

**Legislative Regulation
Review Committee**

2009-065

Insurance Department

CANCER CLINICAL TRIALS

STATE OF CONNECTICUT
REGULATION
OF

NAME OF AGENCY
INSURANCE DEPARTMENT

Cancer Clinical Trials

SECTION 1

Section 38a-504a-3 of the Regulations of Connecticut State Agencies is amended to read as follows:

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] the commissioner shall establish a standardized form to 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.

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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 amend the regulation to enable changes to the preauthorization form for cancer clinical trial coverage without having to undertake the full regulation making process. This will permit more flexibility in keeping the form updated and consistent with the new treatment and trial protocols.

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A. The problems, issues or circumstances that the regulation proposes to address.

Because the preauthorization form is embedded within the regulation, it requires that any changes be undertaken through the regulation making process. The intent is to remove the form from the body of the regulation to permit greater flexibility to make changes on a more responsive timeframe consistent with changes to clinical trials.

B. A summary of the main provisions of the regulation.

Deletes the form content from the body of the regulation

C. The legal effects of the regulation, including all ways that the regulation would change existing regulations or other laws.

No other laws or regulations will be affected.

CERTIFICATION

R-39 REV. 1/77

Be it known that the foregoing:

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Regulations Emergency Regulations

Are:

Adopted Amended as hereinabove stated Repealed

By the aforesaid agency pursuant to:

Sections ~~38a-8, 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 May 19, 2009 _____ and _____ of the notice of the proposal to:

Adopt Amend 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 _____ day of _____.

In Witness Whereof:	DATE <u>10/9/09</u>	SIGNED <i>[Signature]</i> <small>(Head of Board, Agency or Commission)</small>	OFFICIAL TITLE, DULY AUTHORIZED INSURANCE COMMISSIONER
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Approved by the Attorney General as to legal sufficiency In accordance with Sec. 4-169, as amended, C. G. S. :	SIGNED <i>[Signature]</i> <u>10/23/09</u>	OFFICIAL TITLE, DULY AUTHORIZED ATTORNEY GENERAL
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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	SIGNED (Clerk of the Legislative Regulation Review Committee)
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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	SIGNED (Secretary of the State.)	BY
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INSTRUCTION

- 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.
- 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.
- 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.
- 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.