



**COMMONWEALTH of VIRGINIA**  
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**MEMORANDUM**

**TO: VICTORIA P. SIMMONS**  
Regulatory Coordinator  
Department of Medical Assistance Services

**FROM: PAIGE S. FITZGERALD**  
Special Counsel to DMAS

**DATE: September 17, 2004**

**SUBJECT: Emergency Regulations concerning Pharmacy Generic Drug Reimbursement Methodology**

I have reviewed the referenced emergency regulations that implement the Virginia Maximum Allowable Cost (VMAC) to modify the reimbursement methodology used for generic, multiple source drug products in accordance with the General Assembly's mandate.

Based on that review, it is this Office's view that the Director, acting on behalf of the Board pursuant to Va. Code § 32.1-324, has the authority to promulgate these regulations, subject to compliance with the provisions of Article 2 of the Administrative Process Act and has not exceeded that authority.

The authority for these emergency actions is found in Va. Code § 2.2-4011, which provides that an "emergency situation" includes "a situation in which Virginia statutory law or the appropriation act . . . requires that a regulation be effective in 280 days or less from its enactment . . . ." The amendments to the regulations will enable the Director, in lieu of the Board of Medical Assistance Services, to comply with the 2004 Appropriation Act (2004 Acts of Assembly chapter 4), Item 326WW, which states that DMAS "shall amend the State Plan for Medical Assistance to modify the reimbursement methodology used to reimburse for generic drug products. The new methodology shall reimburse for the product cost based on a Maximum Allowable Cost list to be established by the Department." Item 326WW also requires that regulations to enact this item of the Appropriation Act are required to become effective within 280 days or less from the enactment of the Act.

This situation qualifies as an emergency as provided in § 2.2-4011(A)(ii) because the Appropriation Act requires these regulations to be effective within 280 days of enactment of this provision. Without emergency regulations, the Department would be unable to meet the time frame established by the General Assembly for

making these changes. As such, these regulations may be adopted without public comment with the prior approval of the Governor.

Accordingly, with the prior approval of the Governor, these regulations qualify for the “emergency” exemption from Article 2 requirements. Please be advised, however, that under Va. Code § 2.2-4011(A), the Department must state in writing the nature of and necessity for such emergency action, and this appears to have been accomplished in the “Agency Background Document.” In addition, the regulations shall be effective for no more than twelve months. As the Department intends to continue regulating the subject matter governed by this emergency regulation beyond 12 months, it will be necessary to replace these emergency regulations with regulations duly promulgated under Article 2 of the APA. A Notice of Intended Regulatory Action relating to the proposed replacement regulations must be filed with the Registrar within 60 days of the effective date of the emergency regulations (and it appears that this has been done). The proposed replacement regulations must be filed with the Registrar within 180 days after the effective date of the emergency regulations.

If you have any questions or need any additional information, please feel free to call me at 786-0095.

cc: Kim F. Piner, Esquire