

**IC 27-8-25**

Chapter 25. Coverage for Care Related to Clinical Trials

**IC 27-8-25-1**

**"Care method"**

Sec. 1. As used in this chapter, "care method" means the use of a particular drug or device in a particular manner.

*As added by P.L.109-2009, SEC.3.*

**IC 27-8-25-2**

**"Clinical trial"**

Sec. 2. As used in this chapter, "clinical trial" means a Phase I, II, III, or IV research study:

(1) that is conducted:

(A) using a particular care method to prevent, diagnose, or treat a cancer for which:

(i) there is no clearly superior, noninvestigational alternative care method; and

(ii) available clinical or preclinical data provides a reasonable basis from which to believe that the care method used in the research study is at least as effective as any noninvestigational alternative care method;

(B) in a facility where personnel providing the care method to be followed in the research study have:

(i) received training in providing the care method;

(ii) expertise in providing the type of care required for the research study; and

(iii) experience providing the type of care required for the research study to a sufficient volume of patients to maintain expertise; and

(C) to scientifically determine the best care method to prevent, diagnose, or treat the cancer; and

(2) that is approved or funded by one (1) of the following:

(A) A National Institutes of Health institute.

(B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.

(C) The federal Food and Drug Administration.

(D) The United States Department of Veterans Affairs.

(E) The United States Department of Defense.

(F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.

(G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.

*As added by P.L.109-2009, SEC.3.*

**IC 27-8-25-3**

**"Contracted provider"**

Sec. 3. As used in this chapter, "contracted provider" means a health care provider that has entered into an agreement under IC 27-8-11-3 with an insurer that issues a policy of accident and sickness insurance.

*As added by P.L.109-2009, SEC.3.*

**IC 27-8-25-4**

**"Covered individual"**

Sec. 4. As used in this chapter, "covered individual" means an individual entitled to coverage under a policy of accident and sickness insurance.

*As added by P.L.109-2009, SEC.3.*

**IC 27-8-25-5**

**"Noncontracted provider"**

Sec. 5. As used in this chapter, "noncontracted provider" means a health care provider that has not entered into an agreement to serve as a contracted provider.

*As added by P.L.109-2009, SEC.3.*

**IC 27-8-25-6**

**"Policy of accident and sickness insurance"**

Sec. 6. As used in this chapter, "policy of accident and sickness insurance" has the meaning set forth in IC 27-8-5-1.

*As added by P.L.109-2009, SEC.3.*

**IC 27-8-25-7**

**"Routine care cost"**

Sec. 7. As used in this chapter, "routine care cost" means the cost of medically necessary services related to the care method that is under evaluation in a clinical trial. The term does not include the following:

- (1) The health care service, item, or investigational drug that is the subject of the clinical trial.
- (2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.
- (3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.
- (4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.
- (5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility where a clinical trial is conducted.
- (6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.

(7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.

*As added by P.L.109-2009, SEC.3.*

#### **IC 27-8-25-8**

##### **Coverage for routine care costs**

Sec. 8. (a) A policy of accident and sickness insurance must provide coverage for routine care costs that are incurred in the course of a clinical trial if the policy of accident and sickness insurance would provide coverage for the same routine care costs not incurred in a clinical trial.

(b) The coverage that must be provided under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the policy of accident and sickness insurance, including terms, conditions, restrictions, exclusions, or limitations that apply to health care services rendered by contracted providers and noncontracted providers.

(c) This section does not do any of the following:

(1) Require an insurer that issues a policy of accident and sickness insurance to provide coverage for clinical trial services rendered by a contracted provider.

(2) Prohibit an insurer that issues a policy of accident and sickness insurance from providing coverage for clinical trial services rendered by a contracted provider.

(3) Require reimbursement under a policy of accident and sickness insurance for services that are rendered in a clinical trial by a noncontracted provider at the same rate of reimbursement that would apply to the same services rendered by a contracted provider.

*As added by P.L.109-2009, SEC.3.*

#### **IC 27-8-25-9**

##### **No cause of action created by chapter**

Sec. 9. This chapter does not create a cause of action against a person for any harm to a covered individual resulting from a clinical trial.

*As added by P.L.109-2009, SEC.3.*