The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Cheryl B. Cooper.

DIGEST 2020 Regular Session

Talbot

<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) Treatment is being provided with a therapeutic or palliative intent for patients with cancer, or for the prevention or early detection of cancer.
- (2) Treatment is being provided or the studies are being conducted in a Phase II, Phase III, or Phase IV clinical trial for cancer.
- (3) Treatment is being provided in accordance with a clinical trial approved by certain entities.
- (4) 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) 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, noninvestigational approach.
- (7) Available clinical or preclinical data provided a reasonable expectation that the treatment will be at least as efficacious as the noninvestigational alternative.
- (8) 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 the governor or lapse of time for gubernatorial action.

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

SB 202 Original