

SECTION 2: REGULATION with

- STATEMENT OF PURPOSE
- SIGNED AND PROPERLY COMPLETED
CERTIFICATION PAGE

IMPORTANT: Read instructions on back of last page (Certification Page) before completing this form. Failure to comply with instructions may cause disapproval of proposed Regulations

State of Connecticut
REGULATION
of

NAME OF AGENCY Insurance Department
Concerning
SUBJECT MATTER OF REGULATION Clinical Trials

[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

[The standardized]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 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.

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] must 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[.]
- ___ Medicare Clinical Trial Policy

Check one: ____ Single center study ____ Multiple center study

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

SECTION 2

Section 38a-504a-1 to 38a-504a-2, inclusive, of the Regulations of Connecticut State Agencies are repealed.

Statement of Purpose

Pursuant to CGS Section 4-170(b)(3), "Each proposed regulation shall have a statement of its purpose following the final section of the regulation." Enter the statement here.

To amend the regulation consistent with federal and state statutory changes which have expanded coverage for routine care expenses to a broader range of clinical trial. The definitions and filing requirements are redundant to the statute and are therefore being repealed; the form is being updated to remove any references to "cancer".

- A. The problems, issues or circumstances that the regulation proposes to address.
Updates the preauthorization form to remove all references to "cancer" and deletes material which is redundant to the statutes/
- B. A summary of the main provisions of the regulation.
Removes the references to "cancer".
- 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

This certification statement must be completed in full, including items 3 and 4, if they are applicable.

- 1) I hereby certify that the above (check one) Regulations Emergency Regulations
- 2) are (check all that apply) adopted amended repealed by this agency pursuant to the following authority(ies): (complete all that apply)

a. Connecticut General Statutes section(s) 38a-504f and 38a-542f.

b. Public Act Number(s) _____.
(Provide public act number(s) if the act has not yet been codified in the Connecticut General Statutes.)

- 3) And I further certify that notice of intent to adopt, amend or repeal said regulations was published in the **Connecticut Law Journal** on February 7, 2012;
(Insert date of notice publication if publication was required by CGS Section 4-168.)

- 4) And that a public hearing regarding the proposed regulations was held on _____;
(Insert date(s) of public hearing(s) held pursuant to CGS Section 4-168(a)(7), if any, or pursuant to other applicable statute.)

- 5) And that said regulations are **EFFECTIVE** (check one, and complete as applicable)

When filed with the Secretary of the State

OR on (insert date) _____

DATE 3/13/12	SIGNED (Head of Board, Agency or Commission) <i>[Signature]</i>	OFFICIAL TITLE, DULY AUTHORIZED Commissioner
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APPROVED by the Attorney General as to legal sufficiency in accordance with CGS Section 4-169, as amended

DATE 3/21/12	SIGNED (Attorney General or AG's designated representative) <i>[Signature]</i> Joseph Rubin	OFFICIAL TITLE, DULY AUTHORIZED Assoc Atty Gen I
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Proposed regulations are **DEEMED APPROVED** by the Attorney General in accordance with CGS Section 4-169, as amended, if the attorney General fails to give notice to the agency of any legal insufficiency within thirty (30) days of the receipt of the proposed regulation.

(For Regulation Review Committee Use ONLY)

- Approved Rejected without prejudice
- Approved with technical corrections Disapproved in part, (Indicate Section Numbers disapproved only)
- Deemed approved pursuant to CGS Section 4-170(c)

By the Legislative Regulation Review Committee in accordance with CGS Section 4-170, as amended	DATE	SIGNED (Administrator, 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 CGS Section 4-172, as amended.

DATE	SIGNED (Secretary of the State)	BY
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(For Secretary of the State Use ONLY)

GENERAL INSTRUCTIONS

1. All regulations proposed for adoption, amendment or repeal, *except* emergency regulations, must be presented to the Attorney General for his/her determination of legal sufficiency. (See CGS Section 4-169.)
2. After approval by the Attorney General, the original and one electronic copy (in Word format) of all regulations proposed for adoption, amendment or repeal must be presented to the Legislative Regulation Review Committee for its action. (See CGS Sections 4-168 and 4-170 as amended by Public Act 11-150, Sections 18 and 19.)
3. Each proposed regulation section must include the appropriate regulation section number and a section heading. (See CGS Section 4-172.)
4. New language added to an existing regulation must be in underlining or CAPITAL LETTERS, as determined by the Regulation Review Committee. (See CGS 4-170(b).)
5. Existing language to be deleted must be enclosed in brackets []. (See CGS 4-170(b).)
6. A completely new regulation or a new section of an existing regulation must be preceded by the word "(NEW)" in capital letters. (See CGS Section 4-170(b).)
7. The proposed regulation must have a statement of its purpose following the final section of the regulation. (See CGS Section 4-170(b).)
8. The Certification Statement portion of the form must be completed, including all applicable information regarding *Connecticut Law Journal* notice publication date(s) and public hearing(s). (See more specific instructions below.)
9. Additional information regarding rules and procedures of the Legislative Regulation Review Committee can be found on the Committee's web site: <http://www.cga.ct.gov/rr/>.
10. A copy of the Legislative Commissioners' Regulations Drafting Manual is located on the LCO website at http://www.cga.ct.gov/lco/pdfs/Regulations_Drafting_Manual.pdf.

CERTIFICATION STATEMENT INSTRUCTIONS

(Numbers below correspond to the numbered sections of the statement)

1. Indicate whether the regulation is a regular or an emergency regulation adopted under the provisions of CGS Section 4-168(f).
2.
 - a) Indicate whether the regulations contains newly adopted sections, amendments to existing sections, and/or repeals existing sections. Check all cases that apply.
 - b) Indicate the specific legal authority that authorizes or requires adoption, amendment or repeal of the regulation. If the relevant public act has been codified in the most current biennial edition of the *Connecticut General Statutes*, indicate the relevant statute number(s) instead of the public act number. If the public act has not yet been codified, indicate the relevant public act number.
3. Except for emergency regulations adopted under CGS 4-168(f), and technical amendments to an existing regulation adopted under CGS 4-168(g), an agency must publish notice of its intent to adopt a regulation in the *Connecticut Law Journal*. Enter the date of notice publication.
4. CGS Section 4-168(a)(7) prescribes requirements for the holding of an agency public hearing regarding proposed regulations. Enter the date(s) of the hearing(s) held under that section, if any; also enter the date(s) of any hearing(s) the agency was required to hold under the provisions of any other law.
5. As applicable, enter the effective date of the regulation here, or indicate that it is effective upon filing with the Secretary of the State. Please note the information below.

Regulations are effective upon filing with the Secretary of the State or at a later specified date. See CGS Section 4-172(b) which provides that each regulation is effective upon filing, or, if a later date is required by statute or specified in the regulation, the later date is the effective date. An effective date may not precede the effective date of the public act requiring or permitting the regulation. Emergency regulations are effective immediately upon filing with the Secretary of the State, or at a stated date less than twenty days thereafter.