



Proposed Regulation Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation	12 VAC 30 -60-500
Regulation title	Standards Established and Methods Used to Assure High Quality of Care: Alternative Benefits for Disease Management Services
Action title	Disease Management Program
Date this document prepared	

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*.

Brief summary

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

In 2005, the Virginia General Assembly directed the Department of Medical Assistance Services (DMAS) to provide disease-state 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 it difficult to self-manage and adhere to prescribed plans of care.

Such disease-state management programs provide for increased preventive care and patient education to increase participants' ability to effectively manage their condition(s) and ultimately decrease the number of hospitalizations and inappropriate emergency room use. The goals of this disease management (DM) program are to improve the health and quality of life for program participants.

This regulatory action establishes a voluntary alternative benefit package (known as the Healthy ReturnsSM program) that combines traditional Medicaid services with comprehensive disease management (DM) services. The previous emergency regulations provided that both adults and children in fee-for service who are determined to have asthma and diabetes could participate in this program. The previous emergency regulations also provided that individuals 21 years and older having coronary artery disease, (CAD) congestive heart failure, (CHF) and chronic obstructive pulmonary (COPD) were eligible

for the Healthy ReturnsSM program. The substantive change recommended in these proposed stage regulations is to drop the age limit of 21 years for CHF, CAD and COPD to age 18 years and older.

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, § 32.1-325, 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, of the 2007 *Acts of Assembly*, Item 302 FFF required DMAS to add Chronic Obstructive Pulmonary Disease (COPD) to the conditions already covered under the DMAS Disease Management program.

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, the environmental benefits, and the problems the proposal is intended to solve.

The Commonwealth of Virginia seeks to offer a voluntary 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, Public Law 109-171, State Flexibility in Benefits Packages. This option provides states with the opportunity to offer an alternative benefits package to beneficiaries without regard to comparability (42 CFR §440.240) and certain other traditional Medicaid requirements.

The DM program offered through the alternative benefits package is called Healthy ReturnsSM. Healthy ReturnsSM targets chronic care 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.

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 section of the State Plan for Medical Assistance that is affected by this action is Attachment 3.1-C; Standards Established and Methods used to Assure High Quality Care: Alternate Benefits for Disease Management (12 VAC 30-60).

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 ReturnsSM DM services will be offered to all Medicaid and Medicaid Expansion enrollees who meet the criteria for Healthy ReturnsSM with the exception of:

1. Individuals enrolled in managed care organizations (managed care organizations already provide these 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 tool;
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 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.

The previous emergency regulations provided that any qualifying individual in fee-for service who was determined to have asthma and diabetes could participate in this program. The previous emergency regulations also provided that qualifying individuals 21 years and older having coronary artery disease, (CAD) congestive heart failure, (CHF) and chronic obstructive pulmonary (COPD) were eligible for the Healthy ReturnsSM program. In this proposed regulation package, the language "for individuals age 21 and over" has been changed to read "for individuals age 18 and over" to modify the provisions that any fee-for-service individual 18 years or older having CAD, CHF, or COPD may elect to participate in this program.

Healthy ReturnsSM may cover, but will not be limited to covering, the following conditions:

- Asthma (all qualifying fee-for-service individuals);
- Chronic Obstructive Pulmonary Disease (individuals 18 years old and over)--The emergency regulations stated that all qualifying individuals in fee-for-service who have COPD and are aged 21 years or older, are eligible for the Healthy ReturnsSM program. In this proposed regulation package, for COPD, the language has been changed to "individuals age 18 and over" are eligible for the Healthy ReturnsSM program;

- Congestive Heart Failure (CHF) (individuals 18 years old and over)-- The emergency regulations stated that all qualifying individuals in fee-for-service who have CHF and are aged 21 years or older, are eligible for the Healthy ReturnsSM program. In this proposed regulation package, for CHF, the language has been changed to “individuals age 18 and over” are eligible for the Healthy ReturnsSM program;
- Coronary Artery Disease (CAD) (individuals 18 years old and over)-- The emergency regulations stated that all qualifying individuals in fee-for-service who have CAD and are aged 21 years or older, are eligible for the Healthy ReturnsSM program. In this proposed regulation package, for CAD, the language has been changed to “individuals age 18 and over” are eligible for the Healthy ReturnsSM program;
- Diabetes (all qualifying fee-for-service individuals).

The Family Access to Medical Insurance Security (FAMIS) enrollees are shown as being excluded [12VAC 30-60-500(B)(2)(e)] in this additional benefit because they already receive this benefit under Title XXI (see 12 VAC 30-141-200).

Various technical edits and corrections have been made in this proposed stage over the previous emergency regulatory action to conform this new Virginia Administrative Code (VAC) section to the Registrar’s style and format requirements.

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.

Increased preventive care and patient education increases participants’ ability to effectively manage chronic conditions and ultimately decrease the number of hospitalizations and inappropriate emergency room use. The goal of Healthy ReturnsSM is to improve the health and quality of life for program participants. Participants with asthma, COPD, CHF, CAD, and diabetes stand to greatly benefit from the support, education, and interventions provided through disease management.

Since this is strictly an opt-in benefit, the regulatory action poses no disadvantages to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements that exceed applicable federal requirements. Federal statute is permissive with regard to this benefit. It does not require State Medicaid agencies to offer this benefit to recipients. However, based on feedback from the Disease Management program during its pilot-testing period,

participants appreciated and valued the nurse one-on-one attention and educational efforts. Program participants also responded favorably to their nurses' recommended changes in lifestyle (eating and exercise habits) and improved compliance with their physicians' orders.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No locality bears a disproportionate impact. The DM program (Healthy ReturnsSM) is offered through the alternative benefits package statewide to the targeted Medicaid clients eligible for Title XIX Medicaid fee-for-service program.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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, recordkeeping 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 may do so by mail, email or fax to:

Meredith Lee
 Health Care Services Division
 Department of Medical Assistance Services
 600 East Broad Street
 Richmond, VA 23219
 Phone: (804) 786-5040
 Fax: (804) 786-5799
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Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

<p>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</p>	<p>DMAS awarded the contract, through the competitive bidding process established by the Code of VA §2.2-4300 et seq., to the vendor, Health Management Corporation. DMAS paid in FY</p>
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expenditures	2007 \$2.3 million to this vendor. The projected payments for FY 2008 are \$4.2 million.
Projected cost of the regulation on localities	Not applicable
Description of the individuals, businesses or other entities likely to be affected by the regulation	The Disease Management vendor, recipients, and providers will be affected by this regulation.
Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	According to the Disease Management vendor; as of November 2007, 14,488 recipients were actively participating in this voluntary program. This regulatory action will not affect small businesses at all.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There is no cost to the recipient. The disease management program is designed to benefit recipients. There are no projected reporting, recordkeeping and other administrative costs required by small businesses.

Health Management Corporation, the vendor for Healthy ReturnsSM is a subsidiary of Anthem, Inc. HMC’s Healthy ReturnsSM DM program is designed to help maximize member health status, improve health outcomes and control associated health care expenses. The DM program supports the physician/patient relationship and plan of care, and empowers participants to become more effective self-managers of their own health.

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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

If the Department of Medical Assistance Services does not offer this alternative benefits package that combines traditional medical services with new, comprehensive disease management services, then Medicaid participants in the fee-for-service program who have chronic conditions will not receive added support and assistance to better adhere to their providers’ plans of care and to make healthier life style choices regarding their conditions. Proper management of chronic conditions is imperative to maintaining individuals’ quality of life. Without this support, many Medicaid fee-for-service participants may find it difficult to manage their complex conditions. Persons in Medicaid managed care programs already receive this type of service.

The Department considered several alternative program designs while developing this program. The Department considered excluding home- and community-based services (HCBS) waiver populations (as most states do), but chose to include HCBS waiver participants because many of these individuals face the challenge of managing 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 option due to its extremely high costs, 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 Virginia Medicaid population and the likelihood that participants could improve their conditions through appropriate self-management and adherence to their

physicians' prescribed plans of care. Finally, DMAS intended to extend coverage for CHF, CAD and COPD to include individuals under age 18, but determined that models for the management of these conditions for this age group have not yet been developed.

Regulatory flexibility analysis

Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The disease management program will not have any effects on small businesses. It is a contracted function. The program is voluntary on the part of Medicaid recipients. If a recipient elects not to participate, he/she is not penalized.

Public comment

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

DMAS' Notice of Intended Regulatory Action was published in the September 3, 2007, *Virginia Register* (Volume 23, Issue 26) for its public comment period from September 3, 2007, to October 3, 2007. Comments were received from the Virginia Association for Home Care and Hospice.

The submitted comments were as follows:

Commenter	Comment	Agency response
Virginia Association for Home Care and Hospice	Would like the disease management program to be more provider-centric.	Though DM is more patient-centric, DMAS is developing a new chronic care management program that will be more provider focused. DMAS will take the Virginia Association for Home Care and Hospice's comment under consideration.

Family impact

Please assess the 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 increase or decrease disposable 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.

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
N/A	12VAC 30-60-500	There were no existing requirements prior to the emergency regulations.	All qualifying individuals, regardless of age, in fee-for-service who are determined to have asthma or diabetes are eligible to ‘opt-in’ to the Healthy Returns program. Fee-for-service individuals 18 years and over with coronary artery disease (CAD), congestive heart failure (CHF), and chronic obstructive pulmonary disease (COPD) may also elect to participate in this program.