Virginia Regulatory Town Hall

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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 30-50-95 and 30-50-96
Regulation title	Amount, Duration and Scope of Services: Reimbursement of Services: In General
Action title	Requirement of Signature for Medicaid Reimbursement
Final agency action date	July, 1, 2011
Document preparation date	

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(B)] states that an agency may adopt regulations in an "emergency situation" that is defined, in part, as 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. This suggested emergency regulation meets the standard at *COV* 2.2-4011(B) as discussed below.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Administration of Medical Assistance Services: Amount, Duration and Scope of Services: Reimbursement of Services: In General - Requirement of Signature for Medicaid Reimbursement (12 VAC 30-50-95 and 30-50-96) 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 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 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.

The purpose of this action is to comply with Appropriation Act, Item 297.TTTT of the 2011 General Assembly requiring DMAS to specify that the documentation requirements for the signing and dating of medical records, both paper and electronic, by health care providers shall be a mandatory condition of Medicaid reimbursement.

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.

Item 297.TTTT of the 2011 Virginia Appropriations Act directs DMAS as follows:

> *The Department of Medical Assistance Services shall amend the State Plan for Medical Assistance to specify that the documentation requirements for the signing and dating of medical records by health care providers shall be a mandatory condition of Medicaid reimbursement. The department shall have authority to promulgate emergency regulations to implement these changes within 280 days or less from the enactment date of this act.*

The Centers for Medicare and Medicaid Services (CMS), the federal Medicaid authority, requires state Medicaid agencies to ensure that health care providers enrolled with the Medicaid program maintain a high quality of care in their provision of services to Medicaid enrollees. This enforcement of this requirement protects the health and safety of Medicaid enrollees and maintains the integrity of Medicaid reimbursement. 42 CFR 431.107 (b)(1) requires all Medicaid providers to maintain "any records necessary to disclose the extent of services the provider furnished to recipients."

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 importance of verifiable documentation of the provision of health care services in assuring patient health and safety cannot be overstated. Under 42 CFR 455.1(a)(2), the Centers for Medicare and Medicaid Services (CMS), the federal Medicaid oversight agency, requires states "to verify whether services reimbursed by Medicaid were actually furnished to recipients." Where the provision of health care services to a Medicaid enrollee cannot be supported by documentation, DMAS retracts any amounts paid to a provider for the unsupported services.

A key component in the verification of health care documentation to support Medicaid reimbursement is the dated signature of the individual who provided the health care services to a Medicaid enrollee. The signature provides the identification of the individual who provided the services, whereby the qualifications to provide the services may be ascertained, while the date provides vital information to other health care providers involved with the patient of the time frame in which the services, be it treatments, therapies or drugs, were delivered to the enrollee. These two elements are essential to appropriate delivery of health care and the protection of patient safety.

Despite the vital nature of this information, the presence or absence of a dated signature and the legal requirement for it are often the subject of dispute in DMAS provider appeals. The purpose of this regulatory action is to clarify and confirm that the signature of the health care provider responsible for delivery of reimbursed services, dated on the date of service, is an absolute requirement for the receipt of Medicaid reimbursement. DMAS is implementing this clear directive of the General Assembly through this emergency regulatory action.

In this action DMAS shall specifically address two distinct issues. The first is to clarify and specify the definition of a dated signature. Through this regulation DMAS defines the signature as the legibly written out first and last names of the signing health care provider, and their title if applicable, signed and dated on the date of service. Because timing is often a critical element in the provision of medical treatments, therapies or drugs, DMAS requires the signature and dated on the date the service was delivered. This is a reasonable standard that provides maximum protection to DMAS enrollees. The Agency also takes into consideration the reality that, where a health care provider's signature requires their supervisor to co-sign the health care record, the supervisor may not always be directly available to contemporaneously co-sign the record. DMAS makes allowance for this reality by requiring the supervisor's signature within 24 hours of the date of services. Based upon longstanding industry practice, DMAS is making an exception to the contemporaneous signature requirement for the largely non-medical personal care aide services and respite services, in which records are typically compiled on a weekly basis.

The second issue concerns the definition and requirements for electronic signatures on health care records. Many providers have requested DMAS to clarify what constitutes an acceptable electronic signature. DMAS cannot expect or enforce a mandatory signature requirement in the absence of clear guidelines regarding the widespread use of electronic signatures. To address this issue DMAS is promulgating a new regulation, 12 VAC 30-50-96 (Electronic signatures), which defines electronic signatures and provides specific directives on how they are to be created and verified. DMAS could not comply with the mandate of Item 297 TTTT without defining these two essential issues concerning signed medical records.

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.

The General Assembly mandate amounted to a simple clarification of the requirement that medical records be signed as a mandatory precursor to Medicaid reimbursement. It was left to DMAS to determine how this requirement would be implemented through regulation. DMAS faced two choices – either to make one unified rule that set a simple standard of a legible first and last name signed on the date of service, or to make a similar rule with multiple exceptions to address some of the variances of current medical record practice. The trend in medical record standards, both in Medicare and in managed care, is to require a straightforward signature on the date of service. DMAS has chosen this option for two reasons – patient protection, as noted above, and to avoid the potential for confusion about the application of multiple exceptions to the rule and thus avoid controversies and costly appeals. The one exception DMAS is making is with regard to the largely non-medical personal care and respite services.

In addition, DMAS has received numerous inquiries from Medicaid providers regarding acceptable electronic signatures. This is a natural concern as the health care industry is quickly

moving towards the exclusive use of electronic medical records. DMAS determined that could not fulfill the General Assembly mandate without defining electronic signatures in this emergency package. DMAS reviewed a number of standards for electronic signatures currently in use and determined that the electronic signature regulations of the federal Food and Drug Administration (FDA) provided the most clear and comprehensive approach to this issue. DMAS' new electronic signature administrative code section, 12 VAC 30-50-96, is based the FDA electronic signature regulations.

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.

DMAS 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. DMAS 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 Adrienne Fegans, Dept. of Medical Asst. Services, 600 East Broad St., Richmond, Virginia 23219, (804) 786-4112, **Adrienne.Fegans@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.

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 will use the participatory approach to develop a proposal if it receives at least 25 written requests to use the participatory approach prior to the end of the public comment period. Persons requesting the agency use the participatory approach and interested in assisting in the development of a proposal should notify the department contact person by the end of the comment period and provide their name, address, phone number, email address and their

organization (if any). Notification of the composition of the advisory committee will be sent to all applicants.

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, and will not decrease disposable family income.