START\_STATUTE20-1057.07.  Health care services organizations; clinical trials; cancer; definitions

A.  A health care services organization is not obligated to pay any costs, other than covered patient costs, that are directly associated with a cancer clinical trial that is offered in this state and in which the enrollee participates voluntarily. A cancer clinical trial is a course of treatment in which all of the following apply:

1.  The treatment is part of a scientific study of a new therapy or intervention that is being conducted at an institution in this state, that is for the treatment, palliation or prevention of cancer in humans and in which the scientific study includes all of the following:

(a)  Specific goals.

(b)  A rationale and background for the study.

(c)  Criteria for patient selection.

(d)  Specific directions for administering the therapy and monitoring patients.

(e)  A definition of quantitative measures for determining treatment response.

(f)  Methods for documenting and treating adverse reactions.

2.  The treatment is being provided as part of a study being conducted in a phase I, phase II, phase III or phase IV cancer clinical trial.

3.  The treatment is being provided as part of a study being conducted in accordance with a clinical trial approved by at least one of the following:

(a)  One of the national institutes of health.

(b)  A national institutes of health cooperative group or center.

(c)  The United States food and drug administration in the form of an investigational new drug application.

(d)  The United States department of defense.

(e)  The United States department of veterans affairs.

(f)  A qualified research entity that meets the criteria established by the national institutes of health for grant eligibility.

(g)  A panel of qualified recognized experts in clinical research within academic health institutions in this state.

4.  The proposed treatment or study has been reviewed and approved by an institutional review board of an institution in this state.

5.  The personnel providing the treatment or conducting the study:

(a)  Are providing the treatment or conducting the study within their scope of practice, experience and training and are capable of providing the treatment because of their experience, training and volume of patients treated to maintain expertise.

(b)  Agree to accept reimbursement as payment in full from the health care services organization at the rates that are established by the organization and that are not more than the level of reimbursement applicable to other similar services provided by health care providers with the organization's provider network.

6.  There is no clearly superior, noninvestigational treatment alternative.

7.  The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as efficacious as any noninvestigational alternative.

B.  Pursuant to the patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of a cancer clinical trial.

C.  Each contract or evidence of coverage delivered or issued for delivery in this state shall provide benefits under the contract or evidence coverage, and those benefits shall not supplant any portion of the clinical trial that is customarily paid for by government, biotechnical, pharmaceutical or medical device industry sources.

D.  Unless preempted under federal law or unless federal law imposes greater requirements than this section, this section applies to a provider sponsored health care services organization.

E.  This section does not create any private right or cause of action for or on behalf of any patient against the health care services organization. This section provides solely an administrative remedy to the director for any violation of this section or any related rule.

F.  Nothing in this section prohibits the health care services organization from imposing deductibles, coinsurance or other cost sharing measures in relation to benefits provided pursuant to this section.

G.  A trade association that represents health care services organizations and hospital service corporations and medical service corporations as defined in section 20‑822 may select a representative to voluntarily serve on the institutional review board of an institution in this state that reviews and approves the proposed treatment or study conducted during the cancer clinical trial.

H.  For the purposes of this section:

1.  "Cooperative group" means a formal network of facilities that collaborates on research projects and that has an established national institutes of health approved peer review program operating within the group, including the national cancer institute clinical cooperative group and the national cancer institute community clinical oncology program.

2.  "Institutional review board" means any board, committee or other group that is both:

(a)  Formally designated by an institution to approve the initiation of and to conduct periodic review of biomedical research involving human subjects and in which the primary purpose of such review is to assure the protection of the rights and welfare of the human subjects and not to review a clinical trial for scientific merit.

(b)  Approved by the national institutes of health office for protection from research risks.

3.  "Multiple project assurance contract" means a contract between an institution and the United States department of health and human services that defines the relationship of the institution to the United States department of health and human services and that sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

4.  "Patient" means the enrollee or the enrollee's covered dependent.

5.  "Patient cost" means any fee or expense that is covered under the contract or evidence of coverage and that is for a service or treatment that would be required if the patient were receiving usual and customary care.  Patient cost does not include the cost:

(a)  Of any drug or device provided in a phase I cancer clinical trial.

(b)  Of any investigational drug or device.

(c)  Of nonhealth services that might be required for a person to receive treatment or intervention.

(d)  Of managing the research of the clinical trial.

(e)  That would not be covered under the patient's contract.

(f)  Of treatment or services provided outside this state. END\_STATUTE