



Final 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

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

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 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 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 the proposed stage regulations dropped the age limit of 21 years for CHF, CAD and COPD to age 18 years and older.

There are no substantive changes being made in the final stage over the proposed stage.

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 Regulatory Review Summary with the attached amended State Plan pages Alternative benefits for Disease Management Services: Disease Management Program (12VAC 30-60-500) 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.

Date

Patrick W. Finnerty, Director
Dept. of Medical Assistance Services

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 numbers, 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, 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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal 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 has been 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 or give expressed permission to be enrolled in the DM program. 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 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 section of the State Plan for Medical Assistance that is affected by this action is Standards Established and Methods Used to Assure High Quality of Care: Alternative Benefits for Disease Management Services (Disease Management Program) (12 VAC 30-60-500).

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 disease management 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 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 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 the proposed regulation package, the language "for individuals age 21 and over" was 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 the proposed regulation package, for COPD, the language was 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 the proposed regulation package, for CHF, the language was 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 the proposed regulation package, for CAD, the language was 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 were made in the proposed stage over the emergency regulatory action to conform this new Virginia Administrative Code (VAC) section to the Registrar’s style and format requirements.

There are no substantive changes being made in this Final Stage over the Proposed Stage.

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 there are no disadvantages to the public or the Commonwealth, please 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.

This regulatory action poses no disadvantages to the public or the Commonwealth.

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.

No substantive changes were made between the publication of the Proposed regulation and the publication of the Final regulation. There were three non-substantive, clarifying changes made in subsections (B)(4), (C)(3) and (C)(4) of the regulation to reflect that DMAS or its designated agent may perform the disease management services.

Public comment

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

DMAS' proposed regulations were published in the September 15, 2008, *Virginia Register* (VR 25:1) for their public comment period from September 15, 2008, through November 14, 2008. No comments were received for this comment period.

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.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
N/A	12VAC30-60-500	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.

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.

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, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.