WEST VIRGINIA CODE: §33-25F-1

§33-25F-1. Definitions.

For purposes of this article:

(a) A "clinical trial" is a study that determines whether new drugs, treatments or medical procedures are safe and effective on humans. To determine the efficacy of experimental drugs, treatments or procedures, a study is conducted in four phases including the following:

Phase II: The experimental drug or treatment is given to, or a procedure is performed on, a larger group of people to further measure its effectiveness and safety.

Phase III: Further research is conducted to confirm the effectiveness of the drug, treatment or procedure, to monitor the side effects, to compare commonly used treatments and to collect information on safe use.

Phase IV: After the drug, treatment or medical procedure is marketed, investigators continue testing to determine the effects on various populations and to determine whether there are side effects associated with long-term use.

(b) "Cooperative group" means a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group.

(c) "Cooperative group" includes:

(1) The national cancer institute clinical cooperative group;

(2) The national cancer institute community clinical oncology program;

(3) The AIDS clinical trial group; and

(4) The community programs for clinical research in AIDS.

(d) "FDA" means the federal food and drug administration.

(e) "Life-threatening condition" means that the member has a terminal condition or illness that according to current diagnosis has a high probability of death within two years, even with treatment with an existing generally accepted treatment protocol.

(f) "Member" means a policyholder, subscriber, insured, certificate holder or a covered dependent of a policyholder, subscriber, insured or certificate holder.

(g) "Multiple project assurance contract" means a contract between an institution and the

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federal department of health and human services that defines the relationship of the institution to the federal department of health and human services and sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

(h) "NIH" means the national institutes of health.

(i) "Patient cost" means the routine costs of a medically necessary health care service that is incurred by a member as a result of the treatment being provided pursuant to the protocols of the clinical trial. Routine costs of a clinical trial include all items or services that are otherwise generally available to beneficiaries of the insurance policies. "Patient cost" does not include:

(1) The cost of the investigational drug or device;

(2) The cost of nonhealth care services that a patient may be required to receive as a result of the treatment being provided to the member for purposes of the clinical trial;

(3) Services customarily provided by the research sponsor free of charge for any participant in the trial;

(4) Costs associated with managing the research associated with the clinical trial including, but not limited to, services furnished to satisfy data collection and analysis needs that are not used in the direct clinical management of the participant; or

(5) Costs that would not be covered under the participant's policy, plan, or contract for noninvestigational treatments;

(6) Adverse events during treatment are divided into those that reflect the natural history of the disease, or its progression, and those that are unique in the experimental treatment. Costs for the former are the responsibility of the payor as provided in section two of this article, and costs for the later are the responsibility of the sponsor. The sponsor shall hold harmless any payor for any losses and injuries sustained by any member as a result of his or her participation in the clinical trial.

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