

STATE OF CONNECTICUT
REGULATION
OF

NAME OF AGENCY
INSURANCE DEPARTMENT

5962

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 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] have a format substantially as follows. The commissioner may request additional information on the standardized form.

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.

STATE OF CONNECTICUT
REGULATION
OF

NAME OF AGENCY
INSURANCE DEPARTMENT

5962

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.

STATE OF CONNECTICUT
REGULATION
OF

NAME OF AGENCY
INSURANCE DEPARTMENT

5962

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

5962

Be it known that the foregoing:

Page 4 of 4 pages

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>12/15/09</u>	SIGNED (Head of Board, Agency or Commission) <i>[Signature]</i>	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>	DATE <u>12/19/09</u>	OFFICIAL TITLE, DULY AUTHORIZED ASSOC. ATTY. 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 <u>2/23/2010</u>	SIGNED (Clerk of the Legislative Regulation Review Committee) <i>[Signature]</i>
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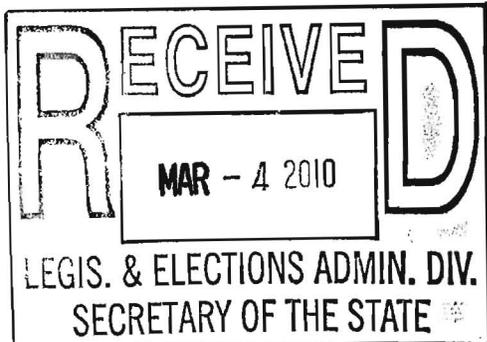
Two certified copies received and filed, and one such copy forwarded to the Commission on Official Legal Publications

In accordance with Section 4-172, as amended, of the General Statutes.

DATE <u>3-4-2010</u>	SIGNED (Secretary of the State) <i>[Signature]</i>	BY <i>[Signature]</i>
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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.



CLERK OF THE SUPERIOR COURT
 LEGISLATION & ELECTIONS ADMINISTRATION DIVISION
 2010 MAR - 4 AM 11:30

5962

Regulations OF Department of Insurance
CONCERNING Cancer Clinical Trials
Approved by the Attorney General December 29, 2009
Approved by the Legislative Regulation Review Committee of General Assembly February 23, 2010
Received and filed in the Office of the Secretary of the State March 4, 2010 Effective Date: March 4, 2010
Published in the Connecticut Law Journal