

[(f) The coverage under subsection (d) of this section may be provided on a case by case basis if the treatment is being provided in a Phase I clinical trial for any life-threatening condition other than cancer.]

[(g)] (F) In conjunction with the provisions of subsection (d) of this section, a policy, plan, or contract shall provide coverage for patient cost incurred for drugs and devices that have been approved for sale by the FDA whether or not the FDA has approved the drug or device for use in treating the patient's particular condition, to the extent that the drugs or devices are not paid for by the manufacturer, distributor, or provider of that drug or device.

[(h)] (G) (1) An entity seeking coverage for treatment in a clinical trial approved by an institutional review board under subsection (e)(2)(v) of this section shall post electronically and keep up-to-date a list of the clinical trials meeting the requirements of subsections (d) and (e) of this section.

(2) The list shall include, for each clinical trial:

- (i) the phase for which the trial is approved;
- (ii) the entity approving the trial;
- (iii) whether the trial is for treatment of cancer or another life-threatening disease and, if not cancer, the particular disease; and
- (iv) the estimated number of participants in the trial.

[(i)] (H) This section may not be construed to affect compliance with § 15-804 of this subtitle regarding coverage for off-label use of drugs.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all new policies, contracts, or health benefit plans issued or delivered in the State on or after July 1, 1999, and to the renewal of all policies, contracts, or health benefit plans in effect before that date, except that any policy, contract, or health benefit plan in effect before July 1, 1999, shall comply with the provisions of this Act no later than January 1, 2000.

SECTION 3. AND BE IT FURTHER ENACTED, That, subject to Section 2 of this Act, this Act shall take effect July 1, 1999.

Approved April 27, 1999.

CHAPTER 146

(House Bill 109)

AN ACT concerning

Health Insurance - Medical Clinical Trials - Coverage

FOR the purpose of requiring certain insurers, nonprofit health service plans, and