STATE OF CONNECTICUT
# REGULATION
OF

NAME OF AGENCY
INSURANCE DEPARTMENT



5537

## Cancer Clinical Trials

**SECTION 1**

The Regulations of Connecticut State Agencies are amended by adding sections 38a-504a-1 to 38a-504a-4, inclusive, as follows:

(NEW) **Sec. 38a-504a-1. Definitions**

As used in Sections 38a-504a-1 to 38a-504a-4, inclusive, of the Regulations of Connecticut State Agencies:

(1) "Commissioner" means the Insurance Commissioner of the State of Connecticut, and

(2) "Coverage policies" means "coverage policies" as used in sections 38a-504g and 38a-542g of the Connecticut General Statutes.

(NEW) **Sec. 38a-504a-2. Filing Requirements**

(a) Any insurer or health care center with coverage policies for care in cancer clinical trials shall submit such policies to the Insurance Department for evaluation and approval. The department shall certify whether the insurer's or health care center's coverage policy for routine patient care costs associated with cancer clinical trials is substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive of the Connecticut General Statutes, or sections 38a-542a to 38a-542g, inclusive of the Connecticut General Statutes. If the department finds that such coverage is substantially equivalent to the requirements of sections 38a-504a to 38a-504g, inclusive of the Connecticut General Statutes, or sections 38a-542a to 38a-542g, inclusive of the Connecticut General Statutes, the insurer or health care center shall be exempt from the provisions of sections 38a-504a to 38a-504g, inclusive, of the Connecticut General Statutes or sections 38a-542a to 38a-542g, inclusive of the Connecticut General Statutes.

(b) A coverage policy shall include at a minimum the following:

(1) criteria for determining whether services constitute a cancer clinical trial;

(2) eligibility requirements for persons seeking coverage for a cancer clinical trial;

(3) a definition of routine patient care costs associated with cancer clinical trials that is consistent with, or substantially equivalent to the term as defined in sections 38a-504d and 38a-542d of the Connecticut General Statutes;

(4) any terms, conditions, exclusions and limitations on routine patient care costs associated with cancer clinical trials;

(5) procedures to request coverage for routine patient care costs associated with cancer clinical trials; and

(6) grievance and appeal processes.

(c) Any such insurer or health care center shall report annually, on a form prescribed by the Commissioner, to the department that there have been no changes in the policy as certified by the department. If there has been any change in the policy, the insurer or health care center shall resubmit its policy for certification by the department.

(NEW) **Sec. 38a-504a-3. Request for Authorization of Coverage**

(a) Pursuant to sections 38a-504f and 38a-542f of the Connecticut General Statutes, the standardized form provisions set forth in subsection (b) of this section, shall be used by all providers, hospitals and institutions for seeking to enroll an insured person in a cancer clinical trial and shall be accepted by every entity that provides coverage pursuant to sections 38a-504a or 38a-542a of the Connecticut General Statutes.

(b) The standardized form to request authorization for coverage of routine patient care costs associated with cancer clinical trials required by sections 38a-504f and 38a-542f of the Connecticut General Statutes shall contain the following provisions:

Section I

Date: _____

Member name: _____

Member ID #: _____

Member Date of Birth: _____

Health Insurer: _____

Treating Physician: _____

Contact Person for Additional Information Regarding Member's Treatment:

Name: _____

Address: _____

Phone number: _____

Fax number: _____

E-mail address: _____

Service requested is: ____ Outpatient ____ Inpatient
____Office Setting

If outpatient or inpatient is checked:

Facility name & address: _____

Clinical Cooperative Group Number: _____
(Please provide Web site address or other reference for accessing information about this trial.)

Please Note: You may be asked to provide additional information about the cancer clinical trial or the member's diagnosis and condition prior to the authorization of this request.

If the clinical cooperative group number is provided above, you do not need to complete Section II. If the clinical group number is unavailable, Section II must be completed.

Section II should be completed only if the Clinical Cooperative Group Number is unavailable.

Section II

Diagnosis code: _____

Proposed treatment protocol: _____

Phase of clinical trial: ____ I ____ II ____ III

Sponsor of clinical trial: _____

Clinical Trial has been reviewed and approved by:

____ National Institutes of Health
____ National Cancer Institute
____ Federal Food and Drug Administration
____ Federal Dept. of Defense
____ Federal Dept. of Veterans Affairs.

Check one: ____ Single center study ____ Multiple center study

List name(s) and address(es) of center(s):

**Statement of purpose:**

To codify Connecticut Insurance Department Bulletin HC-58 and adopt regulations pursuant to sections 38a-504f and 38a-542f of the Connecticut General Statutes regarding health insurance coverage for cancer clinical trials.

# CERTIFICATION

R-39 REV: 1/77

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Be it known that the foregoing:

☒ Regulations ☐ Emergency Regulations

Are:

☐ Adopted ☐ Amended as hereinabove stated ☐ Repealed

By the aforesaid agency pursuant to:

☒ Sections 38a-504f and 38a-542f of the General Statutes.

☐ Section _____ of the General Statutes, as amended by Public Act No._____ of the _____ Public Acts.

☐ Public Act No. ____ of the Public Acts.

After publication in the Connecticut Law Journal on, _____of the notice of the proposal to:

☒ Adopt ☐ Amended ☐ Repeal such regulations

(If applicable): ☐ And the holding of an advertised public hearing on _____day of _____20 ___

WHEREFORE, the foregoing regulations are hereby:

☐ Adopted ☐ Amended as hereinabove stated ☐ Repealed

Effective:

☒ When filed with the Secretary of the State.

(OR)

☐ The 1st day of January, 2005.

| In Witness Whereof: | DATE 6/17/04 | SIGNED (*Head of Board, Agency or Commission*) Susan T. Cogswell | OFFICIAL TITLE, DULY AUTHORIZED INSURANCE COMMISSIONER |
|---|---|---|---|
| Approved by the Attorney General as to legal sufficiency In accordance with Sec. 4-169, as amended, C. G. S. | | SIGNED 7/14/04 | OFFICIAL TITLE, DULY AUTHORIZED Assoc. Atty. General |

☐ ~~Approved~~

☐ Disapproved

☐ Disapproved in part, (Indicate Section Numbers disapproved only)

☐ Rejected without prejudice.

| By the Legislative Regulation Review Committee in accordance With Sec. 4-170, as amended, of the General Statutes. | DATE 8/24/04 | SIGNED (*Clerk of the Legislative Regulation Review Committee*) Pamela B Booth |
|---|---|---|

Two certified copies received and filed, and one such copy forwarded to the Commission on Official Legal Publications In accordance with Section 4-172, as amended, of the General Statutes.

| DATE 8/30/2004 | SIGNED (*Secretary of the State*) Susan Bysiewicz | BY Barbara Kadek |
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**INSTRUCTION**

1. One copy of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the Attorney General for his determination of legal sufficiency. Section 4-169 of the General Statutes.

2. Seventeen copies of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the standing Legislative Regulation Review Committee for its approval. Section 4-170 of the General Statutes.

3. Each regulation must be in the form intended for publication and must include the appropriate regulation section number and section heading. Section 4-172 of the General Statutes.

4. Indicate by "(NEW)" in heading if new regulation. Amended regulations must contain new language in capitol letters and deleted language in brackets. Section 4-170 of the General Statutes.