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Proposed 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	October 25, 2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. 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 natural 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

Legal Basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should 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's overall regulatory authority.

The *Code of Virginia* (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The *Code of Virginia* (1950) as amended, §§ 32.1-324 and 325, authorizes the Director of DMAS to administer and amend the Plan for Medical Assistance according to the Board's requirements. The Medicaid authority as established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a] provides governing authority for payments for services.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is 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 Proposed 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 Proposed 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 Proposed 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 Proposed 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 proposed regulatory action, 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, please indicate.

The current coverages do not conform to best practices and processes, as required by CMS, to ensure quality care and protect the health and safety of Medicaid individuals.

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 identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements in this regulation that are more restrictive than applicable federal requirements.

Localities Particularly Affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No localities will be particularly affected, as this regulation will apply statewide.

Public Participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Charlotte Arbogast, DMAS, 600 E. Broad Street, Richmond, VA 23219, fax: (804) 452-5468, or Charlotte.Arbogast@dmas.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

Economic Impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	$2,308,065 per year (12-month cost projection).
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Members within the allowed age range and criteria. The volume is unknown at this time.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The majority of the Medicaid-enrolled DME providers, totaling around 1,400, are small businesses. However, DMAS anticipates that this regulation will be viewed favorably by the DME providers.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	There are no reporting, recordkeeping, or administrative costs required for compliance by small businesses. There are no costs related to the development of real estate.
Beneficial impact the regulation is designed to produce.	The regulation is designed to update coverage and documentation requirements to better align them with best practices and CMS guidance, and to eliminate unnecessary elements that create confusion among DME providers.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. 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 regulation.

No alternatives would meet the requirements of the legislative mandate.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

This regulatory action does not establish any compliance or reporting requirements or performance standards for small businesses.

Family Impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; nor encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. It does not strengthen or erode the marital commitment, and does not increase or decrease disposable family income.

Public Comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No comments were submitted during the NOIRA public comment period.

Detail of Changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
12VAC30-50-165		Enteral Nutrition: Under the current requirement, enteral nutrition is to be the Medicaid beneficiary's primary or sole source of nutrition. The subsection on enteral nutrition also has documentation requirements that are redundant and required of all providers as stated in an earlier subsection. Infusion Therapy: The current requirement does not follow best practices for delivering home infusion therapy, as mandated by CMS. Delivery Ticket Components: Currently, the delivery ticket requirements are unnecessary and burdensome to DME providers. Replacement DME: The current regulation does not identify a process for providing replacement DME to Medicaid beneficiaries who have lost DME or had DME destroyed as a result of a natural disaster.	Enteral Nutrition: Amend the section to update and conform Medicaid coverage of enteral nutrition to guidance from CMS and to reduce redundant language and requirements. Infusion Therapy: Amend the section to permit the use of implantable pumps for delivering home infusion therapy. Delivery Ticket Components: Amend the delivery ticket requirements to streamline them and reduce unnecessary burden on DME providers. Replacement DME: Amend 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.