Virginia Regulatory Town Hall

townhall.virginia.gov

Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC 30 -50 and 12VAC 30-80
Regulation title	Amount, Duration, and Scope of Medical and Remedial Care Services; Methods and Standards for Establishing Payment Rates—Other Types of Care
Action title	Durable Medical Equipment (DME) Services Updates
Date this document prepared	5/21/2010

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Preamble

The APA (Code of Virginia § 2.2-4011) states that an "emergency situation" is: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date.

1) Please explain why this is an "emergency situation" as described above.
2) Summarize the key provisions of the new regulation or substantive changes to an existing regulation.

The Administrative Process Act (Section 2.2-4011) states that an agency may adopt regulations in an "emergency situation": (A) upon consultation with the Attorney General after the agency has submitted a request stating in writing the nature of the emergency, and at the sole discretion of the Governor; (B) a situation in which Virginia statutory law, the Virginia appropriation act,

or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of Subdivision A.4 of § 2.2-4006; or (C) in a situation in which an agency has an existing emergency regulation, additional emergency regulations may be issued as needed to address the subject matter of the initial emergency regulation provided the amending action does not extend the effective date of the original action. This suggested emergency regulation meets the standard at *COV* § 2.2-4011 (B) 280 day standard as discussed below.

The 2010 Appropriations Act, Chapter 874 (number pending assignment) of the *2010 Acts of Assembly*, Item 297 UUU and WWW require:

"UUU. Effective July 1, 2010, the Department of Medical Assistance Services (DMAS) shall amend the State Plan for Medical Assistance to modify reimbursement for Durable Medical Equipment (DME) to:

a. Reduce reimbursement for DME that has a Durable Medical Equipment Regional Carrier (DMERC) rate from 100 percent of Medicare reimbursement to 90 percent of the Medicare level.
b. Reduce fee schedule rates for DME and supplies by category-specific amounts as recommended in the November 1, 2009, Report on Durable Medical Equipment Reimbursement to the Senate Finance and House Appropriations Committees. The Department of Medical Assistance Services shall also modify the pricing of incontinence supplies from case to item, which is the industry standard.
c. Establish rates for additional procedure codes where benchmark rates are available.
d. Reimburse at cost plus 30 percent for any item not on the fee schedule. Cost shall be no more than the net manufacturer's charge to the provider, less shipping and handling.
e. Determine alternate pricing for any code that does not have a rate.
f. Limit service day reimbursement to intravenous and oxygen therapy equipment.

2. The department shall promulgate regulations to implement this amendment within 280 days or less from the enactment of this act."

"WWW. Effective July 1, 2010, the Department of Medical Assistance Services (DMAS) shall amend the State Plan for Medical Assistance to modify the limit on incontinence supplies prior to requiring prior authorization. The department shall have the authority to implement this reimbursement change effective July 1, 2010, and prior to the completion of any regulatory process undertaken in order to effect such change."

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Durable Medical Equipment Services Updates (DME) (12 VAC 30-50-165; 12VAC 30-80-30) and also authorize the initiation of the promulgation process provided for in § 2.2-4007.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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, 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 subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

Durable medical equipment (DME) is a federally mandated service attached to Home Health Services pursuant to 42 CFR § 440.70.

In response to the previously discussed General Assembly mandate, DMAS proposes these changes in its payment methodology for DME and supplies: (i) rate reductions to the Durable Medical Equipment Regional Carrier (DMERC) rate; (ii) category specific rate reductions to the July 1996 rates; (iii) development of rates for procedure codes that were once not priced and other changes.

Additionally, changes will also be made to the billing unit for incontinence supplies from a ‘case’ amount to an ‘each’ amount or single item such as an individual diaper or panty liner. As a result of the change in the billing unit, prior authorization limits will be changed and DMAS will now allow providers to break cases of diapers while leaving the sealed inner packages intact. Such sealed inner packages can contain 6, 10, or 12 individual diapers, for example, depending on diaper size and the manufacturer. Breaking cases will allow providers better control on the amount of items given to recipients every month. This category of medically needed DME supplies represents the DME program’s highest expenditure per year.

All of these suggested changes constitute an effort to provide cost savings to the Commonwealth due to budget reductions.

Need

Please detail 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, delineate any potential issues that may need to be addressed as the regulation is developed.

Based on post payment audits and appeals conducted over the last several years, DMAS has determined that changes are needed to the incontinence supplies program to strengthen the quality of services, to ensure services are delivered in a cost effective manner and that fraudulent activities are reduced and prevented. Incontinence products should be provided to recipients on an individual basis related to the recipients' medical conditions and degree of incontinence. Greater oversight via the prior authorization process on the part of DMAS and providers should decrease the amount of overuse that has been experienced in this program.

The change in prior authorization requirements does not affect the amount of services that are provided to recipients as it will only lower the threshold at which providers must seek prior authorization before additional incontinence supplies may be provided. The service limit does not represent a restriction as it will be the limit at which providers are required to obtain prior authorization for additional quantities.

The changes to the reimbursements rates will not have a direct impact on Virginia Medicaid recipients. Due to the economic downturn, the agency's budget has been reduced. The agency realizes that these reimbursement reductions may not be well received by the provider population. However, there have been no changes to the DME payment methodology or the reimbursement rates since they were established in July 1, 1996, while other providers' rates have been reduced over the last several years.

DMAS had an independent contractor, CGI Group, Inc. (CGI), conduct a review of the DMAS payment methodologies and current rates as compared to other states. Based on this review, DMAS recommended in a report to the General Assembly money committees that the DME program's reimbursement rates should be reduced to bring the Commonwealth in better alignment with other states of similar financial and demographic makeup. The General Assembly subsequently adopted these recommendations as part of the budget. These reductions are not expected to affect service delivery since the DMAS' rates have been historically higher than most state Medicaid agencies for the same services.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

The sections of the State Plan for Medical Assistance affected by this action are the Amount, Duration, and Scope of Medical and Remedial Care Services (12VAC 30-50-165); and Methods and Standards for Establishing Payment Rates—Other Types of Care (12 VAC 30-80-30).

In January 2004, the Department required providers to use the national Healthcare Common Procedure Coding Systems (HCPCS) codes when billing for durable medical equipment (DME). Durable medical equipment is defined as medical supplies, equipment, and appliances suitable for use in the home (42 CFR 440.70(b)(3)). Such supplies, equipment, and appliances must be ordered by the recipient's physician and such orders must be reviewed at least annually by the physician. These supplies, equipment, and appliances can only be provided by licensed providers who are enrolled with Medicaid as providers.

All HCPCS codes that have a Durable Medical Equipment Regional Carrier (DMERC) rate (as set by Medicare) are reimbursed at the DMERC rate. If the HCPCS code does not have a DMERC rate, but has an established DMAS rate, the provider uses the lesser of either the DMAS rate which was established July 1, 1996, or the provider's actual charge. These rates are incorporated into the fee schedule. If an item or supply does not have a HCPCS code available, the provider uses the miscellaneous code E1399 until a national HCPCS code is developed. All HCPCS codes and rates are noted in Appendix B of the current DME Provider Manual.

These specific changes are discussed below.

Modification of DMERC rates

The agency currently pays 100% of the DMERC rate for HCPCS codes that have a DMERC rate. Chapter 874 of the 2010 Appropriations Act, Item 297 UUU directs DMAS to reduce the DMERC rate by 10%. This reduction will provide the agency with cost savings and bring DMAS' rates more in line with other states of similar financial and demographic makeup offering similar services.

Category Specific Reductions to the July 96 Rates

Currently, if the HCPCS code does not have a DMERC rate, but has an established DMAS rate, the provider uses the lesser of either DMAS rate which was established July 1, 1996, or the provider's actual charge to the public. Based on the study conducted by CGI, DMAS will apply category specific reductions. These category specific reductions will provide an overall 5.5% decrease to the July 96 rates and bring DMAS' rates in line with benchmark rates from other similar states.

Category specific reductions include the following:

Product Category	Reduction
Bed pans, Urinals, Incontinence, Catheters, and Irrigation Equipment and Supplies	10%
Apnea Monitors, Respiratory, Oxygen and Ventilators	5%
Feeding Pumps, Nutritional Supplements, Feeding Kits and	0%

Tubes	
Miscellaneous Durable and Expendable Supplies	5%
Wheelchairs and Accessories	10%
Diabetic Products	15%
I.V. Service Day Rates, I.V. Stands, I.V. Needles and Supplies	20%
Orthotics	0%
Beds, Mattresses and Accessories	0%
Bandages, Dressings, Gauze and Tape	10%
Decubitus/Ulcer Products	0%
Communications Devices	0%
Ostomy and Colostomy Pouches and Accessory Supplies	5%
Dry Heat Application, TENS, NMES	15%
Canes, Crutches and Walkers	0%
Elastic Support Items	15%
Traction Equipment	0%
EPSDT	0%
Burn Garments	0%
Dialysis	0%

Formulation of Set Fees and Reimbursement of Un-priced Codes

Currently, HCPCS codes that have no DMERC rate or July '96 rates are being paid at the provider's usual and customary charge. The agency has found it difficult to monitor and verify charges that are submitted by providers. In an effort to provide cost savings and better oversight to the program, DMAS will set fees for some of the un-priced HCPCS codes based on benchmark data from other state Medicaid agencies. The procedure codes that cannot be priced because of the lack of benchmark data will be converted to an Individual Consideration (IC) payment methodology. This IC method will be reimbursed at the provider's net cost, minus shipping and handling, plus a 30% markup and is the current method of payment used for un-priced miscellaneous codes (E1399). By making this change, all un-priced codes will be reimbursed the same way, which will enable DMAS to confirm accurate pricing and reduce overpayments.

Alternate Pricing and Limits on Service Day Reimbursement

DMAS shall have the authority to establish alternative pricing for HCPCS codes without a DMERC rate. DMAS is not implementing any additional limits to service day reimbursement to intravenous and oxygen therapy equipment. DMAS may consider service limits in the proposed regulation.

Changes to prior authorization limits and the billing unit for incontinence products

Currently the agency reimburses for incontinence supplies by the case. The agency proposes to convert the billing unit from 'case' to 'each or item' for incontinence supplies, such as adult diapers, pull-ups and panty liners. For this provision, providers are not being required to open

the plastic-type sealed inner packaging but only the outer paper-type box. Based on research conducted by the agency and the independent contractor CGI, Virginia is the only state still reimbursing for such products by the 'case' and not by an 'each' unit system. As a result of this change in the billing unit, the agency will allow providers to break cases of diapers and other products while still leaving intact the sealed inner packages. Breaking cases will allow providers tighter control on the amount of overage provided to recipients every month.

Currently the agency allows providers two to three cases (intact outer paper-type box) of incontinence products per month, based on the HCPCS code, prior to the provider being required to seek prior authorization. Along with the change from 'case' to 'each or item', the budget gives DMAS the flexibility to change the prior authorization limit on incontinence products. DMAS intends to modify the monthly limit to 100 items. The allowable limit per month will be posted in Appendix B of the DME manual. These changes will also provide the Commonwealth and the agency a cost savings and increased oversight of providers who supply incontinence products since this category of supplies represents DMAS' highest annual DME/supplies expenditure.

This action will affect 12VAC30-80-30 and 12VAC30-50-165 as follows.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC30-50-165, Section B		Currently providers are required to bill incontinence supplies by the case and must get prior authorization after two cases per month.	The agency is changing the billing unit for incontinence supplies from 'case' to 'each or item' thus conforming Virginia with other state Medicaid agencies. Prior authorization of the incontinence products will now be required once the allowable monthly limit of 100 items has been met. A definition is added of what constitutes DME consistent with the Code of Federal Regulations.
12VAC30-80-30, Section 6		All HCPCS codes that have a DMERC rate would be reimbursed at the DMERC rate. If the HCPCS code does not have a DMERC rate but has an established DMAS rate, the provider would use the DMAS rate which was established July 1, 1996, or the actual charge as incorporated into the DMAS fee schedule. If	Rates for all codes that have a DMERC rate would be decreased by 10%. For DME items that do not have a DMERC rate, the agency will use the agency fee schedule amount. All codes with no DMERC rate or agency fee schedule rate will be reimbursed at the provider's net cost minus shipping and handling, plus 30%. The agency may develop pricing for any code based on agency research that does not have a DMERC rate. Rates will be published in the agency guidance documents (Appendix B of the DME Provider Manual.

		an item or supply does not have a HCPCS code available, the provider can use the miscellaneous code until a national HCPCS code is developed. All HCPCS codes and rates are noted in Appendix B of the DME Manual.	

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be 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.

DMAS engaged an independent company, CGI, to conduct a review of DMAS' rates for durable medical equipment services as compared to other state Medicaid agencies. Based on the results of this review, the agency recommended these changes to the payment methodologies which were subsequently adopted by the General Assembly in the budget as previously discussed. These recommended changes are expected to better align DMAS' rates with those of other state Medicaid agencies. The review conducted by CGI noted DMAS has been paying historically higher reimbursement rates as compared to other states with similar financial and demographic makeup.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include 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 meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elizabeth Flaherty, R.N., Healthcare Compliance Specialist, Division of Long Term Care, DMAS, 600 E. Broad St., Suite 1300, Richmond, VA 23219, phone (804) 786-7953, fax (804) 612-0050; Elizabeth.Flaherty@dmas.virginia.gov. Written comments must include the

name and address of the commenter. In order to be considered, comments must be received by the last day of the public comment period as published in the *Virginia Register* and on the Regulatory Town Hall.

A public meeting will not be held pursuant to an authorization to proceed without holding a public meeting.

Participatory approach

Please indicate the extent to which an ad hoc advisory group will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

DMAS anticipates seeking the comments of the Virginia Association of Durable Medical Equipment Companies in its regulatory development.

Family impact

Assess the potential 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; or 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, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.