STATE OF VERMONT
DEPARTMENT OF BANKING, INSURANCE, SECURITIES AND HEALTH CARE ADMINISTRATION

Regulation H-2005-03

HEALTH INSURANCE COVERAGE FOR CANCER CLINICAL TRIALS

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Section 1. Purpose and Authority

This regulation is issued pursuant to the authority of the Commissioner of the Department of Banking, Insurance, Securities and Health Care Administration under 8 V.S.A. § 15 and 8 V.S.A. § 4088b to issue rules and regulations requiring that health benefit plans provide coverage for routine costs for patients who participate in approved cancer clinical trials.

Section 2. Applicability and Scope

This rule applies to any health insurance policy or health benefit plan in effect on March 1, 2002 and to any such plan offered, issued, or renewed on or after March 1, 2002 in Vermont by a health insurer as defined in 18 V.S.A.§ 9402(7), and to cancer care providers as defined in subsection 3(B) of this regulation. This rule applies to the Vermont Agency of Human Services through its Vermont Medicaid program in the same manner as insurers defined in 18 V.S.A. § 9402(7). The scope of this rule is limited to the coverage of costs for routine patient care services for patients who participate in approved cancer clinical trials as defined in subsection 3(A) of this regulation that are conducted under the auspices of cancer care providers as defined in subsection 3(B) of this regulation.

Section 3. Definitions

A. "Approved cancer clinical trial" means an organized, systematic, scientific study of therapies, tests, or other clinical interventions for purposes of treatment, palliation, or prevention of cancer in human beings. The approved cancer clinical trial must seek to answer a credible and specific medical or scientific question for the purpose of advancing cancer care and:

1. is conducted by a cancer care provider as defined in subsection 3 (B) of this regulation;

2. is conducted by a facility and personnel capable of conducting such a trial by virtue of experience, training and volume of patients treated to maintain expertise;

3. enrolls only those patients for whom there is no clearly superior, non-investigational treatment alternative to the cancer clinical trial and the available clinical or preclinical data provide a reasonable expectation that the treatment obtained in the cancer clinical trial will be at least as effective as the non-investigational alternative;

4. is conducted only after obtaining fully informed, written consent from the patient or the patient's legally authorized representative in a manner that is consistent with current legal and ethical standards and requirements; and

5. is conducted under the auspices of a peer-reviewed protocol that has been approved by one of the following entities:

   a. one of the National Institutes of Health ("NIH");

   b. an NIH-affiliated cooperative group that is a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group;

   c. the FDA in the form of an investigational new drug application or exemption; or

   d. the federal departments of Veterans Affairs or Defense.

B. "Cancer care provider" means the following: the Vermont Cancer Center at Fletcher Allen Health Care, the Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center, and a Vermont hospital and its affiliated, qualified Vermont cancer care providers administering approved cancer clinical trials.

C. "Commissioner" means the commissioner of the Vermont Department of Banking, Insurance, Securities and Health Care Administration.

D. "Department" means the Vermont Department of Banking, Insurance, Securities and Health Care Administration.

E. "Division" means the Division of Health Care Administration of the Department of Banking, Insurance, Securities and Health Care Administration.

F. "Health benefit plan" means any health insurance policy or health benefit plan offered by a health insurer as defined in 18 V.S.A.§ 9402(7).

G. "Health insurer" means any health insurance company, nonprofit hospital and medical service corporation, managed care organizations, and, to the extent permitted by federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities.

H. "Medically-necessary care" means health care services including diagnostic testing, preventive services and aftercare appropriate, in terms of type, amount, frequency, level, setting, and duration to the member's diagnosis or condition. Medically-necessary care must be consistent with generally accepted practice parameters as recognized by health care providers in the same or similar general specialty as typically treat or manage the diagnosis or condition, and

1. help restore or maintain the member's health; or

2. prevent deterioration of or palliate the member's condition; or

3. prevent the reasonably likely onset of a health problem or detect an incipient problem.

I. "Routine patient care services" means those health care services for which a health insurer subject to this regulation is otherwise responsible under the patient's health benefit plan, including any medically necessary health care service that is incurred as a result of the treatment being provided to the patient for the purposes of the approved cancer clinical trial. Routine patient care services include any physician service, diagnostic or laboratory test, hospitalization, or other service provided to the patient during the course of treatment in the approved cancer clinical trial for a condition or one of its complications or for a complication of the treatment provided during the approved cancer clinical trial which is consistent with the usual and customary standard of care and would be covered even if the patient were not enrolled in an approved cancer clinical trial. Routine patient care services do not include the following items:

1. The costs of investigational new drugs that have not been approved for market for any indication by the U.S. Food and Drug Administration ("FDA") or the costs of any drug being studied under an FDA-approved investigational new drug exemption for the purpose of expanding the drug's labeled indications;

2. The costs of non-health care services that may be required as a result of the treatment being provided for the purposes of the approved cancer clinical trial;

3. The costs of services that are clearly inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis and performed specifically to meet the requirements of the approved cancer clinical trial;

4. the costs of any tests or services performed specifically to meet the needs of the approved cancer clinical trial protocol;

5. the costs of running the approved cancer clinical trial and collecting and analyzing data;

6. the costs associated with managing the research associated with the approved clinical trial;

7. costs for non-investigational treatments or services that would not otherwise be covered under the patient's health benefit plan; or

8. any product or service paid for or supplied by the trial sponsor.

Section 4. Services Required to Be Covered

All health insurance policies or health benefit plans in effect on March 1, 2002 and all such plans offered, issued, or renewed on or after March 1, 2002 in Vermont by a health insurer as defined in 18 V.S.A.§ 9402(7) and this regulation shall provide coverage for the costs of routine patient care services for patients who participate in all four types of approved cancer clinical trials (Phases I, II, III, and IV) that are conducted under the auspices of cancer care providers. Such costs shall be covered in a manner that is otherwise consistent with the terms of the patient's health benefit plan, the health insurer's contract with the cancer care provider and applicable state and federal law.

Section 5. Specific Responsibilities of Cancer Care Providers

A. Upon enrolling a patient into an approved cancer clinical trial, the cancer care provider shall provide the patient's health insurer(s) and the patient with information that clearly identifies what services provided to the patient are being done solely to meet the needs of the approved cancer clinical trial protocol, and thus are not the responsibility of the health plan to cover and reimburse.

B. A copy of the document(s) evidencing the fully informed, written consent of the patient or the patient's legally authorized representative shall be made available to the patient's health insurer upon request.

Section 6. Reporting Requirements

On or before July 1, 2004, the Office of Vermont Health Access and the four health insurers with the largest number of covered lives in Vermont on the effective date of this regulation shall submit to the Division data and analysis pertaining to the financial impact of the clinical trial pilot program required by 8 V.S.A. § 4088b on health care insurance premiums based on specifications provided by the Division.

Section 7. Severability

If any provision of this regulation or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the regulation and the application of such provisions to other persons or circumstances shall not be affected thereby.

Section 8. Effective Date and Date of Expiration

The effective date of this regulation is August 5, 2005. .