

R-39 Rev. 03/2012  
(Title 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

6063

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: \_\_\_\_\_

6063

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[.]

6063

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.

6063

**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.

6063

R-39 Rev. 02/2012  
(Certification page—see Instructions on back)

### 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
-----------------	--	---

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
-----------------	--	---

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)

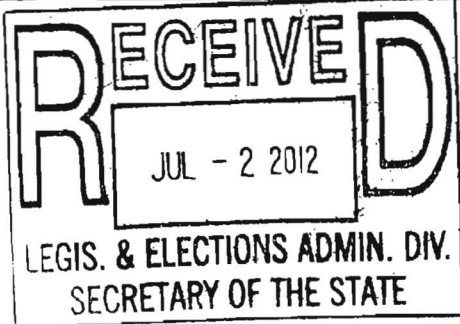
- Approved  Rejected without prejudice
- Approved with technical corrections  Disapproved in part, (Indicate Section Numbers disapproved only)
- Deemed approved pursuant to CGS Section 4-170(c)

By the Legislative Regulation Review Committee in accordance with CGS Section 4-170, as amended	DATE 6/26/2012	SIGNED (Administrator, Legislative Regulation Review Committee) <i>[Signature]</i> Pamela B. Booth
---	-------------------	---

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 7-2-2012	SIGNED (Secretary of the State) <i>[Signature]</i>	BY <i>[Signature]</i>
------------------	---	--------------------------

(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](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.

6063

Regulations of the <b>Department of Insurance</b>
CONCERNING <b>Clinical Trials</b>
Approved by the Attorney General <b>March 21, 2012</b>
Approved by the Legislative Regulation Review Committee on <b>June 26, 2012</b>
Received and filed in the Office of the Secretary of the State  July 2, 2012 <b>Effective Date: July 2, 2012</b>
Published in the Connecticut Law Journal