DISTRICT OF COLUMBIA

OFFICIAL CODE

TITLE 31.

INSURANCE AND SECURITIES.

CHAPTER 29B.

CLINICAL TRIALS INSURANCE COVERAGE.

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§ 31-2993.01. DEFINITIONS.

For the purposes of this chapter, the term:

(1) "Approved clinical trial" means:

(A) A clinical research study or clinical investigation approved or funded in full or in part by one or more of the following:

(i) The National Institutes of Health;

(ii) The Centers for Disease Control and Prevention;

(iii) The Agency for Health Care Research and Quality;

(iv) The Centers for Medicare and Medicaid Services;

(v) A bona fide clinical trial cooperative group, including the National Cancer Institute Clinical Trials Cooperative Group, the National Cancer Institute Community Clinical Oncology Program, the AIDS Clinical Trials Group, and the Community Programs for Clinical Research in AIDS; or

(vi) The Department of Defense, the Department of Veterans Affairs, or the Department of Energy, or a qualified nongovernmental research entity to which the National Cancer Institute has awarded a support grant;

(B) A study or investigation approved by the Food and Drug Administration ("FDA"), including those conducted under an investigational new drug or device application reviewed by the FDA; or

(C) An investigation or study approved by an Institutional Review Board registered with the Department of Health and Human Services that is associated with an institution that has a federal-wide assurance approved by the Department of Health and Human Services specifying compliance with 45 C.F.R. Part 46.

(2) "Health benefit plan" means any accident and health insurance policy or certificate, hospital and medical services corporation contract, health maintenance organization subscriber contract, plan provided by a multiple employer welfare arrangement, or plan provided by another benefit arrangement. The term "health benefit plan" shall not include accident-only, credit, or disability insurance; coverage of Medicare services or federal employee health plans, pursuant to contracts with the United States government; Medicare supplemental or long-term care insurance; dental-only or vision-only insurance; specified disease insurance; hospital confinement indemnity coverage; limited benefit health coverage; coverage issued as a supplement to liability insurance, insurance arising out of a workers' compensation or similar law; automobile medical payment insurance; medical expense and loss of income benefits; or insurance under which benefits are payable with or without regard to fault and that is statutorily required to be contained in any liability insurance policy or equivalent self-insurance.

(3) "Health insurer" means:

(A) Any person that provides one or more health benefit plans or insurance in the District, including an insurer, a hospital and medical services corporation, a fraternal benefit society, a health maintenance organization, a multiple employer welfare arrangement, or any other person providing a plan of health insurance subject to the authority of the Commissioner;

(B) A provider service organization;

(C) The District of Columbia Medicaid agency;

(D) Other governmental medical assistance programs, including their contracted insurers, whether providing services on a managed care or fee-for-service basis;

(E) The District's children's health insurance program; or

(F) Any other plans covering public employees.

(4) "Qualified individual" means:

(A)(i) An individual who is a policyholder, subscriber, insured, certificate holder, or enrollee of a health benefit plan;

(ii) A beneficiary of a District of Columbia public health program; or

(iii) A covered dependent of a policyholder, subscriber, insured, certificate holder, or enrollee; and

(B) Who meets the following conditions:

(i) The individual is eligible to participate in an approved clinical trial; and

(ii) The approved clinical trial is undertaken for the purposes of the prevention, early detection, treatment, or monitoring of cancer, chronic disease, or life-threatening illness.

(5)(A) "Routine patient care costs" means:

(i) Items, drugs, and services that are typically provided absent a clinical trial;

(ii) Items, drugs, and services required solely for the provision of the investigational item or service (such as the administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

(iii) Items, drugs, and services needed for reasonable and necessary care arising from the provision of an investigational item or service, including the diagnosis or treatment of complications.

(B) Routine patient care costs shall not include:

(i) The cost of tests or measurements conducted primarily for the purpose of the clinical trial involved or items, drugs, or services provided solely to satisfy data collection and analysis needs; or

(ii) Items, drugs, or services customarily provided by the research sponsors free of charge for any qualified individual enrolled in the trial.

(June 5, 2008, D.C. Law 17-166, § 2, 55 DCR 5174.)

HISTORICAL AND STATUTORY NOTES

Legislative History of Laws

Law 17-166, the "Clinical Trials Insurance Coverage Amendment Act of 2008", was introduced in Council and assigned Bill No.17-469 which was referred to the Committee on Public Service and Consumer Affairs. The Bill was adopted on first and second readings on March 4, 2008, and April 1, 2008, respectively. Signed by the Mayor on April 14, 2008, it was assigned Act No. 17-340 and transmitted to both Houses of Congress for its review. D.C. Law 17-166 became effective on June 5, 2008.

§ 31-2993.02. COVERED TRIALS.

(a) A health insurer shall not limit or deny coverage, or impose additional conditions on the payment for the coverage, of routine patient care costs of items, drugs, and services furnished to a qualified individual in connection with participation in an approved clinical trial. A health insurer shall not be required to pay for costs of items, services, or drugs that are customarily provided by the sponsors of an approved clinical trial.

(b) In the case of health care services provided by a participating provider, the payment rate shall be at the network negotiated rate, based on the member's plan design. In case of a non-participating provider, the payment shall be at the rate that the member's plan would otherwise pay to a non-participating provider for the same services, less any applicable co-payments and deductibles.

(June 5, 2008, D.C. Law 17-166, § 3, 55 DCR 5174.)

HISTORICAL AND STATUTORY NOTES

Legislative History of Laws

For Law 17-166, see notes following § 31-2993.01.

§ 31-2993.03. RIGHT TO FILE GRIEVANCE.

This chapter shall not limit, prohibit, or modify a qualified individual's right to:

(1) File a grievance and use an independent review process, if available; or

(2) Use the independent medical review system.

(June 5, 2008, D.C. Law 17-166, § 4, 55 DCR 5174.)

HISTORICAL AND STATUTORY NOTES

Legislative History of Laws

For Law 17-166, see notes following § 31-2993.01.