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	Requirement for Tamper Resistant Rx Pads
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(i) as discussed below.

The United State Congress recently passed an amended appropriation bill (Public Law 110-28) that adds a new requirement to the federal Medicaid reimbursement process for prescription drugs. The new mandate, part of the "U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007," prohibits federal financial participation for outpatient drugs where the written prescription for the drug was not written on a tamper-resistant prescription pad. This mandate is currently scheduled to go into effect October 1, 2007. The provision aims to save the federal Medicaid program money and prevent patients from illegally obtaining drugs. Currently, the Department of Medical Assistance (DMAS) does not require the use of tamper-resistant prescription pads for Medicaid-covered prescriptions. This state regulatory action will bring state Medicaid pharmacy reimbursement in line with the new federal mandate by implementing the requirement that all Medicaid covered prescription drugs based upon a written prescription must be supported by a prescription executed on a tamper-resistant pad.

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 -- Fee-for-service providers: pharmacy (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.

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 comply with the requirement of Public Law 110-28, mandating the use of tamper-resistant prescription pads for written prescription s for Medicaid-covered 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.

DMAS is promulgating this regulation pursuant to a federal mandate.

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

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 and services.

This action meets the emergency regulation authority requirements of exemption provided by the *Code of Virginia* §2.2 – 4011 because it conforms the attached regulations to the federal requirement of Public Law 110-28 (amending Section 1902(i) of the Social Security Act and must be implemented within 280 days of the federal Act's passage. Details of this mandatory change are set forth below:

This change is being made in 12 VAC 30-80-40 (Fee-for-service providers: Pharmacy). DMAS is adding a new paragraph, numbered ten, at the end of this section. The new paragraph describes the new requirement as follows:

> **10. Tamper resistant prescription pads: For prescriptions written on or after October 1, 2007, DMAS shall not provide reimbursement for covered outpatient drugs (as defined in section 1927(k)(2) of the Social Security Act) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad. Tamper resistant pads are defined as pads that contain security features specifically**

designed to prevent alterations and forgeries, and as further defined in Agency guidance documents.

DMAS based the language of this requirement directly on the language in the federal budget mandate (P.L. 110-28), but added sentence defining "tamper resistant pad" to provide additional guidance to Medicaid providers.

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.

The federal law is a straightforward mandate and the language of the emergency regulation tracks the Public Law closely. The federal government has not yet published any official guidelines regarding enforcement. Any change that may be required pursuant to published federal guidelines shall be accounted for in either the proposed or final regulations promulgated by the Department of Medical Assistance Services.

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 Rachel Cain, Division of Healthcare Services, Pharmacy Unit, 600 East Broad Street, Richmond, Virginia, 23219, e-mail address: Rachel.Cain@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 a proposal. Persons interested in assisting in the development of a proposal 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.