- (b) 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.
- (c) This section does not apply to a policy, plan, or contract paid for under Title XVIII or Title XIX of the Social Security Act.
- (d) 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, early detection, and treatment studies on cancer.
 - (e) The coverage under subsection (d) of this section shall be required if:
- (1) (i) the treatment is being provided or the studies are being conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer; or
- (ii) the treatment is being provided in a PHASE I, Phase II, Phase III, or Phase IV clinical trial for any other life-threatening condition;
 - (2) the treatment is being provided in a clinical trial approved by:
 - · (i) one of the National Institutes of Health;
 - (ii) an NIH cooperative group or an NIH center;
 - (iii) the FDA in the form of an investigational new drug application;
 - (iv) the federal Department of Veterans Affairs; or
- (v) 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 Institutions 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; and
- (5) the available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative.