



# STATE OF CONNECTICUT

## INSURANCE DEPARTMENT

### NOTICE OF INTENT TO AMEND A REGULATION

In accordance with section 4-168(a) of the Connecticut General Statutes, notice is hereby given that the Insurance Commissioner, pursuant to the authority of sections 38a-504f and 38a-542f of the Connecticut General Statutes, proposes to amend a regulation concerning Cancer Clinical Trials.

**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.

All interested persons are invited to submit written data, views or arguments in connection with the proposed action within thirty days following publication of this notice in the Connecticut Law Journal to the State of Connecticut, Insurance Department, Attention: N. Beth Cook, P.O. Box 816, Hartford, CT 06142-0816.

Copies of the proposed regulation may be obtained by writing to the Insurance Department at the above address or sending an e-mail to [Beth.Cook@ct.gov](mailto:Beth.Cook@ct.gov). The proposed regulation may also be viewed by visiting the Insurance Department's Internet Web site at [www.ct.gov/cid](http://www.ct.gov/cid) and clicking on "Proposed Regulations".

Thomas R. Sullivan  
Insurance Commissioner

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**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: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
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\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_ ]

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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.