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Emergency Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC30-50-165
VAC Chapter title(s)	Durable medical equipment suitable for use in the home
Action title	Clarifications for Durable Medical Equipment and Supplies—Revisions
Date this document prepared	August 26, 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 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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).

The purpose of this action is to amend section 12VAC30-150-165 of the Durable Medical Equipment & Supplies (DME) regulations in order to align the regulations with federal requirements. Based on the Home Health final rule for DME, the Centers for Medicare and Medicaid Services (CMS) is mandating a change to the DME definition that will increase access to DME for community use. CMS is also requiring DMAS to remove several items from our non-covered services list and add appeal rights to the regulation language that is already a part of the DME provider guidance manual. Additionally, changes are being made to align the regulations with 42 CFR 440.70(b)(3), which allows that DME may be ordered by a physician or "other licensed practitioner."

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.

CMS = Centers for Medicare and Medicaid Services
DMAS = Department of Medical Assistance Services
DME = Durable Medical Equipment & Supplies
F2F = Face-to-Face

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.

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled "Clarifications for Durable Medical Equipment and Supplies—Revisions" in accordance with Section 2.2-4011 B of the Code of Virginia.

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 of 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.

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment.

The 2021 Appropriation Act (Special Session 1), Item 313.QQQQQ, the 2022 Appropriation Act (Special Session 1), Item 304.QQQ, the 2023 Appropriation Act (Special Session 1), Item 304.QQQ, the 2024 Appropriation Act (Special Session 1), Item 288.RRR, the 2025 Appropriation Act, Item 288.RRR, and the 2026 Appropriation Act (Special Session 1), Item 291.MMM, state that DMAS shall "expand the definition of durable medical equipment per 42 CFR 440.70 (b) (3), so that the definition is no longer limited to items primarily used in the home but also extends to any setting where normal activities take place. The Department shall have the authority to promulgate emergency regulations to implement this amendment within 280 days or less from the enactment 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.

The purpose of this regulatory action is to amend section 12VAC30-150-165 of the DME regulations in order to align the regulations with federal requirements in accordance with Item 313.QQQQQ of the 2021 Appropriation Act, Item 304.QQQ of the 2022 Appropriation Act, Item 304.QQQ of the 2023 Appropriation Act, Item 288.RRR of the 2024 Appropriation Act (Special Session 1), Item 288.RRR of the 2025 Appropriation Act, and Item 291.MMM of the 2026 Appropriation Act (Special Session 1). Prior to this change in the DME definition, DMAS required DME to be primarily used in the home. The new DME definition removes this requirement and allows for the use of DME in any environment where normal life activities take place. These changes also allow for DME to be ordered by a physician or other licensed practitioners in accordance with 42 CFR 440.70(b)(3). This will allow better access to community settings for Medicaid members.

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.

These changes are being made to align with the Home Health final rule which includes the DME definition change and face-to-face (F2F) requirements. Prior to this amendment to the DME definition, DMAS required that DME be used primarily in a home setting. The new DME definition removes this requirement and allows DME use in any environment where normal life activities take place. This will allow better access to, and enhanced participation in, community settings.

During CMS review of a state plan amendment on this topic, CMS required DMAS to remove specific non-covered services from the State Plan. This regulatory action mirrors those changes. Appeals rights language has been added to the regulations as well, to match the State Plan text.

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.

There are no disadvantages that result from this regulatory action. This action will increase coverage and program access for community members.

Alternatives to Regulation

Describe all viable alternatives to the proposed regulatory action that have been considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

No other alternatives to regulatory action would meet the requirements of the legislative mandate.

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 section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
12VAC30-50-165		DME definition includes 'primarily used in the home'.	To align the DME definition with 42 CFR 440.70(b)(3) and remove 'primarily used in the home'.
12VAC30-50-165		F2F requirement was added to the DME provider manual (7/19) and to the State Plan (10/20).	Added F2F requirements to regulations to align with State Plan and DMAS guidance manual.
12VAC30-50-165		Regulations includes listing of non-covered services.	Per CMS guidance, DMAS removed several services from the non-covered

			list as they are covered under other programs, though not by DME.
12VAC30-50-165		Appeals language not included.	Adds appeals rights language to the regulations, per CMS-directive.
12VAC30-50-165		Defines “practitioner” according to 42 CFR 440.50	Adds that “practitioner” can also be defined as a provider of “other licensed practitioner services” as defined in 42 CFR 440.60.
12VAC30-50-165		Requires that “physician” orders shall not be changed.	Replaces the word “physician” with “practitioner” to reflect that “practitioner orders shall not be changed.”