Virginia Regulatory Town Hall
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Emergency Regulation
Agency Background Document

Agency name	Department of Medical Assistance Services
Virginia Administrative Code (VAC) citation	12 VAC 30-50, 130-1000
Regulation title	Amount, Duration, and Scope of Services: Prior Authorization (PA) of Pharmacy Services and Preferred Drug List (PDL)
Action title	PA of Pharmacy Services and PDL
Document preparation date	; NEED GOV APPROVAL BY

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.

This action is an additional emergency regulation needed to address the subject of a previous emergency regulation, as authorized by *Code of Virginia* § 2.2-4011(A). That Code section permits the agency to "issue additional emergency regulations as needed addressing the subject matter of the initial emergency regulation." This regulatory action is not otherwise exempt under the provisions of the *Code* § 2.2-4006.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Amount, Duration, and Scope of Services: Prior Authorization of Pharmacy Services and Preferred Drug List (12 VAC 30-50-210, 30-130-1000).

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 twofold: to revise the definition of "Emergency supply" and to expand the description of the duties of the Medicaid Pharmacy and Therapeutics Committee (P&T Committee). This regulatory action follows up on a previous emergency regulation concerning the Preferred Drug List regulations (12 VAC 30-50-210 and 12 VAC 30-130-1000), published in the Virginia Register on December 29, 2003 (VR 20:8). That regulatory action contained a definition of the term "Emergency supply" that defined this term as the "medication that is dispensed if the physician is not available to consult with the pharmacist." This definition was superceded by a subsequently published emergency regulation, Utilization Review of High Drug Thresholds, published January 26, 2004 (VR 20:10). The High Drug Thresholds emergency regulation also covered 12 VAC 30-50-210; it contained a definition of "Emergency supply" that defined that term as the "medication that may be dispensed if the prescriber cannot readily obtain authorization, or if the physician is not available to consult with the pharmacist." The subsequent definition found in the High Drug Thresholds emergency regulation allows the pharmacist to exercise his professional judgment in dispensing an emergency supply.

In addition, the description of duties of the P&T Committee contained in the initial emergency regulation did not set forth any protocols for reviewing recently approved drugs entering the market or for regular reviews of the PDL. 12 VAC 30-130-1000 is being amended to address these two issues.

Legal basis

1) Please confirm that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.
2) Please indicate that the regulation is not otherwise exempt under the provisions of subdivision A.4 of Section 2.2-4006 of the APA.

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.

The *Code of Virginia* § 2.2-4011(A) states that following the enactment of an emergency regulation "an agency may issue additional emergency regulations as needed addressing the subject matter of the initial emergency regulation, but any such additional emergency regulations shall not be effective beyond the twelve-month period from the effective date of the initial

emergency regulation." This current action is such an additional emergency regulation. The Office of the Attorney General has certified that this agency has the authority to promulgate this emergency regulation and that it comports with applicable state and federal laws and regulations. Additionally, these emergency regulations are not otherwise exempt under the COV § 2.2-4006.

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.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC30-50-210		Definition of "Emergency supply" is "medication that is dispensed if the physician is not available to consult with the pharmacist." Description of duties of P&T committee contains no requirement for review of new prescription drugs entering market, and no requirement for annual review	Modified section defines "Emergency supply as the "medication that may be dispensed if the prescriber cannot readily obtain authorization, or if the physician is not available to consult with the pharmacist." Adds new duties to the P&T committee description to include protocol for review of recently approved prescription drugs and for annual review of the PDL.
	12VAC30-130-1000	Definition of "Emergency supply" is "medication that is dispensed if the physician is not available to consult with the pharmacist." Description of duties of P&T committee contains no requirement for review of new prescription drugs entering market, and no requirement for annual review	Modified section defines "Emergency supply as the "medication that may be dispensed if the prescriber cannot readily obtain authorization, or if the physician is not available to consult with the pharmacist." Adds new duties to the P&T committee description to include protocol for review of recently approved prescription drugs and for annual review of the PDL.

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 only two choices available to address this situation were to leave the definition of "Emergency supply" in the initial PDL emergency regulation intact, or to change the definition to conform it to the definition in the subsequently published High Drug Thresholds emergency regulation. Because the definition of "Emergency supply" the Agency seeks to modify is contained solely in an emergency regulation, it cannot be addressed in any manner other than through another emergency regulation. Therefore DMAS is going forward with this action in order to avoid confusion among pharmacists pending the adoption of final regulations in which this anomaly will be addressed.

Although the Department made it a matter of policy that the P&T committee would address new drugs on the market in a timely fashion, as well as perform annual reviews of the PDL, these guidelines for the P&T committee were not initially cast as regulations. After consultation with representatives of pharmacy providers and the Attorney General's office, the Department decided to finalize these two matters as regulations.

Family impact

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

This regulatory action does not have any impact on the institution of the family and family stability including strengthening or eroding the authority and rights of parents in the education, nurturing, and supervision of their children; encouraging or discouraging economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents, strengthening or eroding the marital commitment; nor increasing or decreasing disposable family income.