

2020 Regular Session

HOUSE BILL NO. 407

BY REPRESENTATIVE LACOMBE

INSURANCE/HEALTH: Provides for health insurance coverage for participants in clinical trials

1 AN ACT

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

6 Be it enacted by the Legislature of Louisiana:

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

8 §1044. Health coverage; participants in clinical trials

9 * * *

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

12 * * *

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

15 * * *

16 Section 2. This Act shall become effective upon signature by the governor or, if not
17 signed by the governor, upon expiration of the time for bills to become law without signature
18 by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If
19 vetoed by the governor and subsequently approved by the legislature, this Act shall become
20 effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 407 Original

2020 Regular Session

LaCombe

Abstract: Requires health insurance coverage for a treatment provided or study conducted in a Phase I clinical trial for cancer.

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) 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.

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 governor or lapse of time for gubernatorial action.

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