Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC 30 -50, 12 VAC 30-60, 12 VAC 30-80
Regulation title	Amount, Duration, and Scope of Medical and Remedial Care Services; Standards Established and Methods Used to Assure High Quality Care; Methods and Standards for Establishing Payment Rates - Other Types of Care.
Action title	Durable Medical Equipment (DME) and Supplies Services Update
Date this document prepared	

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.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The regulatory action updates the current regulations for DME and supplies so that the regulations and agency guidance documents are consistent. The changes to the regulations will include discontinuing the use of the DMAS-116 form that is used for enteral nutrition, addition of another item under non-covered services section, technical corrections and additional clarification of policy.

The Agency made changes to the payment methodology for DME and Supplies under emergency regulation authority. The changes included rate reductions to the Durable Medical Equipment Regional Carrier (DMERC) rate, category specific rate reductions to the July 96 rates and the development of rates for codes that were once un-priced in an effort to provide cost savings to the Commonwealth due to budget reductions.

Changes are also made to the billing unit for the category of incontinence supplies, changing the covered item from a ‘case’ amount to an ‘each’ or single item. As a result of the change in the billing unit, service authorization limits will change and the agency will allow providers to open

cases of diapers while leaving the sealed inner packages intact. Opening cases will allow providers to have tighter control on the amount of extra supplies (overage) that are dispensed monthly to the member.

Further changes are included in this proposed regulation to incorporate longstanding agency policies in the regulations: (i) providers shall not have a claim of ownership on DME reimbursed by Virginia Medicaid once it has been delivered to the Medicaid individual; (ii) certain fields of information on Certificates of Medical Necessity will be required; and (iii) providers are prohibited from billing for DME prior to its delivery to the Medicaid individual.

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.

DME – Durable Medical Equipment

DMERC – Durable Medical Equipment Regional Carrier

DMAS-116 – Enteral nutrition form used by providers to document the 6 month face-to-face assessment and orders for enteral nutrition.

CMN (DMAS-352) – Certificate of Medical Necessity

CGI – CGI Group, Inc., - Independent contractor hired by the State to conduct an assessment of the DME program reimbursement methodologies.

HCPCS – Healthcare Common Procedure Coding System as developed and published by the Centers for Medicare and Medicaid Services

UCC – Usual and Customary Charge

IC – Individual Consideration

Service Limit – the amount allowed, of a specific product, prior to service authorization being required.

Overage – If the provider has to deliver more supplies than are ordered because the supply cannot be opened due to sanitation reasons. The amount of supplies that exceeds the ordered amount would be considered overage.

Frequency of use – means the number of times per day/week/month a supply is used by the individual which provides the justification for the unique quantity of supplies ordered on the Certificate of Medical Necessity.

Quantity - means the total number of supplies ordered on a monthly basis. The total amount is dependent on the frequency of use.

Legal basis

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., the 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 and 32.1-325, authorize the Director of DMAS to administer and amend the Plan for Medical Assistance according to the Board's requirements. Pursuant to these provisions, the Director of DMAS is authorized to regulate generally the provision of durable medical equipment and supplies to Medicaid individuals. 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.

Chapter 874 of the *2010 Acts of Assembly*, Item 297 UUU and WWW mandated changes to DMAS' reimbursement methodology for durable medical equipment and service limits for incontinence products. These mandated changes were initially promulgated with an emergency regulation that became effective July 1, 2010. These same changes enclosed herein will make the previous temporary changes part of the permanent regulations. Further changes reflected in this proposed regulation are made pursuant to the Director's authority to prepare, administer and amend the Plan for Medical Assistance.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

Durable medical equipment (DME) is a federally mandated service attached to Home Health Services pursuant to 42 CFR § 440.70. As such, it is essential to the health, safety, and welfare of Medicaid individuals that this service meets their identified medical needs and enables them to live safely in their homes and communities.

This proposal has several goals: (i) to better define and establish the requirements of the DME program; (ii) to modify and better define the agency's reimbursement method for this service; (iii) to reduce waste and inappropriately rendered services in order to reach projected budget reductions.

In the Medicaid DME program prior to the current emergency regulation, DMAS experienced problems with providers' incorrect, inappropriate billing practices; product waste, and; provision of inappropriate, non-ordered services.

DMAS is also incorporating language for the coverage of enteral nutrition products from a waiver regulation chapter (Chapter 120) into a State Plan chapter (Chapter 50). Enteral nutrition products have been covered for all Medicaid recipients since March 2000.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

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); Standards Established and Methods Used to Assure High Quality Care (12 VAC 30-60-75), 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 individual's licensed practitioner and such orders must be reviewed at least annually by the licensed practitioner. These supplies, equipment, and appliances can only be provided by licensed providers who are enrolled with Medicaid as DME service providers.

The agency had an independent contractor, CGI Group, Inc., (CGI) conduct a review, in November 2009, of the agency's payment methodologies and current rates compared to other states. Based on this review and the agency's review, it was found 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 make up. Based on this independent review, these reductions should not impact services since the agency's rates have been historically higher than most state Medicaid agencies.

Currently, all HCPCS codes that have a Durable Medical Equipment Regional Carrier (DMERC) rate 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 DMAS' rate which was established July 1, 1996, reduced by 4.5%, or the provider's actual charge. These rates were incorporated into the fee schedule in 1996. 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. There have been no changes to the DME payment methodology or July 1, 1996, rates since that implementation.

The Agency currently requires providers to complete the DMAS-115 (formerly DMAS-116) every 6 months in addition to the CMN for Medicaid members who need enteral nutrition.

Currently the agency allows providers 2-3 cases of incontinence products per month, based on the HCPCS code, prior to the provider being required to seek service authorization. The agency's billing unit for incontinence supplies is currently per case.

The new recommended policy changes are discussed below:

Modification of rates (12 VAC 30-80-30)

The agency currently pays 100% of the DMERC rate for HCPCS codes that have a DMERC rate. Based on the study conducted by CGI, DMAS proposes to reduce the DMERC rate by 10% as recommended by CGI. This reduction will provide the agency with modest cost savings and bring DMAS' rates more in line with other states of similar financial and demographic makeup.

Currently, if the HCPCS code does not have a DMERC rate, but had an established DMAS rate, the provider would use the lower of either the DMAS rate, which was established July 1, 1996, less 4.5%, or the provider's actual charge to the public. Based on the study conducted by CGI, DMAS will apply category specific reductions, as recommended by CGI. 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 states with similar financial and demographic makeup. The DMAS rate will be noted in the Appendix B of the DME Manual.

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, the agency will set fees for some of the un-priced HCPCS codes based on benchmark data from other state Medicaid agencies. The procedure codes that can not be priced because of the lack of benchmark data will be converted to an Individual Consideration (IC) payment. IC is reimbursed at the provider's net cost, minus shipping and handling, plus a 30% markup. IC 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 thereby providing greater oversight which will enable DMAS to confirm accurate pricing and decrease overpayments.

The agency has also added five additional miscellaneous codes to the Appendix B in an effort to better define miscellaneous codes by category. The five new miscellaneous codes will be category specific allowing the agency to evaluate spending for miscellaneous codes by product category.

Changes to Service Authorization Limits and Billing Unit for Incontinence Products (12 VAC 30-50-165)

Currently the agency provides reimbursement for incontinence supplies by the case. The agency will convert the billing unit from 'case' to 'each' for incontinence supplies. 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 while still

leaving intact the sealed inner packages to preserve the product's sanitation. Breaking cases will allow providers tighter control on the amount of overage given to members every month.

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 condition 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 as this category of supplies represents DMAS' highest DME expenditure per year.

Currently the agency allows providers 2-3 cases of incontinence products per month, based on the HCPCS code, prior to the provider being required to seek service authorization. Along with the change from 'case' to 'each', the agency will change the service authorization limit on incontinence products (diapers/pullups/liners) to 100 each month. 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 increase the oversight of providers who supply incontinence products. This action will affect 12VAC30-80-30 and 12VAC30-50-165.

The agency will also now require providers to make affirmative contact with the Medicaid member receiving incontinence products prior to the monthly refill to confirm the member still needs incontinence products, the products are appropriate, the number of products continue to be accurate and the amount of overage is confirmed. These additions to the policy will allow the agency and the provider to better manage the amount of inappropriate supplies delivered, increase oversight, and increase the quality of services being provided.

Discontinuation of the DMAS-116

Discontinuation of the DMAS-116 (Nutritional Status Evaluation Form) will decrease the documentation burden of providers since the information contained on this form can now be included on the Certificate of Medical Necessity (CMN).

Providers have asked for this change due to the difficulty of getting two forms completed by the ordering practitioner. Clinical requirements will remain intact, however; the CMN will be revised to better capture these requirements. Providers will also be allowed to use supporting documentation to meet these requirements if not contained on the CMN.

Coverage of Enteral Nutrition Products

DMAS began covering enteral nutrition products for all eligible, appropriate Medicaid individuals in March 2000. At that time, the agency relied for this change on its enteral nutrition regulations as set out for the HIV/AIDS waiver (12 VAC 30-120-195). Since Chapter 120 is reserved for the home and community based waiver programs, the regulations for this service for all approved Medicaid recipients have been established in Chapter 50. Therefore, this technical

correction is being made in this regulatory action. The new Chapter 50 regulations are being updated to incorporate reference to the DMAS-352 and to eliminate duplicative text.

Provider Recovery of Delivered DME (12 VAC 30-50-165 and 12 VAC 30-60-75)

The agency is adding to the regulations language that prohibits a provider from recovering DME from a Medicaid recipient once it has been delivered to the recipient's home. Providers have sought to reclaim delivered DME in response to post-payment audits, wherein findings revealed the provider had not complied with agency regulations and policies.

To permit this to happen would create a significant undue hardship on the Medicaid recipients as the durable medical equipment allows these individuals to function more independently. As DME is a federally mandated service attached to Home Health Services, it is essential to the health, safety, and welfare of Medicaid individuals to meet their medical needs. Providers shall not have a claim of ownership on DME reimbursed by Virginia Medicaid once it has been delivered to the Medicaid individual. The DME provider serves as a conduit for the delivery of the Medicaid member's owned equipment.

The DME provider does not have a claim to such equipment that has been delivered to a Medicaid individual and paid for by Medicaid even when a post payment audit results in payment retractions. Payment retractions are DMAS' primary method to enforce its requirements with providers who fail to comply with agency policies and regulations and have never been intended to penalize Medicaid recipients. Other providers, physicians, dentists, or transportation providers do not have the option of taking back the services that they have rendered to Medicaid recipients; therefore, DME providers cannot be permitted to do so. The regulations affected by these changes are 12 VAC 30-50-165 and 12 VAC 30-60-75.

Certificate of Medical Necessity Requirements (12 VAC 30-60-75)

Additional changes conform the regulations to agency guidance document policies. The clarification language will apply to i) the Certificate of Medical Necessity (CMN) (DMAS-352) form which contains the physician's order and therefore must have specific fields completed. Absent the required form-352 information, the CMN will be considered invalid and the DME provider will be at risk for non-coverage; ii) providers are not permitted to bill for dates of service prior to delivery of the DME.

The agency will include the minimum documentation requirements, such as the licensed practitioner's order and the clinical diagnosis, for all DME and supplies. The documentation requirements are required regardless of whether a service authorization is required. A definition of frequency of use and quantity will be included with these documentation requirements to add emphasis to the difference between these two requirements.

Details are set out for the pieces of information required on the CMN.

Medical Necessity Requirement for Diapers for Children (12 VAC 30-50-165)

The agency does not provide reimbursement for the routine use of diapers for children younger than three years of age who have not yet been toilet trained. Service authorizations for diapers for these young children must be associated with medical conditions. This limitation in services is listed in the incontinence section of the agency guidance documents. The agency will add this as an additional item under the non-covered services listed in 12VAC 30-50-165.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

The changes to the reimbursements rates will not have a direct impact on the Virginia Medicaid member. The change in service authorization requirements for incontinence products does not impact the amount of services that are provided to members as it will only lower the threshold at which the provider must seek service authorization before additional supplies will be provided. The service limit does not represent a restriction as it will be the limit at which the provider is required to obtain authorization for additional quantities.

Providers will be able to open cases of diapers as long as they do not break the inner sealed packages. This change will allow providers to deliver a more accurate amount of incontinence supplies each month and decrease the amount of overage. Less overage delivered each month will decrease the opportunity for overuse or fraudulent activity and will provide increased oversight. Service authorization changes will provide the Commonwealth and the Agency a cost savings and increase the oversight of providers who supply incontinence products. This category of medically needed DME supplies represents the DME program's highest annual expenditure.

Based on post payment audits and appeals conducted over the last several years DMAS has determined that changes are needed to the policy related to incontinence supplies to strengthen the quality of services, to ensure services are delivered in a cost effective manner. Incontinence products should be provided to members on an individual basis related to the member's medical condition and degree of incontinence.

The agency has also developed a new guidance document, published on the agency's website, which can be used as an assessment tool. This form will be optional, but may assist the provider with determining the appropriate amount (both frequency and quantify) and type of incontinent supplies. In addition, this form will assist the provider in meeting program policy documentation requirements. The agency does realize these changes will not be well received by all providers

but the Agency believes these changes are greatly needed and justified based on research and audit results.

The discontinuation of the required DMAS-116 form will decrease the documentation burden for providers allowing a better opportunity to meet policy requirements.

Due to the economic downturn, the agency's budget has been reduced. The agency realizes that some of these rate changes will not be well received by the provider population. However, there have been no changes to the DME payment methodology or July 1, 1996, rates since implementation and Virginia Medicaid has been paying higher than average DME rates for some time.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal, which are 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 that exceed applicable federal requirements for the DME and supplies program.

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.

This change is proposed for all DME providers across Virginia so the agency does not foresee any impact to a particular geographic location.

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.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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 may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to Elizabeth Flaherty, R.N., Division of Long Term Care Services, DMAS, 600 East Broad Street, Suite 1300, Richmond, VA 23219, 804/786-1680, **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 date 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, and (b) a delineation of one-time versus on-going expenditures.	There will be a one time increase in the amount of service authorizations, however; the amount of service authorizations will level off and become a routine amount. The agency does anticipate that the use of incontinence products will decrease due to the service authorization limit changes. DMAS believes some of the providers who have not been typically supplying amounts over the service authorization limit will continue that practice or stop providing incontinence supplies all together. As there are adequate numbers of providers across the Commonwealth, this is not expected to cause issues of access to care. There will be no added cost to change the payment methodology. The Agency will be able to make reimbursement changes to the VaMMIS system internally.
Projected cost of the *new regulations or changes to existing regulations* on localities.	Providers will see an increase in the amount of service authorization (SA) that is required. This increase may require more staff time. However, the agency anticipates the cost of overage or overuse will be decreased since the provider can now open cases to deliver a more accurate amount of supplies. The rate changes will affect the amount of reimburse-ment the provider receives for a particular item. However, the DME program has not seen changes to the payment methodology or the July 1, 1996, rates since implementation. Based on research the agency has historically had higher reimbursement rates than other comparable state Medicaid agencies.
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	This will affect all 1,958 DME providers enrolled with Virginia Medicaid.
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,	All enrolled DME providers will be affected since rate changes will be made across all HCPCS code categories. Since DMAS does not collect information about small businesses, a definitive statement cannot be made as to

including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	what percentage of DME providers meet this standard. However, it is estimated that the majority of DME providers meet this standard.
All projected costs of the *new regulations or changes to existing regulations* for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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.	Providers are currently required to maintain member records related to covered supplies dispensed by the provider. Any DME provider who supplies incontinence supplies will see an increase in the amount of SA required which may require additional administrative costs for staffing time. The rate changes will affect the amount of reimbursement the provider receives for a particular item. This will cause a loss of revenue depending on the type and amount of supplies they provide but will not cause an increase in operational costs.
Beneficial impact the regulation is designed to produce.	Saving for the Agency in FY11 (total funds) $3,832,075 rate changes $2,847,434 diaper limits $6,679,509 combined (both GF/NGF)

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.

Pursuant to 42 CFR 440.70, durable medical equipment is considered to be part of home health services even though access to DME cannot be restricted by the homebound criterion associated with home health services.

The Agency 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 is recommending these changes to the payment methodologies and reducing rates. 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 historically paying higher reimbursement rates as compared to other states with similar financial and demographic makeup. The Commonwealth will also consider implementation of competitive bidding of incontinence supplies for fiscal year 2012, to provider further cost savings to the agency.

Regulatory flexibility analysis

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.

Due to the economic down turn, the Medicaid budget has been reduced. The Agency had an independent contractor, CGI, to conduct a review of DMAS' DME payment methodologies and current rates as compared to other states. Based on the review findings, it was determined that the DME program reimbursement rates needed be reduced to bring the Commonwealth in better alignment with other states of similar financial and demographic makeup. Based on the independent review completed by CGI in November of 2009, these cuts should not reduce services since DMAS' rates have been historically higher than most state Medicaid agencies.

Discontinuation of the DMAS-116 will decrease the documentation burden of providers since the information contained on these forms can now be included on the Certificate of Medical Necessity (CMN). Providers have asked for this change due to the difficulty of getting two forms completed by the ordering practitioner. Clinical requirements will remain intact, however; the CMN will be revised to better capture these requirements. Providers will also be allowed to use supporting documentation to meet these requirements if not contained on the CMN.

The documentation requirements proposed in these regulations are necessary to support DMAS' post payment review audit practices. Providers must be able to prove that the service that DMAS is asked to reimburse for has been duly ordered by a licensed practitioner and that it has been provided in accordance with those orders. This expectation is supported in federal law as well as in the Commonwealth's licensing standards.

DMAS does not propose to impose performance standards on any of its providers. Furthermore, DMAS cannot exempt its small business DME providers from any of these requirements as such exemptions are not permitted in Medicaid's federal enabling statutes.

Public comment

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

DMAS' Notice of Intended Regulatory Action was published in the July 19, 2010, *Virginia Register* (VR 26:23) for its public comment period from July 19, 2010, to September 1, 2010. Comments were received from one individual in support of the regulatory action as follows:

Commenter	Comment	Agency response
Littelton MIlles	"I really support this is *(sic)* and think more needs to be put into it."	DMAS notes the general comment.

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; 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.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please detail the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the 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, rationale, and consequences
12VAC30-50-165 A		Definitions.	New definitions are added as needed.
12VAC30-50-165, Section B		Sets out general DME requirements.	General requirements are expanded to emphasize completion of required Certificate of Medical Necessity (CMN), to emphasize DME provider requirements relative to the CMN and other program requirements. Technical language changes are made for clarity and to eliminate redundancy.
		DMAS draws a distinction by age of the Medicaid individual for how long the CMN can remain in effect: CMNs for children can remain effective 6 months; CMNs for adults can remain effective 12 months.	The age distinction for the effective period for CMNs derives from the fact that medical needs typically change faster for children than adults. Technical change, not a policy change, because regs were worded inaccurately.

		No current requirements for affirmative contacts. Currently, providers have just been sending post cards that do not require response. No existing provision to prohibit a provider from re-claiming delivered DME when charged with audit overpayments.	Providers have been sending postcards to individuals/caregivers and even in the absence of responses, have been shipping DME supplies (typically diapers). This requirement has been designed to stop this practice thereby saving the expenditures for supplies that are no longer needed or not appropriate. Provision made to prohibit providers, who have been charged with audit repayments, from re-claiming DME which has already been delivered to recipients. Codifies agency policy that delivered DME is deemed property of the receiving Medicaid recipient.
50-165 C		Contains billing unit of cases and requires PA for incontinence products in excess of two cases per month.	New service limit established by Chap. 874 Item 297 VVV. Establishes the new billing unit of each product and requires PA in amounts in excess of those set out in the agency's relevant guidance documents.
50-165 D		Lists medical supplies that are not covered by Medicaid. List is not meant to be all inclusive.	Adds new provision that routine infant diapers are not covered for children less than 3 years of age who have not yet been toilet trained.
50-165 E		Provides for coverage of blood glucose meters for pregnant women.	No changes.
50-165 F		Sets out rules for coverage of home infusion therapy.	Removes the 3-month service limit and substitutes established criteria in place of prior authorization. Other changes are technical and formatting.
50-165 G, H, and I		Existing requirements.	Technical, updating of terminology.
50-165 J		Requirement for coverage of enteral nutrition therapy (EN).	EN text deleted and provisions moved to new M. New J provides for the medical documentation requirements for DME. These are providers' standards that must be met in order to not be subjected to recovery of expenditures resulting from audits.
	50-165 K	New section.	DME provider responsibilities in order to receive DMAS' reimbursement. Failure to meet these standards may result in DMAS recovering expenditures as a result of provider audits.
	50-165 L	New section.	Establishes providers' requirements that must be met in order to show proof of delivery of DME items for purposes of

			quality assurance and provider audits.
	50-165 M	New section. Existing text in a waiver program currently sets out these requirements and references DMAS-116 form. The waiver regulations at 12 VAC 30-120-195 are left intact to function for the HIV/AIDS waiver.	Establishes new section in State Plan chapter providing for coverage of EN for all qualifying Medicaid recipients. Text from waiver regs (12VAC30-120-195) has been copied, with slight modification, into the Plan. Providers requested the elimination of the DMAS-116. Clinical requirements are remaining the same as in the current waiver regulations (120-195), however; the CMN has been revised to better capture these requirements. Providers will also be allowed to use supporting documentation to meet these requirements if not documented on the CMN.
12 VAC 30-60-75		Quality assurance chapter. No provisions dictating required fields in DMAS-352, Certificate of Medical Necessity, form.	New provision for Medicaid recipient's ownership of DME so that provider is prohibited from re-claiming it. Technical updates to CMN references. Provision made for recovery of expenditures when service is not reflected on CMN. Provision is made to establish form's fields that are required to be completed by the DME provider in order for the CMN to stand as a legitimate order subject to DMAS' reimbursement.
12VAC30-80-30, Section 6		All HCPCS codes that have a DMERC rate would be reimbursed at the DMERC rate. DME rate to be the lower of state agency fee schedule in place prior to 7/1/1996 less 4.5% or the actual provider charge. Nutritional supplement payments to be the lower of either agency fee or actual charge. No provision prohibiting DME provider from billing DMAS prior to delivery of ordered equipment.	All HCPCS codes that have a DMERC rate would be decreased by 10%. If the HCPCS code is reimbursed using the July 1, 1996, rate, then the rate will be reduced by a certain percentage, depending on the DME category, based on the recommenddation in the November 1, 2009 report by CGI. All code with a reimbursement rate of Usual and Customary Charge (UCC) will be changed to Individual Consideration (IC). IC will be reimbursed uniformly, at the providers net cost minus shipping and handling plus a 30% mark-up. The agency will establish rates for additional procedure codes that do not have a set rate when a benchmark rate is available. The agency will also determine alternate pricing for any code that does not have a rate. Provision is made that requires DME providers to deliver the ordered equipment prior to submitting their claims for Medicaid reimbursement.