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 30-50 and 30-130
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 DEC 30TH

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 325 ZZ, subparts 1-6)* that must be effective within 280 days from the date of its enactment and this regulatory action is 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, 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 Amount, Duration, and Scope of Services: Prior Authorization of Pharmacy Services and Preferred Drug List (12 VAC 30-50-210 and 130-1000) and also authorize the initiation of the 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 preferred drug list and prior authorization program for pharmacy services provided to Medicaid fee-for-service clients. For those therapeutic classes of drugs subject to the preferred drug list program, a preferred drug is one which meets the safety, clinical efficacy, and pricing standards employed by the Pharmacy and Therapeutics Committee. Non-preferred drugs are those that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. The non-preferred drugs require prior authorization prior to dispensing. The Pharmacy and Therapeutics Committee may also recommend prior authorization requirements or clinical guidance regarding preferred drugs or other drugs. This action also establishes the parameters for action by the Pharmacy and Therapeutics Committee as well as the Department's contractor for pharmacy services benefits management. The goal of the program is to improve the quality of pharmaceutical services and to reduce the significant increases in the cost of prescription drugs in the Medicaid fee-for-service program.

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 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
12VAC30-50-210		Definitions, requirements related to the Medicaid Prior Authorization Advisory Committee	Repeals definitions and all requirements related to the Medicaid Prior Authorization Advisory Committee
12VAC30-50-210 and 130-1000		Prior authorization of prescription drug products; coverage	Adds language related to the pharmacy prior authorization, Preferred Drug List, supplemental rebate agreements, P and T Committee structure and function, agency purview of pharmacy benefits contract, and annual reporting requirements.

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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 preferred drug list and prior authorization requirements for pharmacy services as contained herein have been mandated by the General Assembly through the *2003 Acts of Assembly, Chapter 1042*, thereby eliminating discussions of possible alternative policies. The regulatory changes suggested herein are intended to conform the agency's current policies to changes required in this *Act* and also by the Governor. Failure to implement the programs will negatively impact the projected budget savings and will have negative monetary consequences for the Commonwealth.

Family impact

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

Only to the extent that this preferred drug list and prior authorization requirements provide improved quality of care will this regulatory action 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; and increasing or decreasing disposable family income.