Virginia Regulatory Town Hall

Final Regulation
Agency Background Document

Agency Name:	Dept. of Medical Assistance Services; 12 VAC 30
VAC Chapter Number:	12 VAC 30-80
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); Revised Dispensing Fee
Date:	04/16/2003; GOV APPROVAL NEEDED BEFORE 4/30

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

This regulatory action changes the reimbursement methodology for pharmaceutical products. Currently, the Dept. of Medical Assistance Services (DMAS) uses the estimated acquisition cost (EAC) or reference cost of the Average Wholesale Price (AWP) discounted by a factor of 9%. The 2002 General Assembly mandated the increase of the percentage deducted from the AWP to be 10.25%. Additionally, an additional mandate redefined the Virginia Maximum Allowable Cost methodology to include all products that participate in the pharmaceutical manufacturers' rebate program.

This regulatory action also changes the agency's dispensing fee for legend drugs as a result of a legislative mandate.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

Minor editorial changes were made to the VMAC/AWP proposed text, however, the dispensing fee was changed from $4.25 to $3.75 as mandated by the 2003 General Assembly.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

I hereby approve the foregoing Regulatory Review Summary with the attached amended State Plan pages regarding Fee For Service: Pharmacy Virginia Maximum Allowable Cost (VMAC), Average Wholesale Price (AWP), and Dispensing Fee, and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012, of the Administrative Process Act.

_4/16/2003_____ _/s/ for Patrick W. Finnerty_/cbj_____

Date Patrick W. Finnerty, Director

Dept. of Medical Assistance Services

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site

addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final 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 comment period for the Notice of Intended Regulatory Action ended on August 28, 2002. The comment period for the proposed regulations began on January 27, 2003, and ended March 28, 2003.

Additionally, the 2003 General Assembly directed DMAS, in the budget bill, to reduce its pharmacy dispensing fee from the current $4.25 to $3.75. Since this change was mandated to the agency and there is no discretion in its implementation, this action is exempt from public comment requirements pursuant to *COV* § 2.2-4006(A)(4)(a).

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purposes of this regulatory action are two-fold: (i) to implement permanent regulations providing for increasing the offset percentage applied to the Average Wholesale Price and redefining the Virginia Maximum Allowable Cost methodology to include all products that participate in the pharmaceutical manufacturers' rebate program; (ii) to revise the dispensing fee reimbursed for legend drugs. This proposed regulatory action will have no affect on the health, safety, or welfare of the citizens of the Commonwealth.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

This 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 Chapter 899,

Items 325 FF and JJ as passed by the 2002 General Assembly and adopted by the Governor on May 17, 2002.

Revised Estimated Acquisition Cost

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

Item 325 FF of the Chapter 899 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 thereby saving the Commonwealth expenditures or providing a greater level of services due to decreased costs per unit.

Virginia Maximum Allowable Cost (VMAC) Changes

Item 325 JJ (2) of Chapter 899 amended 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.

Revised Dispensing Fee

Effective since July 1, 1995, DMAS has reimbursed pharmacists $4.25 for every legend drug prescription they filled for Medicaid recipients. The 2003 General Assembly directed the agency to reduce its legend drug dispensing fee to $3.75 (pursuant to the conference report).

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

The advantages of the VMAC and AWP changes are to Medicaid recipients, the public, and the Commonwealth. The adjustment in Medicaid payments for prescription drugs will not affect Medicaid recipients directly in any way. The redefinition of the VMAC allows DMAS to establish a price and make generic drugs available under Medicaid more quickly. The public will benefit because the costs of this important Medicaid covered service may decrease. The

Commonwealth will benefit because the cost of this important service will decline to be more in line with the costs of the products being purchased for Medicaid recipients.

The disadvantages of the VMAC/AWP changes will be to the pharmaceutical manufacturers, drug distribution business, and pharmacies whose profit margins will not be quite as large under the previous reimbursement methodology.

The advantage of the reduction of the pharmaceutical dispensing fee is mainly to the Commonwealth in that it reduces expenditures for pharmaceutical services. It is expected to be viewed as a disadvantage by pharmacy providers because they will not be reimbursed as much for providing the same service.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

DMAS did not receive any public comments during the NOIRA comment period.

DMAS' proposed regulations were published in the January 27, 2003, Virginia Register for their public comment period from January 27 through March 28, 2003. No comments were received during this public comment period.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

VAC	EMERGENCY REGULATIONS	PROP REGS	FINAL REGS
12VAC30-80-40, Item 2	Deleted reference to Virginia Voluntary Formulary and added Virginia Medicaid Maximum Allowable Cost to expand the list of possible choices of covered drugs	Same.	Same.

12VAC30-80-40, Item 8	Changed the percentage to reduce the AWP from 9% to 10.25%.	Same.	Same.
12VAC30-80-40, Items 6 and 8	Issue not included.	Issue not included.	Reduce dispensing fee from $ 4.25 to $ 3.75

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

This regulatory action will not have any negative effects on the institution of the family or family stability. It will not increase or decrease disposable family income or erode the marital commitment. It will not discourage economic self-sufficiency, self-pride, or the assumption of family responsibilities.