Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Dept. of Medical Assistance Services
VAC Chapter Number:	Chapter 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:	12/3/2002; NEED GOV APPROVAL BY 12/27/2002

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed 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.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed 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 purpose of this regulatory action is 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.

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 providing detail of the regulatory action's changes.

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.

Issues

Please provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

The advantages of both of these 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 both of these 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.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget

activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

These changes are expected to save the Commonwealth approximately $5,600,000 in Fiscal Year 2003 and 5,700,000 in Fiscal Year 2004.

It is anticipated that implementation costs will be minimal and include only a minor change in calculation. Enforcement costs will be negligible.

No cost to localities will occur. Entities affected by this change are pharmaceutical companies.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

VAC	EMERGENCY REGULATIONS	PROPOSED REGULATIONS
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.
12VAC30-80-40, Item 8	Changed the percentage to reduce the AWP from 9% to 10.25%.	Same.

Alternatives

Please describe the specific 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.

The Introduced budget for the 2002-2004 Biennium budget, submitted to the 2002 General Assembly Session, included language reducing the pharmacy rate to the Average Wholesale Price (AWP) minus 11 percentage points. The General Assembly amended the language to set the rate at AWP minus 10.25%. No other alternative was considered since this change was mandated through the Appropriation Act.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

No comments were received during the NOIRA comment period.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

DMAS has examined these regulations and, in so far as is possible, has ensured that they are clearly written and easily understandable by the individuals and entities affected.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

DMAS will include the monitoring, in collaboration with the affected industry, of this regulatory action as part of its ongoing management of State Plan policies and its Executive Order 21(02) activities.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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.