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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Virginia Department of Medical Assistance Services (DMAS)
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	March 13, 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.*

Subject Matter and Intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

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.

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

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.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

CURRENT POLICY

The below outlines the current policy for several items proposed for amending under 12VAC30-50-165 for DME and supplies:

1. Enteral Nutrition: 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.

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

3. Delivery Ticket Components: 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.

4. Replacement DME: 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.

ISSUES

The below outlines the issues with the items for which amendments have been proposed:

1. Enteral Nutrition: 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.

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

3. Delivery Ticket Components: The delivery ticket requirements are unnecessary and burdensome to DME providers.

4. Replacement DME: 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 natural 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.

RECOMMENDATIONS

DMAS recommends:

1. Enteral Nutrition: 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: Amending the section to permit the use of implantable pumps for delivering home infusion therapy.

3. Delivery Ticket Components: Amending the delivery ticket requirements to streamline them and reduce unnecessary burden on DME providers.

4. Replacement DME: 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.

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.

There are no alternatives that would update DMAS regulations to reflect CMS guidance and best practices.

Public Participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

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.