DIGEST

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HB 407 Original	2020 Regular Session	LaCombe
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Abstract: Requires health insurance coverage for a treatment provided or study conducted in a Phase I clinical trial for cancer.

<u>Present law</u> requires a health insurance issuer to provide coverage for the costs of investigational treatments and associated protocol-related patient care if all of the following criteria are met:

- (1) The treatment is being provided with a therapeutic or palliative intent for patients with cancer, or for the prevention or early detection of cancer.
- (2) The treatment is being provided or the studies are being conducted in a Phase II, Phase III, or Phase IV clinical trial for cancer.
- (3) The treatment is being provided in accordance with a clinical trial approved by certain entities.
- (4) The proposed protocol has been reviewed and approved by a qualified institutional review board which operates in this state and which has a multiple project assurance contract approved by the office of protection from research risks.
- (5) The facility and personnel providing the protocol provided the treatment within their scope of practice, experience, and training and are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise.
- (6) There is no clearly superior, non-investigational approach.
- (7) The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as efficacious as the non-investigational alternative.
- (8) The patient has signed an institutional review board-approved consent form.

<u>Proposed law</u> retains <u>present law</u> and extends coverage to a treatment provided or study conducted in a Phase I clinical trial for cancer.

Effective upon signature of governor or lapse of time for gubernatorial action.

(Amends R.S. 22:1044(E)(2))