SLS 20RS-513 **ORIGINAL**

2020 Regular Session

SENATE BILL NO. 202

BY SENATOR TALBOT

INSURANCE POLICIES. Provides for health insurance coverage for participants in clinical trials. (8/1/20)

AN ACT

To amend and reenact R.S. 22:1044(E)(2), relative to insurance coverage for participation in a clinical trial; to require health insurance coverage for a treatment provided or study conducted in a Phase I clinical trial for cancer; to provide for an effective date; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1044(E)(2) is hereby amended and reenacted to read as follows:

§1044. Health coverage; participants in clinical trials

* * *

E. Costs of investigational treatments and costs of associated protocol-related patient care shall be covered if all of the following criteria are met:

* * *

(2) The treatment is being provided or the studies are being conducted in a **Phase I,** Phase II, Phase III, or Phase IV clinical trial for cancer.

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Section 2. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature

by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

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

DIGEST

SB 202 Original 2020 Regular Session Talbot

Present law 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.

Proposed law retains present law 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))