Virginia
Regulatory
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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 30-60-500
Regulation title	Disease Management Program
Action title	Standards Established and Methods used to Assure High Quality of Care: Alternative Benefits for Disease Management Services
Date this document prepared	May 18, 2007

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 branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Preamble

The APA (Code of Virginia § 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.

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1) The 2007 Virginia Appropriation Act (section GG.1.) states that this regulation shall be effective in 280 days or less from its enactment.

2) This regulation establishes an alternative benefit package that combines traditional Medicaid services with comprehensive chronic condition disease management (DM) services.

Legal basis

Other than the emergency authority described above, 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., 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, 32.1-325, 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. This action was also mandated by the 2006 Appropriation Act, Items 302 CC and GG. In Chapter 847, Item 302 FFF the General Assembly required DMAS to add Chronic Obstructive Pulmonary Disease (COPD) to the conditions covered under the DMAS Disease Management program.

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 Commonwealth of Virginia seeks to offer an alternative benefits package that combines traditional Medicaid services with new, comprehensive disease management (DM) services. This initiative will be established under authority granted by the Deficit Reduction Act of 2005, State Flexibility in Benefits Packages. This option provides states with the opportunity to offer an alternative benefits package to beneficiaries without regard to comparability and certain other traditional Medicaid requirements.

The DM program offered through the alternative benefits package is called Healthy Returns^{SM}. Healthy Returns^{SM} targets chronic conditions in both children and adults. It provides DM services statewide to Medicaid clients eligible for Title XIX Medicaid fee-for-service. The program provides services on an "opt-in" basis, so individuals eligible for the program must proactively enroll to receive DM services. The goal of this program is to improve a patient's ability to manage his or her condition(s) and thereby improve his or her health and quality of life.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

In 2005, the Virginia General Assembly directed the Department of Medical Assistance Services (DMAS) to provide disease-state and chronic care management programs for Medicaid fee-for-service recipients. Individuals targeted for this program include some of Virginia's most vulnerable Medicaid beneficiaries, many of whom have multiple health conditions and limitations that make self-management and adherence to a prescribed plan of care difficult.

Increased preventive care and patient education is expected to increase participants' ability to effectively manage their condition(s) and ultimately decrease the number of hospitalizations and inappropriate

emergency room use. The goal of the disease management (DM) program is to improve the health and quality of life for program participants.

Substance

Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.

The alternative benefits disease management program is described in a new regulatory section, 12 VAC 30-60-500. The alternative benefits package that includes *Healthy Returns*[SM] DM services will be offered to all Medicaid and Medicaid Expansion enrollees who meet the criteria for *Healthy Returns*[SM] with the exception of:

1. Individuals enrolled in managed care organizations (managed care organizations provide the same DM services to their beneficiaries);
2. Individuals enrolled in Medicare and Medicaid (dual eligibles);
3. Individuals who live in institutional settings (such as nursing homes); and
4. Individuals who have third party insurance.

The Virginia program will also include individuals who receive home and community-based 1915(c) waiver services. Virginia currently has seven home and community-based services waiver programs.

Virginia's chronic condition alternative benefits program is designed to meet the following objectives:

1. Identification, evaluation, and management of disease state(s) specified in the contract;
2. Adherence to national evidence-based disease management practice guidelines in order to improve participants' health status;
3. Integration of preventive care into the clinical management model;
4. Overall reduction of acute medical expenditures, on average, for the population of participants served;
5. Reduction in hospital admissions and non-emergent emergency department use;
6. Coordination and reduction of unnecessary or inappropriate medication;
7. Increased participant and provider education and participant self-management skills;
8. Measured indication of participant and provider satisfaction with program;
9. Coordination of participant care including establishment of coordination between providers, the participant, and the community; and
10. Regular reporting of clinical outcome measures, profiles of participants and providers, and Medicaid health care expenditures of participants.

Healthy Returns[SM] may cover, but will not be limited to covering, the following conditions:

- Asthma (children and adults);
- Chronic Obstructive Pulmonary Disease (adults only);
- Congestive Heart Failure (CHF) (adults only);
- Coronary Artery Disease (CAD) (adults only); and/or
- Diabetes (children and adults).

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. Also describe the process by which the agency has considered or will consider, other alternatives for achieving the need in the most cost-effective manner.

If the Department of Medical Assistance Services does not offer this alternative benefits package that combines traditional Medicaid services with new, comprehensive disease management services, then Medicaid participants in the fee-for-service program who have chronic conditions will not receive support and assistance to better adhere to their provider's plan of care and to make healthier choices regarding their condition. Proper management of chronic conditions is imperative to maintaining an individual's quality of life. Without this support, many Medicaid participants find it difficult to manage their complex and often life-threatening conditions.

The Department considered several alternative program designs while developing this program. The Department considered excluding home and community-based (HCBS) waiver populations (as most states do), but chose to include HCBS waiver participants since many of these individuals face the challenge of managing progressed chronic conditions in addition to long-term care needs. The Department also considered including face-to-face contact as part of the DM program, but decided not to proceed with this service due to its extremely high cost, especially in rural areas of the Commonwealth. Lastly, numerous other chronic conditions were considered for the program. DMAS selected the currently covered five conditions due to their high prevalence in the DMAS population and the likelihood that participants could improve their condition through appropriate self-management and adherence to their prescribed plan of care.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments on this notice.

The agency/board is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, record keeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to:
Suzanne Gore
Department of Medical Assistance Services
600 East Broad Street, Suite 1300
Richmond, Virginia 23219
(804) 786-1609
(804) 786-1680 (fax)
Suzanne.Gore@dmas.virginia.gov

Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public meeting will not be held pursuant to an authorization to proceed without holding a public meeting.

Participatory approach

Please indicate the extent to which an ad hoc advisory group will be used in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

DMAS involved numerous stakeholders in the development of the DM program. DMAS gathered extensive input from HCBS waiver program stakeholders in order to develop special protocols to effectively work with HCBS waiver participants. DMAS also worked closely with representatives of the pediatric community to ensure that DM protocols would not interfere with or contradict the care they provide for their patients. The DM program is designed to support the participant's adherence to the provider's plan of care, not change or interfere with it.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; or encourage or discourage economic self-sufficiency, self pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. It does not strengthen or erode the marital commitment and is not expected to affect disposable family income.