



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 Clinical Trials.

Statement of purpose: 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 The definitions and filing requirements are redundant to the statute and are therefore being repealed.

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. The proposed regulation may also be viewed by visiting the Insurance Department's Internet Web site at www.ct.gov/cid and clicking on "Proposed Regulations".

Thomas B. Leonardi
Insurance Commissioner

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

[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.

STATE OF CONNECTICUT
REGULATION
OF

NAME OF AGENCY
INSURANCE DEPARTMENT

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.

STATE OF CONNECTICUT
REGULATION
OF

NAME OF AGENCY
INSURANCE DEPARTMENT

Statement of purpose:

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.

DRY
DRAFT