Virginia Regulatory Town Hall

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Proposed 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 branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

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 proposed 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.

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.

Legal basis

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., 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 briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

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 directs 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.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	High Drug Threshold: approximately $27,000 GF per year.
Projected cost of the regulation on localities	There is no cost to localities to implement this regulation.
Description of the individuals, businesses or other entities likely to be affected by the regulation	FAMIS enrollees, medical providers (prescribers), pharmacists, and pharmaceutical companies.
Agency's best estimate of the number of such entities that will be affected	There are currently 7,232 FAMIS enrollees in the fee-for-service and PCCM programs affected, 27,000 medical providers (prescribers) and 1600 pharmacy providers

Projected cost of the regulation for affected individuals, businesses, or other entities	No cost to FAMIS enrollees, medical providers (prescribers), pharmacists or pharmaceutical companies

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The General Assembly mandate (2003 Acts of Assembly, Chapter 1042, 324, Item H) specified that DMAS was to implement utilization review of high drug use for non-institutionalized FAMIS enrollees for whom "more than nine unique prescriptions have been prescribed within a 180 day period." The specificity of the mandate does not allow for alternatives for either the threshold number or the timeframe. Alternatives considered by Agency include whether to implement a retrospective system, a prospective system, or a mixture of both. The Agency decided upon a retrospective system with one prospective element. The retrospective system does not require the enrollee's entire prescription drug history to be available to the dispensing pharmacist at the point of sale and is therefore much more efficient. However, drug-to-drug Level One interactions become more critical where an enrollee is receiving higher numbers of drugs; the Agency concluded that the threshold program must address this safety concern, and therefore it is included in this package.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

No public comments were received on the NOIRA.

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.

Detail of changes

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

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC30-141-500		Benefits reimbursement: Pharmacy.	Require review of drugs for non-institutionalized FAMIS recipients receiving fee-for-service benefits when they exceed nine unique prescriptions within a 180-day period. Language added subsequent to the previous emergency regulation describes a ***review and*** prior authorization process consistent with 12 VAC 30-50-21(A)(7). This program does not apply to FAMIS recipients enrolled in managed care organizations.