WEST VIRGINIA CODE CHAPTER 33 ARTICLE 25F

§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 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.

§33-25F-2. Coverage applicable under this article.

(a) This section applies to:

(1) Insurers and nonprofit health service plans that provide hospital, medical, surgical or pharmaceutical benefits to individuals or groups on an expense-incurred basis under a health insurance policy or contract issued or delivered in the state; and

(2) Health maintenance organizations that provide hospital, medical, surgical or pharmaceutical benefits to individuals or groups under contracts that are issued or delivered in the state.

(b) This section does not apply to a policy, plan or contract paid for under Title XVIII of the Social Security Act.

(c) A policy, plan or contract subject to this section shall provide coverage for patient cost to a member in a clinical trial, as a result of:

(1) Treatment provided for a life-threatening condition; or

(2) Prevention of, early detection of or treatment studies on cancer.

(d) The coverage under subsection (c) of this section is required if:

(1)(A) The treatment is being provided or the studies are being conducted in a Phase II, Phase III or Phase IV clinical trial for cancer and has therapeutic intent; or

(B) The treatment is being provided in a Phase II, Phase III or Phase IV clinical trial for any other life-threatening condition and has therapeutic intent;

(2) The treatment is being provided in a clinical trial approved by:

(A) One of the national institutes of health;

(B) An NIH cooperative group or an NIH center;

(C) The FDA in the form of an investigational new drug application or investigational device exemption;

(D) The federal department of Veterans Affairs; or

(E) An institutional review board of an institution in the state which has a multiple project assurance contract approved by the office of protection from research risks of the national institutes of health;

(3) The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise;

(4) There is no clearly superior, noninvestigational treatment alternative;

(5) The available clinical or preclinical data provide a reasonable expectation that the treatment will be more effective than the noninvestigational treatment alternative;

(6) The treatment is provided in this state: Provided, That, if the treatment is provided outside of this state, the treatment must be approved by the payor designated in subsection (a) of this section;

(7) Reimbursement for treatment is subject to all coinsurance, copayment and deductibles and is otherwise subject to all restrictions and obligations of the health plan; and

(8) Reimbursement for treatment by an out of network or noncontracting provider shall be reimbursed at a rate which is no greater than that provided by an in network or contracting provider. Coverage shall not be required if the out of network or noncontracting provider will not accept this level of reimbursement.

(e) Payment for patient costs for a clinical trial is not required by the provisions of this section, if:

(1) The purpose of the clinical trial is designed to extend the patent of any existing drug, to gain approval or coverage of a metabolite of an existing drug, or to gain approval or coverage relating to additional clinical indications for an existing drug; or

(2) The purpose of the clinical trial is designed to keep a generic version of a drug from becoming available on the market; or

(3) The purpose of the clinical trial is to gain approval of or coverage for a reformulated or repackaged version of an existing drug.

(f) Any provider billing a third party payor for services or products provided to a patient in a clinical trial shall provide written notice to the payor that specifically identifies the services as part of a clinical trial.

(g) Notwithstanding any provision in this section to the contrary, coverage is not required for Phase I of any clinical trial.