

# **Florida Clinical Trials Agreement**

## **Agreement to Reduce Cancer Morbidity and Mortality in Florida**

The undersigned parties to this Florida Clinical Trials Agreement (Agreement) acknowledge that Florida ranks higher than the national average in the incidence and mortality of cancer. The undersigned parties to this Agreement acknowledge that cancer is a leading cause of death in Florida. The parties further acknowledge that many cancers can be treated successfully if detected early. The undersigned health insurers, health maintenance organizations, and self-insured governmental employers have a compelling interest in improving the methods of cancer detection, treatment, and prevention.

### **Purpose of this Agreement**

The intent and purpose of this Agreement is to provide for insurance coverage for certain services related to cancer for those Floridians covered by the health benefit plans issued by the undersigned health insurers, health maintenance organizations, and self-insured governmental employers. Such coverage will promote the health and welfare of the people of Florida. There are two general areas covered pursuant to this Agreement: (1) coverage of the routine patient care costs for persons participating in cancer clinical trials within Florida; and (2) coverage of screening tests as described in section 2.0 of this Agreement.

### **1.0 Cancer Clinical Trials**

#### **1.0.1 Importance of Cancer Clinical Trials**

All standard cancer treatments in use today began as clinical trials. Most of the advances in cancer therapies have occurred as a direct result of studies in which doctors have been able to determine the most effective forms of treatment. Although cancer clinical research has improved patient care dramatically, only a small segment of those with cancer in Florida participate in cancer clinical trials. Without strong cancer clinical trial participation, it will be impossible to evaluate and improve detection, treatment, and prevention options.

#### **1.0.2 Cancer Clinical Trials Covered Pursuant to this Agreement**

The parties to this Agreement agree that for all those insured, diagnosed with cancer, and accepted into a Phase II, Phase III, or Phase IV clinical trial for cancer, group health plan contracts, as defined in the Employee Retirement Income and Security Act of 1974, and self-insured governmental employers coverage issued by the undersigned that provide for hospital, medical, or surgical coverage in this state shall provide coverage for all routine patient care costs related to a clinical trial in cancer if a physician who is providing or is authorized to provide covered healthcare services to the insured under the insured's health benefit plan contract recommends participation in the cancer clinical trial. That determination must be made after determining that participation in the cancer clinical trial has a meaningful potential to benefit the insured. A cancer clinical trial's endpoints shall not be defined exclusively to test toxicity, but shall have a therapeutic intent.

For purposes of this Agreement, a cancer clinical trial must either (1) involve a drug that is exempt under federal regulations from a new drug application, or (2) be a trial that is approved by one of the following:

- A. Cooperative Group or one of the National Institutes of Health.
- B. The federal Food and Drug Administration, in the form of an investigational new drug application.
- C. The United States Department of Defense.
- D. The United States Veterans' Administration.
- E. The National Cancer Institute.

- F. An accredited institutional review board of any accredited school of medicine, nursing or pharmacy or licensed children's specialty hospital in Florida.

Notwithstanding the foregoing, to be covered, all clinical trials must be approved and managed by an institutional review board.

### **1.0.3 Routine Patient Care Costs Defined**

Routine patient care costs, for purposes of this Agreement, is defined as those costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the plan or contract if those drugs, items, devices, and services were not provided in connection with an approved cancer clinical trial program, including the following:

- A. Health care services covered absent a cancer clinical trial.
- B. Health care services required solely for the provision of the investigational drug, item, device or service.
- C. Health care services required for the clinically appropriate monitoring of the investigational item or service.
- D. Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.

For purposes of this Agreement and this Agreement only, routine patient care costs does not include the costs of any of the following:

- A. Drugs or devices that have not been approved by the federal Food and Drug Administration associated with the cancer clinical trial or drugs or devices that have not been approved by the federal Food and Drug Administration for the specific use associated with the cancer clinical trial.
- B. Services other than health care services, such as travel, housing, companion expenses, and other non clinical expenses, that an insured may require as a result of the treatment being provided for purposes of the cancer clinical trial.
- C. Any item or service that is provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient.
- D. Health care services which, except for the fact they are being provided in a cancer clinical trial, are otherwise specifically excluded from coverage under the insured's health plan.
- E. Health care services customarily provided by the research sponsors free of charge for any enrollee in a cancer clinical trial.
- F. The cost of an oncologic drug if the clinical trial's purpose is to study the use of the oncologic drug in the particular cancer in question or study the administration of the drug in a new manner.

For the purposes of this Agreement, patient care costs such as additional tests that may or may not be fully covered by the clinical trial sponsor and/or research institution and reimbursement issues need to be resolved by the clinical trial sponsor and the participant's health plan.

### **1.0.4 Payment Rate**

In the case of health care services provided by a contracting provider, the payment rate shall be at the agreed-upon rate less applicable insured cost-sharing (e.g. copayments, coinsurance, and/or deductibles). In the case of a non-contracting provider, the payment shall be at the negotiated rate or what the insurer would otherwise pay to a non-participating provider for the same covered services, less applicable out-of-network cost-sharing. Nothing in this Agreement shall be construed to:

- A. Prohibit a health insurer, health maintenance organization, or self-insured governmental employer from restricting coverage for cancer clinical trials to hospitals and physicians in Florida unless the protocol for the cancer clinical trial is not available at a Florida hospital or with a Florida-licensed physician; or
- B. Require a health maintenance organization or exclusive provider organization to pay for the services of a non-contracted provider unless payment would otherwise be required under state or federal law, or the subscriber contract.

## **2.0 Cancer Screenings**

### **2.0.1 Importance of Early Detection**

Despite remarkable treatment options available to cancer patients, one of the most important factors in five-year survival rates for cancer patients remains early detection. Early detection examinations are known to save lives, even in certain asymptomatic people. To that end, the American Cancer Society (ACS), the National Institutes of Health (NIH), the National Cancer Institute (NCI), the United States Public Health Service (USPHS), the Centers for Disease Control (CDC), the U.S. Preventive Services Task Force (PSTF), the National Comprehensive Cancer Network (NCCN), and other nationally recognized health care organizations have established guidelines to detect cancer early. Health plans have adopted one or more of these guidelines in whole or in part to serve as the basis of their individual clinical practice guidelines. Additionally, the undersigned health insurers, health maintenance organizations, and self-insured governmental employers provide benefits for certain cancer screenings in those plans that provide benefits for preventive care. The ACS, NIH, NCI, USPHS, CDC, PSTF, NCCN, and the undersigned plans unequivocally believe that early detection examinations and tests can help save lives. Some examples of such testing include mammography, the PAP test, the PSA blood test, skin examinations and colonoscopies. Early detection not only saves lives, but it also saves money. For cancers addressed by the ACS early detection guidelines, early detection can result in a relatively low-cost treatment option.

### **2.0.2 Those Screenings Covered by this Agreement**

The parties to this Agreement agree that every health benefit plan that provides coverage for preventive care and screening shall provide coverage for cancer screenings and examinations in accordance with the most recently published guidelines and recommendations established by any of the following: ACS, NIH, NCI, USPHS, CDC, PSTF, NCCN, or other nationally recognized health care organization.

## **3.0 Miscellaneous Provisions**

- A. The provision of services when required by this Agreement shall not, in itself, give rise to liability on the part of the health insurers, health maintenance organizations, and self-insured governmental employers.
- B. Nothing in this Agreement shall be construed to prohibit, limit, or modify an insured's rights to any available internal and independent review process.
- C. Nothing in this Agreement shall be construed to prohibit the managing of benefits through the application of any authorization requirement, utilization review or medical management practices.
- D. Nothing in this Agreement shall be construed to otherwise limit or modify any existing requirements under state or federal law, or to prevent application of cost-sharing provisions or otherwise generally applicable benefit exclusions contained in a health benefit plan.
- E. Cost-sharing provisions applied to services delivered pursuant to this Agreement, including satisfying deductibles in a high-deductible benefit plan, shall be the same as those applied to the same services if not delivered pursuant to this Agreement.
- F. Nothing in this Agreement shall be construed to prohibit the parties to it from providing or continuing to provide an accident and sickness insurance benefit plan, policy, or contract which has benefits that are greater than the minimum benefits required by this Agreement

or from providing or continuing to provide any accident and sickness insurance plan, policy, or contract which provides benefits which are generally more favorable to the insured than those required by this Agreement.

- G. Each party to this Agreement will perform its activities as an independent contractor and not as a partner, agent or joint venturer with the other. No party will have the power to create obligations or liabilities for the other. No party will be bound by any representation, act or omission of the other.
- H. Nothing in this Agreement shall be construed to require an insurer, that is an Undersigned Party, to provide coverage for Cancer Clinical Trials for customers for whom the insurer provides third-party administrative services.
- I. Nothing in this agreement shall be construed to require an undersigned party to cover out-of-network services where the underlying health benefit plan does not provide coverage for out-of-network services.
- J. Nothing in this agreement shall be construed to require an Undersigned Party to cover benefits under clinical trials that are otherwise not covered under the health plan for other conditions.
- K. Each party to this Agreement will encourage policyholders enrolled in clinical trials to notify their primary care physician, or other health professional responsible for coordinating the patient's care, of said enrollment.
- L. Coverage under this Agreement only applies to the patient while he/she is enrolled in the health plan or self-insured governmental employers' benefit plan consistent with state law.
- M. Coverage under this Agreement is applicable to all group health plan contracts and policies issued or renewed on or after July 1, 2010.

### **Parties to this Agreement**

In recognition of the importance of reducing the cancer morbidity and mortality rates in Florida, in an effort to establish a voluntary process to further participation in cancer clinical trials as well as early detection of cancer, and contingent upon the receipt of a Antitrust No-action Letter as authorized under s. 408.18, F.S., the organizations signing below agree to abide by the provisions of this Agreement to make all best efforts to facilitate participation of their members in cancer clinical trials. The parties reserve the right to review periodically the administration and efficacy of this agreement in order to suggest modifications in its terms or termination of the agreement in its entirety.

**Organizations Participating in the Clinical Trials Agreement**

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**Addendum – Endorsing Entities**

The following entities endorse the Clinical Trial Agreement: