Virginia Regulatory Town Hall

townhall.state.va.us

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 30-141
Regulation title	Family Access to Medical Insurance Security Plan (FAMIS): Utilization Review of High Drug Thresholds
Action title	UR of High Drug Thresholds for FAMIS
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 regulatory action qualifies as an emergency, pursuant to the authority of the *Code of Virginia*, 1950 as amended, § 2.2-4011, because it is responding to mandates in the Virginia Appropriations Act (the *2003 Acts of Assembly*, *Chapter 1042 Item 324 H)* that must be effective within 280 days from the date of its enactment and these regulatory changes are not otherwise

exempt under the provisions of the *Code* § 2.2-4006. To enable the Director, in lieu of the Board of Medical Assistance Services (BMAS), to comply with changes in the Virginia Appropriation Act, he must adopt these regulatory changes as an emergency action. Since the Department of Medical Assistance Services (DMAS) intends to continue regulating the issue contained in this emergency regulation past the effective period permitted by this emergency action, it is also requesting approval of its Notice of Intended Regulatory Action in conformance with § 2.2-4007.

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled Family Access to Medical Insurance Security Plan: Utilization Review of High Drug Thresholds (12 VAC 30-141-500) and also authorize the initiation of the permanent regulations promulgation process provided for in § 2.2-4007.

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 to implement a program of prospective and retrospective utilization review of pharmacy services for non-institutionalized fee-for-service and PCCM FAMIS enrollees who are prescribed large numbers of different prescription (legend) drugs within specific time periods.

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 BMAS the authority to administer and amend the Title XXI Plan (FAMIS). 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 2003 Appropriations Act, Chap. 1042, Item 324(H) mandated that DMAS promulgate regulations to implement a program for FAMIS to require "prior authorization of prescription drugs for non-institutionalized recipients when more than nine unique prescriptions have been prescribed within a 180 day period." Section 2102(a)(7) of the federal Social Security Act requires states "to assure the quality and appropriateness of care" in Title XXI SCHIP programs. Finally, 42 CFR § 457.495(d) requires prior authorization decisions to be in "accordance with the medical needs of the patient."

The Office of the Attorney General has certified that this agency has the authority to promulgate emergency regulations and that such emergency regulations comport 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
12VAC30-141-500		Benefits reimbursement: Pharmacy.	Require prior authorization of drugs for non-institutionalized FAMIS recipients receiving fee-for-service benefits when they exceed the established thresholds within the specified time frames. This program does not apply to FAMIS recipients enrolled in managed care organizations.

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 creation of utilization review requirements for high drug thresholds for the FAMIS program, as contained herein, was mandated by the General Assembly through the *2003 Acts of Assembly, Chapter 1042, 324, Item H*, thereby eliminating consideration of alternatives. The regulatory changes proposed herein conform the agency's current policies to changes required by the *Act*.

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.