Virginia Regulatory Town Hall

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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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.
Action title	MAC Reimbursement Methodology for Specialty Drugs
Document preparation date	

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 branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Preamble

The APA (Code of Virginia § 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.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Methods and Standards for Establishing Payment Rates: Other Types of Care -- MAC Reimbursement Methodology for Specialty Drugs (12 VAC 30-80-40) and also authorize the initiation of the permanent regulatory promulgation process provided for in § 2.2-4007.

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. Item 302 JJ of the 2008 Appropriations Act directs DMAS to "modify the delivery system of pharmaceutical products to include a specialty drug program." This Budget Item included emergency regulatory authority.

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 Department is promulgating this regulation to create a specialty drug reimbursement methodology based upon the Wholesale Acquisition Cost (WAC) of designated specialty drugs. Specialty drug products are products used to treat chronic, high-cost or rare diseases, including drugs for the treatment of certain diseases such as Hepatitis-C and Multiple Sclerosis, as well as drugs such as growth hormone agents and interferon. These drugs tend to be much higher in cost than standard pharmaceutical products, and this action implements a new methodology to help contain the higher costs associated with these drugs.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

Specialty pharmaceuticals represent the fastest growing segment of the prescription drug market in the U.S. Industry projections have the growth rate at 20% per year. Typically, these products are used to treat chronic and/or rare diseases, are high-cost, and can be administered by injection, infusion inhalation, or orally. DMAS is promulgating this regulation in an effort to help contain the costs of these complex and expensive drugs. Pharmacy reimbursement is one of the highest dollar expenditures in the Medicaid budget.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

The section of the Virginia Administrative Code that is affected by this action is: Methods and Standards for Establishing Payment Rates: Other Types of Care -- Fee-for-service providers: pharmacy (12 VAC 30-80-40).

This action implements a new methodology for the reimbursement of designated specialty drugs. The new methodology, described in a new subsection 10 of 12 VAC 30-80-40, is a formula based upon the Wholesale Acquisition Cost (WAC) of these specialty drugs. The methodology computes a price above a given percentage of the WAC for each specified drug. The current percentage value is 4.7%. In addition to the formula, the new subsection also references the location of the list of designated drugs subject to the new methodology on the DMAS website, and states that the new pricing methodology is reviewed and subject to the same dispute resolution and appeal rights as the standard Maximum Allowable Cost pricing methodology.

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. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

This action is based upon Item 302 JJ of the 2008 General Assembly, calling for DMAS to develop a specialty drug program to control drug expenditures. There were several approaches available to DMAS to accomplish this goal; DMAS has chosen a hybrid approach to this mandate in order to maximize available savings while not compromising clinical management of

the complex conditions associated with the use of these drugs. To gain experience in this new area, DMAS is approaching the specialty drug program through a phased implementation. To date, specialty drugs have been addressed through collection of rebates for physician-administered specialty drugs and the introduction of two specialty drug classes on Virginia Medicaid's Preferred Drug List, which achieves both clinical management and cost savings (via supplemental rebates) for these two classes. Finally, DMAS has determined that not all specialty drug classes are eligible for the program due to the complexities of clinical management and market conditions related to the drugs.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Katina Goodwyn, Division of Healthcare Services, Pharmacy Unit, 600 East Broad Street, Richmond, Virginia, 23219, e-mail address: Katina.Goodwyn@dmas.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

Participatory approach

Please indicate the extent to which an ad hoc advisory group will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

DMAS is using the participatory approach to develop this regulatory scheme. Persons interested in assisting in the development of this methodology should notify the department contact person by the end of the comment period and provide their name, address, phone number, email address and the organization you represent (if any).

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent 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.

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.