Virginia Regulatory Town Hall

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Final Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation	12 VAC 30, Chapter 80
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	

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).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

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 new pricing methodology for generic drugs more accurately reflects market prices and acquisition costs of generic drugs for pharmacy providers. The new regulations also establish requirements for the publication of VMAC rates and for dispute resolution with pharmacy providers.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

I hereby approve the foregoing Agency Background Document with the attached amended State Plan pages Methods and Standards for Establishing Payment Rates -- Other Types of Care: Pharmacy Reimbursement (12 VAC 30-80-40), 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 and is full, true, and correctly dated.

_____ _____

Date

Patrick W. Finnerty, Director

Dept. of Medical Assistance Services

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the 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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

This change will not have any direct affect on the health, safety, or welfare of the citizens of the Commonwealth or on Medicaid recipients.

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.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The sections of the State Plan for Medical Assistance that are affected by these changes are the Methods and Standards for Establishing Payment Rates-Other Types of Care (12 VAC 30-80-40).

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.

For dates prior to December 1, 2004, the Virginia Medicaid program reimburses pharmacies based on the lowest of the following pricing methodologies:

- Federal Upper Limit (FUL)

- 75th percentile cost level (VMAC)
- 60th percentile cost level for unit-dose drugs (VMAC)
- 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 (MAC) 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 implemented the VMAC program in accordance with the 2004 Appropriations Act language and also required the selected vendor to administer the program in accordance with this directive. By instituting a VMAC reimbursement methodology for generics, DMAS now reimburses pharmacies an amount that more accurately reflects their acquisition costs plus an appropriate profit margin. Drug availability, costs, and other market changes are monitored by the contractor to ensure pricing is appropriate.

DMAS and its contractor 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.

Issues

Please identify the issues associated with the proposed regulatory action, including:
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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

The primary advantage to the Commonwealth and to the agency is that this regulatory action will generate significant cost savings on generic drugs, which is a substantial expense in the Medicaid budget. While pharmacy providers stand to lose some profits due to this change, it brings the DMAS generic pricing methodology more in line with the payment structure used by commercial insurance that is prevalent in the industry.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

This is the only change made in this regulation from the proposed to the final regulation.

Section number	Requirement in proposed regulation	Proposed change in final regulation and rationale
12VAC30-80-40 (2)(a)	a. Identify three different suppliers, including either manufacturers or wholesalers, that are able to supply, in sufficient quantities, pharmaceutical products.	a. Identify three different suppliers, including [~~either~~] manufacturers [~~or wholesalers~~], that are able to supply, in sufficient quantities, pharmaceutical products.

Public comment

Please summarize all comment received during the public comment period following the publication of the proposed stage, and provide the agency response. If no public comment was received, please so indicate.

DMAS' proposed regulations were published in the *Virginia Register (21:23), July 25, 2005* for their public comment period from July 25 through September 23, 2005. One comment was received from Virginia Pharmacists Association. A summary of the comments received and the agency's response follows.

Commenter	Comment	Agency response
Virginia Pharmacists Association (VPA)	Expressed concern that the addition of wholesalers to the list of available generic drug sources in 12VAC30-80-40(2)(a). The VPA believes the addition of wholesalers works counter to the intent of the concept behind the VMAC.	DMAS agrees with the VPA's statement. In response to this comment DMAS removed the reference to wholesalers from 12 VAC 30-80-40(2)(a) in the final regulation.

CVS Pharmacy	CVS suggests that VMAC program savings must be capped at a savings goal that is known to all those impacted and once reached reexamined to allow pharmacies to achieve a more reasonable margin. In addition, CVS suggests that DMAS consider an incentive program for Virginia pharmacy providers to continue supporting the Commonwealth's efforts to save the program money by dispensing generic drugs.	The Agency is aware of the vast difference between the prices of generic and brand prescription drugs. DMAS has taken great care to implement the VMAC program to be fair to all pharmacy providers and with consideration given to the current market environment. The Agency is aware that private, commercial insurance companies operate MAC programs that are much more aggressive that the VMAC program, which permit far less of a profit margin. In addition, the Agency has implemented a comprehensive dispute resolution process that may be used by any pharmacy provider that has a specific pricing dispute. To date the State has only received one such dispute, which was resolved favorably to the pharmacy provider. Finally, in creating and implementing the VMAC program, with the extensive input of the pharmacy community, the Agency was carrying out a mandate of the Virginia Assembly. Under this mandate DMAS must keep the pricing level within a fixed percentage of current market prices, which creates an inherent limit on savings. VMAC program savings are designed to be sensitive to the market forces highlighted in CVS's comment because savings will fluctuate according to prescription volumes or utilization and changes in market prices. Therefore at the present time DMAS has no plan to implement a savings cap. With respect to an incentive program for dispensing generic drugs, this past year DMAS raised the dispensing fee it pays for generic drugs from $3.75 to $4.00. DMAS also implemented a mandatory generic drug program. Therefore, the Agency believes that further incentives are not required at the present time in order to promote generic drug dispensing.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

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 MAC program and adds language related to the Virginia Maximum Allowable Cost (VMAC) program.
**12VAC30-80-40(2)(a)		a. Identify three different suppliers, including either manufacturers or wholesalers, that are able to supply, in sufficient quantities, pharmaceutical products.	a. Identify three different suppliers, including ~~either~~ manufacturers ~~or wholesalers~~, that are able to supply, in sufficient quantities, pharmaceutical products.

Family impact

Please assess the impact of the proposed 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, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.