WEST VIRGINIA CODE: §9-2-12

§9-2-12. Coverage for patient cost of clinical trials.

(a) The provisions of this section and section twelve-a of this article apply to the health plans regulated by this article.

(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

WV Legislature

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.

WV Legislature