304.17A-136 Coverage for cancer clinical trials.

(1) As used in this section, unless the context requires otherwise:

(a) "Cancer clinical trial" means a clinical trial that:

1. Is approved by:

a. The National Institutes of Health, or any institutional review board recognized by the National Institutes of Health;

b. The United States Food and Drug Administration;

c. The United States Department of Defense; or

d. The United States Department of Veterans Affairs; and

2. Does one (1) of the following:

a. Tests how to administer a health care service, item, or drug for the treatment of cancer;

b. Tests responses to a health care service, item, or drug for the treatment of cancer;

c. Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer; or

d. Studies new uses of health care services, items, or drugs for the treatment of cancer; and

(b) "Routine patient healthcare costs" means all healthcare services, items, and drugs for the treatment of cancer, except for the following:

1. The health care service, item, or investigational drug that is the subject of the cancer clinical trial;

2. Any treatment modality outside the usual and customary standard of care required to administer or support the healthcare service, item, or investigational drug that is the subject of the cancer clinical trial;

3. Any healthcare service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient;

4. An investigational drug or device that has not been approved for market by the United States Food and Drug Administration;

5. Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the cancer clinical trial;

6. Any services, items, or drugs provided by the cancer clinical trial sponsors free of charge for any new patient; or

7. Any services, items, or drugs that are eligible for reimbursement by a person other than the insurer, including the sponsor of the clinical trial.

(2) A health benefit plan shall not exclude coverage for routine patient healthcare costs that are incurred in the course of a cancer clinical trial if the health benefit plan would provide coverage for the routine patient healthcare costs had they not been incurred in a cancer clinical trial.

(3) The coverage that may not be excluded under this section shall be subject to all terms, conditions, restrictions, exclusions, and limitations that apply to any other coverage under the policy, plan, or contract, including the treatment under the policy, plan, or contract of services performed by participating and nonparticipating providers.

(4) (a) Nothing in this section requires a policy, plan, or contract to offer cancer clinical trial services by a participating provider.

(b) Nothing in this section prohibits a policy, plan, or contract from offering cancer clinical trial services by a participating provider.

(c) Nothing in this section requires services that are performed in a cancer clinical trial by a nonparticipating provider of a policy, plan, or contract to be reimbursed at the same rate as those performed by a participating provider of the policy, plan, or contract.

(5) Nothing in this section shall be construed as imposing a new health benefit mandate.

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History: Amended 2017 Ky. Acts ch. 42, sec. 14, effective June 29, 2017. -- Created 2010 Ky. Acts ch. 23, sec. 1, effective July 15, 2010.