



Virginia
Regulatory
Town Hall

Emergency Regulation Agency Background Document

Agency Name:	Dept. of Medical Assistance Services; 12 VAC 30
VAC Chapter Number:	80
Regulation Title:	Methods and Standards for Establishing Payment Rates – Other Types of Care
Action Title:	Fee For Service: Pharmacy Virginia Maximum Allowable Cost (VMAC) and Average Wholesale Price (AWP)
Date:	Approved April 30, 2002; Effective date 07/01/2002

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

Emergency Preamble

Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an “emergency situation” means: (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. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

Please include a brief summary of the emergency action. There is no need to state each provision or amendment.

The Governor is hereby requested to approve this agency's adoption of the emergency regulation which amends the regulations for the Methods and Standards for Establishing Payment Rates – Other Types of Care. This regulation implements the changes directed by the Appropriations Act of the 2002 Session of the General Assembly.

The Code § 2.2-4011 provides for regulations which an agency finds are necessitated by an emergency situation. To enable the Director, in lieu of the Board of Medical Assistance

Services, to comply with the 2002 General Assembly’s mandates, he must adopt this emergency regulation. This issue qualifies as an emergency regulation as provided for in § 2.2-4011 because the Appropriation Act requires this regulation to become effective within 280 days from the enactment of the law or regulation. As such, this regulation may be adopted without public comment with the prior approval of the Governor.

This regulatory action changes the reimbursement methodology for pharmaceutical products. Currently, the Agency uses the estimated acquisition cost (EAC) or reference cost of the Average Wholesale Price (AWP) discounted by a factor of 9%. This legislative mandate increases the percentage deducted from the AWP to 10.25%. Additionally, this mandate redefines the Virginia Maximum Allowable Cost methodology to include all products that participate in the pharmaceutical manufacturers’ rebate program.

This action was mandated by House Bill 30, Items 325 FF and JJ(2) (Chapter _____) which was passed by the General Assembly and adopted by the Governor.

Basis

Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

The Code of Virginia (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services (BMAS) the authority to administer and amend the Plan for Medical Assistance. The Code of Virginia (1950) as amended § 32.1-324, grants the Director of the Department of Medical Assistance Services (DMAS) the authority to administer and amend the Plan for Medical Assistance in lieu of BMAS action pursuant to BMAS’ requirements. The Code also provides, in the Administrative Process Act (APA) § 2.2-4011, for an agency’s adoption of emergency regulations subject to the Governor’s prior approval.

Subsequent to the emergency adoption action and filing with the Registrar of Regulations, this agency intends to initiate the public notice and comment process contained in Article 2 of the APA. Therefore, approval to file the required Notice of Intended Regulatory Action is also necessary and hereby being requested by this action.

Substance

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement

should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

This emergency regulation action amends the Methods and Standards for Establishing Payment Rate; Other Types of Care (12 VAC 30-80-40 and Attachment 4.19 B). These changes are mandated by House Bill 30 as passed by the General Assembly and adopted by the Governor.

Revised Estimated Acquisition Cost

The Agency's current reimbursement for drug products uses an estimated acquisition cost (EAC or reference cost) of Average Wholesale Price (AWP) discounted by a factor of 9%.

Item 325 FF of House Bill 30 decreased the EAC by changing the discount factor to 10.25%. This is based on reports at the national level that the actual price paid for pharmaceuticals is less than what most state Medicaid programs are paying. Using an increased discount factor will reduce the purchase cost of pharmaceutical products.

This emergency action will allow the Agency to conserve funds or to provide a greater level of service to Medicaid recipients by increased funding capability related to decreased costs per unit.

Virginia Maximum Allowable Cost (VMAC) Changes

Item 325 JJ (2) amends the definition of the Virginia Maximum Allowable Cost (VMAC) basing it on the availability of generic drugs in Virginia. Currently, the VMAC is defined based on the utilization of the Virginia Voluntary Formulary. The Omnibus Budget Reconciliation Act (OBRA) of 1990 mandated that Medicaid programs include coverage for all pharmaceutical products that participate in a rebate program as defined by OBRA '90. As a result of the OBRA legislation, the Agency's listing of covered products has expanded and the new VMAC definition will allow the Agency to price pharmaceutical products accordingly.

Alternatives

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

This emergency regulatory action is mandated by House Bill 30, Items FF and JJ(2) which was passed by the General Assembly during the 2002 Session and adopted by the Governor. This mandate does not discuss any alternatives to this regulatory action.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the 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.

This emergency regulatory action will not have any direct impact on the institution of the family and the stability of the family. It will not strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; it will not encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, or one's children and/or elderly parents; it will not strengthen or erode the marital commitment; it will not increase or decrease disposable family income.