.S. Department of Agriculture.

   CMS has provided new, written guidance to Virginia on coverage for enteral nutrition. This includes the elimination of the requirement that such enteral nutrition be the Medicaid beneficiary's primary or sole source of nutrition. The guidance further spells out coverage requirements as they relate to medical foods, over the counter products, and dietary

restrictions. Lastly, the subsection on enteral nutrition has documentation requirements that are redundant and required of all providers as stated in an earlier subsection.

DMAS Recommends the Final Changes:

Amending the section to update and conform Medicaid coverage of enteral nutrition to guidance from CMS and to reduce redundant language and requirements.

2. Infusion Therapy:

Current Coverage Requires:

Current coverage in Virginia defines home infusion therapy as the administration of intravenous fluids, drugs, chemical agents, or nutritional supplements.

Best practices for delivering home infusion therapy now include the option for providing such services intravenously (I.V.) or through an implantable pump.

DMAS Recommends the Final Changes:

Amending the section to permit the use of implantable pumps for delivering home infusion therapy.

3. Delivery Ticket Components:

Current Coverage Requires:

DME providers are currently required to include the Medicaid beneficiary's name and Medicaid number or date of birth on the delivery ticket. Further, DME providers must include the serial number(s) or the product numbers of the DME or supplies.

The delivery ticket requirements are unnecessary and burdensome to DME providers.

DMAS Recommends the Final Changes:

Amending the delivery ticket requirements to streamline them/enhance flexibility, and by providing an alternative option of utilizing an individual's medical record number.

4. **Replacement DME**:

Current Coverage Requires:

The regulation does not currently identify a process for providing replacement DME to Medicaid beneficiaries who have lost DME or had DME destroyed as a result of a disaster.

It has become evident to DMAS that a process should be developed and implemented to ensure quality care and protect the health and safety of Medicaid beneficiaries.

DMAS Recommends the Final Changes:

Amending the section to identify the process and requirements for providing replacement DME to Medicaid beneficiaries who have lost DME or had DME destroyed as a result of a disaster.

Issues

Please 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.

Some of DMAS' current DME coverage and requirements are no longer in step with evolving industry practices. These changes will ensure that the Agency's regulations are in line with current best practice.

The primary advantages to the public, the Agency, and the Commonwealth from this regulatory package include enhanced service delivery to DME beneficiaries, and greater consistency between Virginia regulations and current CMS practice. There are no disadvantages to the public or the Commonwealth as a result of these regulatory changes.

Requirements More Restrictive than Federal

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no changes to the previously-reported information: there are no requirements in this regulation that are more restrictive than applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no changes to the previously-reported information: no agencies, localities, or other entities will be particularly affected, as this regulation will apply statewide.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

No comments were received during the Proposed Stage public comment period.

Detail of Changes Made Since the Previous Stage

*Please list all changes that made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

Changes since proposed stage: there are no changes to the previously-reported information.