Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	DEPT. OF MEDICAL ASSISTANCE SERVICES
VAC Chapter Number:	12 VAC 30, Chapter 80
Regulation Title:	Methods and Standards for Establishing Payment Rates-Other Types of Care: Reimbursement for Pharmacy Services
Action Title:	Unit Dose
Date:	12/11/2002

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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 suggested regulatory action addresses two items regarding reimbursement for pharmacy services in Medicaid. It proposes to conform, for Medicaid reimbursement purposes, the definition of unit dose dispensing system to the definition employed by the Board of Pharmacy. It also proposes to change the reimbursement rate for the service of "unit dose dispensing" to a per capita monthly fee.

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 also provides, in the Administrative Process Act (APA) §§2.2-4007 and 2.2-4013, for this agency's promulgation of proposed regulations subject to the Governor's review.

Pursuant to the regulatory review requirements of Executive Order 21(02), Periodic Review of Existing Regulations, DMAS reviewed its controlling regulations for its reimbursement of pharmacy services and determined that modifications in pharmacy reimbursement were indicated.

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 purposes of this suggested regulatory action are:

1. To conform this Department’s definition of "unit dose dispensing system" to the definition used by Virginia Board of Pharmacy regulations. Conforming this agency’s regulation for this issue to that of the Virginia Board of Pharmacy’s related regulation is expected to eliminate an unnecessary barrier to service provision for practicing pharmacists.

2. To change the reimbursement rate for the service of "unit dose dispensing" to a per capita monthly fee. This will eliminate the current reimbursement rate which is a dispensing fee for each unit provided through a "unit dose dispensing system".

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.

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

This regulatory action is not mandated by either Federal or State law but, currently DMAS' definition of the term 'unit dose' is more restrictive than regulations promulgated by the Board of Pharmacy, thereby creating conflicts and barriers to the provision of services by enrolled pharmacists. The Board of Pharmacy has expanded its definition of unit dose to permit a maximum of 7 days' supply under its regulations. This action proposes to re-align the DMAS payment regulations with this Board of Pharmacy regulation.

Misunderstanding by providers of DMAS' current definition of a unit dose dispensing system has caused certain billing errors for prescription drugs. Standardization of this definition would allow dispensing to occur as determined to be safe and reasonable by the Virginia Board of Pharmacy.

Payment algorithms currently in use by DMAS, in its computerized claims processing system, are poorly understood by providers of "unit dose dispensing". Providers are over billing and are being overpaid for their unit dose services. As a consequence, DMAS is being required to re-process pharmacy claims that have already been processed and paid in error.

A single charge for this service, billed once monthly, would provide clear documentation that the pharmacy provider is certifying the use of unit dose products for the specific patient during the previous month, in accordance with the DMAS definition.

It is anticipated this regulation will be budget neutral.

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 primary advantage in the Commonwealth is the facilitation of pharmacy services due to the use of a consistent definition of unit dose dispensing for Medicaid recipients and non-Medicaid users of pharmacy services. Modifying the reimbursement computer algorithm to one dispensing payment per month will simplify the payment methodology thereby reducing claims processing

errors and overpayments. The Commonwealth's pharmacy community supports this modification. This modification will be transparent to citizens of the Commonwealth.

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.

The costs to implement a regulatory change include both direct and indirect costs. In the case of this change, these costs are expected to be minimal. Activities necessary to implement this changes include are Information Systems Request (ISR), provider manual revisions, and training. It is anticipated that the efficiencies resulting from this change will offset these implementation costs. Payment processing costs experienced by DMAS with regard to time are expected to decrease slightly. Economics are anticipated in streamlining this process and through a reduction in payment errors.

No cost to localities is expected. Businesses affected include pharmacies and repackagers. The costs related to this change that are experienced by these businesses is expected to slightly decrease as the result of replacing the per dosage cost with a monthly cost; processing expenses related to billing and payment will decrease, although not to a significant degree.

Conclusion: The effects of this regulatory change are budget neutral.

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.

Affected Subsection	Suggested Change
12 VAC 30-80-40	
Subsection 1	Technical correction to update name of federal funding agency.
Subsection 7	New definition of unit dose dispensing system to be consistent with the definition used by the Board of Pharmacy. Limit to one dispensing fee per month per nursing facility patient is

	also recommended.
Subsection 8	Note is added to address modification being made to Average Wholesale Price as contained in a separate regulatory action.

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.

No other alternatives were considered, as the purpose of this change, in part, was to eliminate the existing inconsistency between DMAS' definition of unit dose dispensing system and the definition employed by the Board of Pharmacy. This change is expected to increase efficiency by reducing errors.

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.