Virginia Regulatory Town Hall

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Final Regulation
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	

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).

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

DMAS proposes to amend its coverage of pharmacy services for enrollees in the Family Access to Medical Insurance Security (FAMIS) Plan. Under these suggested regulations, FAMIS enrollees who are prescribed more than nine unique prescriptions in a 180-day period shall receive retrospective utilization review of their drug profiles. In addition, for enrollees who meet the threshold requirement *and* where the utilization reveals their drug regimen could cause a potentially harmful drug-to-drug Level One interaction, the program will require the dispensing pharmacist to obtain prior authorization before dispensing the prescribed drug. (A Level One interaction is the most severe category of adverse drug events.)

FAMIS covers children who lack access to health insurance and with income levels at or below 200% of the federal poverty level. High numbers of prescription drugs can pose particular hazards to their health and safety.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

I hereby approve the foregoing Agency Background Document with the attached amended regulations, Family Access to Medical Insurance Security Plan (FAMIS): Utilization Review of High Drug Thresholds (12 VAC 30-141-500) and adopt the action stated therein. I certify that this final regulatory action has completed all the requirements of the Code of Virginia § 2.2-4012, of the Administrative Process Act and is full, true, and correctly dated.

_____ _____

Date

Patrick W. Finnerty, Director

Dept. of Medical Assistance Services

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the 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, § 32.1-351, grants to the BMAS the authority to administer and amend the Title XXI Plan (FAMIS). The *Code of Virginia* (1950) as amended, § 32.1-351(K), authorizes the Director of DMAS to "adopt, promulgate and enforce such regulations pursuant to the Administrative Process Act (§ 2.2-400 et. seq.) as may be necessary for the implementation and administration of the Family Access to Medical Insurance Security Plan." 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."

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of this action is to implement a program of retrospective and prospective utilization review of pharmacy services for non-institutionalized fee-for-service and PCCM FAMIS enrollees who are prescribed more than nine unique prescriptions within a 180-day period.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The Virginia Administrative Code section affected by the suggested regulations is 12 VAC 30-141. The new provisions require retrospective review of drugs for non-institutionalized FAMIS recipients receiving fee-for-service benefits when they exceed nine unique prescriptions within a 180-day period. In addition, the program will require the dispensing pharmacist to obtain prior authorization before dispensing any prescription that meets the threshold requirements *and* that may cause a potentially harmful drug-to-drug Level One interaction. Unlike the Prospective Drug Utilization Review process, which allows the dispensing pharmacist to override the drug interaction alert, when an enrollee exceeds the threshold of nine unique prescriptions and the enrollee's drug regimen contains a potentially harmful drug-to-drug Level One interaction, the threshold program does not permit the dispensing pharmacist to override the prior authorization requirement. Rather, the pharmacist is required to obtain a prior authorization before dispensing the prescribed drug. This program does not apply to FAMIS recipients enrolled in managed care organizations.

High drug thresholds for FAMIS enrollees is addressed in both the existing emergency regulation concerning this issue and the FAMIS State Plan Amendment, submitted to CMS for approval on June 15, 2004. The amendment describes the limitations and utilization review requirements for non-institutionalized FAMIS enrollees who receive high numbers of prescriptions for legend drugs. The 2003 General Assembly mandated this modification to the FAMIS regulations for pharmacy services, and directed DMAS to implement this modification.

Issues

Please identify the issues associated with the proposed regulatory action, including:
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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

There are no disadvantages to the public in this change. The greatest advantage to the public is an increase in the health and safety of FAMIS enrollees who receive threshold review. FAMIS enrollees can be expected to benefit the most from this change because the higher level of scrutiny of their drug profiles will better ensure their health and safety.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes made since the proposed stage.

Public comment

Please summarize all comment received during the public comment period following the publication of the proposed stage, and provide the agency response. If no public comment was received, please so indicate.

DMAS' proposed regulations were published in the 11/29/2004 issue of the *Virginia Register* (Volume 21, Issue 6) for their public comment period from 11/29/2004 through 1/28/2005. No comments were received during the public comment period from 11/29/2004 through 1/28/2005.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

There were no changes in this regulation since the emergency regulation was adopted.

Family impact

Please assess the impact of the proposed 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.