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 30-80-40
Regulation title	Methods and Standards for Establishing Payment Rates—Other Types of Care: Pharmacy Reimbursement Method
Action title	Pharmacy Generic Drug Reimbursement Methodology (VMAC)
Document preparation date	; **NEED GOV APPROVAL BY NOV 29, 2004**

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 review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Preamble

The APA (Section 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) 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. This suggested emergency regulation meets the standard at *COV* 2.2-4011(ii) as discussed below.

Chapter 4 of the *2004 Acts of the Assembly*, Item 326 WW (1) - (3) directs DMAS to amend the State Plan for Medical Assistance to modify the reimbursement methodology used to reimburse for generic drug products. This amendment must be effective within 280 days of the date of enactment of Chapter 4 so therefore qualifies under the authority of the COV 2.2-4011(ii) as an emergency regulation.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations titled Methods and Standards for Establishing Payment Rates—Other Types of Care: Pharmacy Reimbursement Method 'Pharmacy Generic Drug Reimbursement Methodology (VMAC)' (12 VAC 30-80-40) and also authorize the initiation of the permanent regulation promulgation process provided for in § 2.2-4007.

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 implement the Virginia Maximum Allowable Cost (VMAC) to modify the reimbursement methodology used for generic, multiple source drug products. The VMAC will replace the existing generic drug methodology and will be more responsive to and more accurately reflect prices of multi-source drugs in today's marketplace. Also, this action establishes the criteria for the Department to develop VMAC pricing methodology, publish prices, and maintain a procedure whereby pharmacists may dispute the DMAS price for generic drugs and have their disputes resolved quickly. As a result of this change, DMAS will post to its website a monthly listing of generic drugs, prices, information sources, with comparisons to reference standards.

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, 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.

Substance

Please detail any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons why the regulation is essential to protect the health, safety, or welfare of Virginians. Delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

The section of the State Plan for Medical Assistance that is affected by this action is the Methods and Standards for Establishing Payment Rates—Other Types of Care: Pharmacy Reimbursement (Attachment 4.19-B (12 VAC 30-80-40)).

Pharmaceuticals are an increasingly important part of medical care and health care costs, and the fastest growing component of health care spending, including the Medicaid program. Medicaid programs face the challenge of managing pharmacy expenditures in a difficult economic environment while maintaining beneficiary access to appropriate care. Pharmacy costs in Virginia are one of the top Medicaid cost drivers. For recipients receiving fee-for-service medical services, DMAS spent approximately $115 million (27%) of the total $425 million (total funds) in expenditures in pharmacy costs on generic drugs in fiscal year 2003.

Prescription drug coverage is an optional benefit that all state Medicaid programs currently provide. This benefit provides access to a broad range of prescription drugs to a population that otherwise may be unable to get necessary but expensive drug therapy, including those recipients with severe mental illnesses or HIV/AIDS.

In Virginia, the Medicaid and FAMIS prescription drug benefit is provided through fee-for-service and managed care organization delivery systems. Currently, the 263,000 Medicaid clients and 5,000 FAMIS clients who obtain services through fee-for-service delivery systems are those who live in areas of the Commonwealth that currently do not have a managed care organization available or who are excluded from the managed care programs (such as persons in nursing facilities, community based care waiver programs, and foster care children). Approximately 340,000 Medicaid and FAMIS clients receive pharmacy benefits through one of seven managed care organizations and are not affected by this regulatory action.

Currently, the Virginia Medicaid program reimburses pharmacies based on the lowest of the following pricing methodologies:

- Federal Upper Limit (FUL)
- 75th percentile cost level (MAC)
- 60th percentile cost level for unit-dose drugs
- Average Wholesale Price minus 10.25%
- Pharmacy's usual and customary charge to the general public

Virginia Medicaid payments for fee-for-service pharmacy costs have increased by 111 percent since 1997, from $201 million to $425 million in fiscal year 2003 after drug rebates, in spite of major shifts of recipients to Medicaid managed care plans (1996 through December 2001). Over this same period, fee-for-service pharmacy costs, as a percentage of total medical costs, increased from 8.9 percent to 11.9 percent. Some of the factors of this cost escalation have been the cost per unit of pharmaceutical products as well as an increase in overall utilization. Similar trends have been seen in states across the country.

Within Federal guidelines, Virginia has several tools at its disposal to control prescription drug utilization and spending. Prior to 2002, Virginia implemented the following cost containment strategies in its fee-for-service pharmacy program that are still in effect:

- Generic substitution for brand-name drugs. DMAS implemented a reminder message to the dispensing pharmacist at point-of-sale for its mandatory generic program;
- Drug utilization review, both through online messages to pharmacies and retrospective reviews;
- Federally mandated drug rebates from manufacturers; and
- Pharmacy lock-in for fraud and abuse cases.

Since 2002, cost control strategies that have been implemented in the fee-for-service program with savings included:

- Reduced Medicaid reimbursement for pharmacies from average wholesale price (AWP) minus nine percent to AWP minus 10.25 percent
- Expedited access to generic drug products
- Revised pricing for anti-hemophilia drugs
- Established 34-day supply limit
- Increased recipient co-pay for brand-name drugs to $2
- Improved third party coverage cost avoidance at point-of-sale

Additional DMAS' cost savings strategies that have been implemented in 2003-2004 are as follows:

- Established and implemented a Preferred Drug List;
- Established prior authorization requirements for recipients who require more than nine unique prescriptions (to be effective 10/1/2004);
- Increased recipient co-pay for brand-name drugs from $2.00 to $3.00; and
- Implemented changes to the Prospective Drug Review (ProDUR) program for pharmacy claims.
- Mandatory use of generic drugs began effective 9/1/2004

The purpose of this regulatory action is to implement and administer a Maximum Allowable Cost (VMAC) program for the Department's fee-for-service population's (both Medicaid recipients and FAMIS participants) use of pharmacy services. VMAC is a methodology commonly used by Medicaid programs to control the costs of generic multiple source drugs by setting a maximum reimbursement amount. Drugs are considered "multiple source" or "multi-

source" when the drug is available as both brand-name and generic or a brand-name product is priced as generic. In order to develop and manage its VMAC methodology, DMAS required the assistance of a contracted vendor. In order to secure the needed services and the best rate available to the Commonwealth, DMAS solicited proposals that met the following overall program objectives:

- Create a new VMAC program to implement cost savings for the Department;
- Establish prices for generic multiple source drugs, which shall not be less than 110 percent of the lowest published wholesale acquisition cost for products widely available for purchase in the Commonwealth and included in the national pricing compendia;
- Monitor market conditions for fluctuations in pricing to ensure proper reimbursement to providers;
- Provide a timely process for communication, review, and resolution of providers' reimbursement discrepancies; and
- Provide a mechanism to evaluate program outcomes and compliance rate.

DMAS will implement the VMAC program in accordance with the 2004 Appropriations Act language and also will require the selected vendor to administer the program in accordance with this directive. By instituting a VMAC reimbursement methodology for generics, DMAS will reimburse pharmacies an amount that more accurately reflects their acquisition costs plus an appropriate profit margin. Drug availability, costs, and other market changes will be monitored by the contractor to ensure pricing is appropriate.

DMAS and its contractor will consider reference products, Federal Upper Limit (FUL) values, Wholesale Acquisition Cost (WAC) and other factors to determine appropriate market pricing as it is typically influenced by many factors. The pricing values developed from this process become the foundation upon which VMAC pricing is based.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC30-80-40		Definition and requirements related to the maximum allowable cost (MAC) program	Repeals definitions and all requirements related to the maximum allowable cost program. Adds language related to the Virginia Maximum Allowable Cost (VMAC) program.

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.

The creation of Virginia Maximum Allowable Cost (VMAC) program requirements for generic drug products as contained herein has been mandated by *Chapter 4 of the 2004 Acts of Assembly*,

Item 326WW, thereby eliminating discussions of possible alternative policies. The required features of this new pricing methodology were set out in the referenced *Act* as follows:

(i) publish the factors used to set state MAC rates;
(ii) identify three different suppliers that are able to supply the product;
(iii) identify that the use of a MAC rate is lower than the FUL or the development of a MAC rate that does not have a FUL will not result in the use of higher-cost innovator brand name or single source drugs in Medicaid;
(iv) distribute the list of state MAC rates to pharmacy providers in a timely manner prior to implementation of MAC rates.

Additionally, the *Act* required that DMAS:

(i) review and update the list of MAC rates at least quarterly;
(ii) implement and maintain a procedure to eliminate products from the list, or modify MAC rates, consistent with changes in the marketplace; and
(iii) provide an administrative appeals procedure to allow a dispensing provider to contest a listed MAC rate.

The regulatory changes suggested herein are intended to conform the agency's current policies to changes required in this *Act* and also by the Governor. Failure to implement this new payment methodology will negatively impact the projected budget savings.

Family impact

Please assess the impact of the emergency regulatory action on the institution of the family and family stability.

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 nor affect disposable family income.