



## Senate

General Assembly

**File No. 153**

January Session, 2001

Substitute Senate Bill No. 325

*Senate, April 9, 2001*

The Committee on Public Health reported through SEN. HARP of the 10th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

### **AN ACT CONCERNING HEALTH INSURANCE COVERAGE DURING CLINICAL TRIALS.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) Each group health insurance policy providing  
2 coverage of the type specified in subdivisions (1), (2), (4), (11) and (12)  
3 of section 38a-469 of the general statutes delivered, issued for delivery  
4 or renewed in this state on or after January 1, 2002, shall provide  
5 coverage for the routine patient care costs, as defined in section 4 of  
6 this act, associated with cancer clinical trials, in accordance with  
7 sections 2 to 7, inclusive, of this act. As used in this section and sections  
8 2 to 7, inclusive, of this act, "cancer clinical trial" means an organized,  
9 systematic, scientific study of therapies, tests or other clinical  
10 interventions for purposes of treatment or palliation or therapeutic  
11 intervention for the prevention of cancer in human beings, except that  
12 a clinical trial for the prevention of cancer is eligible for coverage only  
13 if it involves a therapeutic intervention and is a phase III clinical trial  
14 approved by one of the entities identified in section 2 of this act and is

15 conducted at multiple institutions.

16       Sec. 2. (NEW) In order to be eligible for coverage of routine patient  
17 care costs, as defined in section 4 of this act, a cancer clinical trial shall  
18 be conducted under the auspices of an independent peer-reviewed  
19 protocol that has been reviewed and approved by: (1) One of the  
20 National Institutes of Health; or (2) a National Cancer Institute  
21 affiliated cooperative group; or (3) the federal Food and Drug  
22 Administration as part of an investigational new drug or device  
23 exemption; or (4) the federal Department of Defense or Veterans  
24 Affairs. Nothing in sections 1 to 7, inclusive, of this act shall be  
25 construed to require coverage for any single institution cancer clinical  
26 trial conducted solely under the approval of the institutional review  
27 board of an institution.

28       Sec. 3. (NEW) In order to be eligible for coverage of routine patient  
29 care costs, as defined in section 4 of this act, the insurer, health care  
30 center or plan administrator may require that the person or entity  
31 seeking coverage for the cancer clinical trial provide: (1) Evidence  
32 satisfactory to the insurer, health care center or plan administrator that  
33 the insured person receiving coverage meets all of the patient selection  
34 criteria for the cancer clinical trial, including credible evidence in the  
35 form of clinical or pre-clinical data showing that the cancer clinical trial  
36 is likely to have a benefit for the insured person that is commensurate  
37 with the risks of participation in the cancer clinical trial to treat the  
38 person's condition; and (2) evidence that the appropriate informed  
39 consent has been received from the insured person; and (3) copies of  
40 any medical records, protocols, test results or other clinical information  
41 used by the physician or institution seeking to enroll the insured  
42 person in the cancer clinical trial; and (4) a summary of the anticipated  
43 routine patient care costs in excess of the costs for standard treatment;  
44 and (5) information from the physician or institution seeking to enroll  
45 the insured person in the clinical trial regarding those items, including  
46 any routine patient care costs, that are eligible for reimbursement by

47 an entity other than the insurer or health care center, including the  
48 entity sponsoring the clinical trial; and (6) any additional information  
49 that may be reasonably required for the review of a request for  
50 coverage of the cancer clinical trial. The health plan or insurer shall  
51 request any additional information about a cancer clinical trial within  
52 five business days of receiving a request for coverage from an insured  
53 person or a physician seeking to enroll an insured person in a cancer  
54 clinical trial. Nothing in sections 1 to 7, inclusive, of this act shall be  
55 construed to require the insurer or health care center to provide  
56 coverage for routine patient care costs that are eligible for  
57 reimbursement by an entity other than the insurer, including the entity  
58 sponsoring the cancer clinical trial.

59       Sec. 4. (NEW) (a) For purposes of sections 1 to 7, inclusive, of this  
60 act, "routine patient care costs" means: (1) Coverage for medically  
61 necessary health care services that are incurred as a result of the  
62 treatment being provided to the insured person for purposes of the  
63 cancer clinical trial that would otherwise be covered if such services  
64 were not rendered pursuant to a cancer clinical trial. Such services  
65 shall include those rendered by a physician, diagnostic or laboratory  
66 tests, hospitalization or other services provided to the patient during  
67 the course of treatment in the cancer clinical trial for a condition, or  
68 one of its complications, that is consistent with the usual and  
69 customary standard of care and would be covered if the insured  
70 person were not enrolled in a cancer clinical trial; and (2) coverage for  
71 routine patient care costs incurred for drugs and devices provided to  
72 the insured person, in accordance with section 38a-518b of the general  
73 statutes, provided such drugs or devices have been approved for sale  
74 by the federal Food and Drug Administration.

75       (b) Routine patient care costs shall be subject to the terms,  
76 conditions, restrictions, exclusions and limitations of the contract  
77 between the subscriber and the insurer or health plan, including  
78 limitations on out-of-network care. The insurer or health care center

79 may require that any routine tests or services required under the  
80 cancer clinical trial protocol be performed by providers or institutions  
81 under contract with the insurer or health care center.

82 (c) Notwithstanding the provisions of subsection (a) of this section,  
83 routine patient care costs shall not include: (1) The cost of an  
84 investigational new drug or device that has not been approved for  
85 market for any indication by the federal Food and Drug  
86 Administration; (2) the cost of a nonhealth care service that an insured  
87 person may be required to receive as a result of the treatment being  
88 provided for the purposes of the cancer clinical trial; (3) facility,  
89 ancillary, professional services and drug costs that are paid for by  
90 grants or funding for the cancer clinical trial; (4) costs of services that  
91 (A) are inconsistent with widely accepted and established regional or  
92 national standards of care for a particular diagnosis, or (B) are  
93 performed specifically to meet the requirements of the cancer clinical  
94 trial; (5) costs that would not be covered under the insured person's  
95 policy for noninvestigational treatments, including, but not limited to,  
96 items excluded from coverage under the insured person's contract  
97 with the insurer or health plan; and (6) transportation, lodging, food or  
98 any other expenses associated with travel to or from a facility  
99 providing the cancer clinical trial, for the insured person or any family  
100 member or companion.

101 Sec. 5. (NEW) (a) Providers, hospitals and institutions that provide  
102 routine patient care services as set forth in subsection (a) of section 4 of  
103 this act as part of a cancer clinical trial that meets the requirements of  
104 sections 1 to 7, inclusive, of this act and is approved for coverage by  
105 the insurer or health care center shall not bill the insurer or health care  
106 center or the insured person for any facility, ancillary or professional  
107 services or costs that are not routine patient care services as set forth in  
108 subsection (a) of section 4 of this act or for any product or service that  
109 is paid by the entity sponsoring or funding the cancer clinical trial.

110 (b) Providers, hospitals, institutions and insured persons may  
111 appeal a health plan's denials of payment for services only to the  
112 extent permitted by the contract between the insurer or health care  
113 center and the provider, hospital or institution.

114 (c) Providers, hospitals or institutions that have contracts with the  
115 insurer or health care center to render covered routine patient care  
116 services to insured persons as part of a cancer clinical trial may not bill  
117 the insured person for the cost of any covered routine patient care  
118 service.

119 (d) Providers, hospitals or institutions that do not have a contract  
120 with the insurer or health care center to render covered routine patient  
121 care services to insured persons as part of a cancer clinical trial may  
122 not bill the insured person for the cost of any covered routine patient  
123 care service.

124 (e) Nothing in this section shall be construed to prohibit a provider,  
125 hospital or institution from collecting a deductible or copayment as set  
126 forth in the insured person's contract for any covered routine patient  
127 care service.

128 (f) Pursuant to subsection (b) of section 4 of this act, insurers or  
129 health care centers shall be required to pay providers, hospitals and  
130 institutions that do not have a contract with the insurer or health care  
131 center to render covered routine patient care services to insured  
132 persons the lesser of (1) the lowest contracted per diem, fee schedule  
133 rate or case rate that the insurer or health care center pays to any  
134 participating provider in the state of Connecticut for similar in-  
135 network services, or (2) the billed charges. Providers, hospitals or  
136 institutions may not collect any amount more than the total amount  
137 paid by the insurer or health care center and the insured person in the  
138 form of a deductible or copayment set forth in the insured person's  
139 contract. Such amount shall be deemed by the provider, hospital or  
140 institution to be payment in full.

141       Sec. 6. (NEW) (a) For purposes of cancer clinical trials, the Insurance  
142 Department, in cooperation with the Connecticut Oncology  
143 Association, the American Cancer Society, the Connecticut Association  
144 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a  
145 standardized form that all providers, hospitals and institutions shall  
146 submit to the insurer or health care center when seeking to enroll an  
147 insured person in a cancer clinical trial. An insurer or health care  
148 center may not substitute any other approval request form for the form  
149 developed by the department, except that any insurer or health care  
150 center that has entered into an agreement approved pursuant to  
151 section 7 of this act may use the form or process established by such  
152 agreement.

153       (b) Any insurer or health care center that receives the department  
154 form from a provider, hospital or institution seeking coverage for the  
155 routine patient care costs of an insured person in a cancer clinical trial  
156 shall approve or deny coverage for such services within five business  
157 days of receiving such request and any other reasonable supporting  
158 materials requested by the insurer or health plan pursuant to section 3  
159 of this act, except that an insurer or health care center that utilizes  
160 independent experts to review such requests shall respond within ten  
161 business days. Requests for coverage of phase III clinical trials for the  
162 prevention of cancer pursuant to section 1 of this act shall be approved  
163 or denied within fourteen business days.

164       (c) Providers may appeal any denial of coverage for medical  
165 necessity to an external, independent review pursuant to section 38a-  
166 478n of the general statutes. Such external review shall be conducted  
167 by a properly qualified review agent whom the department has  
168 determined does not have a conflict of interest regarding the cancer  
169 clinical trial.

170       (d) The Insurance Commissioner may adopt regulations, in  
171 accordance with chapter 54 of the general statutes, to implement the

172 provisions of this section.

173       Sec. 7. (NEW) (a) Any insurer or health care center with coverage  
174 policies for care in cancer clinical trials shall submit such policies to the  
175 Insurance Department for evaluation and approval. The department  
176 shall certify whether the insurer's or health care center's coverage  
177 policy for routine patient care costs associated with cancer clinical  
178 trials is substantially equivalent to the requirements of sections 1 to 7,  
179 inclusive, of this act. If the department finds that such coverage is  
180 substantially equivalent to the requirements of sections 1 to 7,  
181 inclusive, of this act, the insurer or health care center shall be exempt  
182 from the provisions of sections 1 to 7, inclusive, of this act.

183       (b) Any such insurer or health care center shall report annually, in  
184 writing, to the department that there have been no changes in the  
185 policy as certified by the department. If there has been any change in  
186 the policy, the insurer or health care center shall resubmit its policy for  
187 certification by the department.

188       (c) Any insurer or health care center coverage policy found by the  
189 department not to be substantially equivalent to the requirements of  
190 sections 1 to 7, inclusive, of this act shall abide by the requirements of  
191 sections 1 to 7, inclusive, of this act until the insurer or health care  
192 center has received such certification by the department.

**PH**           *JOINT FAVORABLE SUBST.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

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**OFA Fiscal Note**

**State Impact:** Future Indeterminate Cost

**Affected Agencies:** Department of Insurance, Office of the State Comptroller

**Municipal Impact:** Potential Cost

**Explanation**

**State Impact:**

The bill requires certain group health insurance policies to cover routine patient care costs associated with cancer clinical trials. The bill applies to group medical plans offered by HMOs and group health insurance policies delivered, issued or renewed in Connecticut after December 31, 2001 that offer coverage for expenses that include basic hospital, basic medical-surgical, major-medical; and hospital and medical.

Routine patient care costs as defined in Sec. 4 of the bill are already covered by the state's employees and retirees health plans and would not result in any fiscal impact to the state as an employer. However, Sec 5(f) appears to require coverage for out of network services that may not be currently covered under the states' plans. This would result in future costs to the state that cannot be determined at this time.

The bill requires the Insurance commissioner to develop a

standardized form that all providers, hospitals and institutions shall submit to an insurer or health care center when seeking to enroll an insured person in a cancer clinical trial. There will be a workload increase for the Department of Insurance that can be handled within anticipated budgetary resources.

The bill also requires an insurer and health care center with coverage policies for care in cancer clinical trials to submit such policies to the Department of Insurance for review and approval. There will be an increase in workload for the Department of Insurance that can be handled within the anticipated resources of the department.

The Department of Insurance may also receive an increase in external appeals that can be handled within normal budgetary resources.

***Municipal Impact:***

To the extent that municipalities do not provide coverage for care in cancer clinical trials, there may be increased costs to provide it. The bill's impact on municipalities depends on how many municipalities provide this coverage and that cannot be determined at this time.

**OLR Bill Analysis**

sSB 325

***AN ACT CONCERNING HEALTH INSURANCE COVERAGE DURING CLINICAL TRIALS.*****SUMMARY:**

This bill requires certain group health insurance policies to cover routine patient care costs associated with cancer clinical trials. It applies to trials for treatment or palliation and to Phase III trials for prevention that involve therapeutic intervention. It requires coverage for medically necessary services incurred because of the trial such as physicians, testing, hospitalization, and drugs and medical devices for which the patient would be covered if he or she were not participating in the trial. It excludes costs not normally covered by the patient's policy, non-healthcare costs, costs paid by the trial sponsors, and other costs.

The bill establishes an application process, conditions for trial and patient eligibility, and terms for payment and appeal. It exempts insurers and HMOs from its provisions if the Insurance Department determines that their policies are substantially equivalent to its requirements.

The bill applies to group medical service plans offered by HMOs and group health insurance policies delivered, issued, or renewed in Connecticut after December 31, 2001 that offer coverage for the following expenses: (1) basic hospital, (2) basic medical-surgical, (3) major medical, and (4) hospital or medical.

EFFECTIVE DATE: October 1, 2001

**TRIAL ELIGIBILITY**

The bill applies to trials conducted under an independent, peer-review protocol approved by (1) one of the National Institutes of Health, (2) a

National Cancer Institute affiliated cooperative group, (3) the Food and Drug Administration (FDA) as part of an investigational new drug or device exemption, or (4) the U.S. Defense or Veterans' departments. It does not require coverage for a trial a single institution conducts solely under the approval of an institutional review board. A cancer prevention trial must be a Phase III trial, involve therapeutic intervention, and be conducted at several institutions.

## **PATIENT ELIGIBILITY**

***Determining Eligibility.*** To determine a person's eligibility for coverage, the bill allows the insurer, HMO, or third party plan administrator to ask the person or the entity seeking coverage for:

1. satisfactory evidence that the person meets all patient selection criteria for the trial;
2. clinical or pre-clinical data that show credibly that the person's likely benefit from the trial corresponds to the risks of participating;
3. evidence that the person has given appropriate informed consent;
4. copies of medical records, test results, protocols, or other clinical information the doctor or institution seeking to enroll the person used;
5. a summary of anticipated routine patient care costs above the costs of standard treatment;
6. information from the doctor or institution concerning items, including routine patient care costs, that could be reimbursed by someone else, including the entity sponsoring the trial; and
7. any other information they may reasonably require to review the request for coverage.

The HMO or insurer (but not the plan administrator) must ask for this additional information within five business days of receiving a request for coverage from a person or doctor (but not an institution) seeking to enroll the person.

The bill specifies that it does not require an insurer or HMO to cover routine costs that can be reimbursed by a party other than the insurer (but not other than the HMO), including the trial's sponsor.

**Applying for Coverage.** The bill requires the Insurance Department to develop a standardized form that all providers, hospitals, and institutions must submit to an insurer or HMO when they want to enroll a person in a cancer clinical trial. The department must cooperate with the Connecticut Oncology Association, the American Cancer Society, the Connecticut Association of Health Plans, and Anthem Blue Cross of Connecticut, Inc. in developing the form.

An insurer or HMOs cannot use any other form except, apparently, if the insurance commissioner finds its policies provide coverage substantially equivalent to the bill's requirements (see COMMENT).

The bill gives an insurer or HMO five business days to approve or deny coverage from the time it receives the department-developed form and supporting eligibility information it asks for. If it uses independent experts to review requests for clinical trial cost coverage, it has 10 business days. Requests for coverage for Phase III prevention trials must be decided within 14 business days.

Providers can appeal to the insurance commissioner using existing statutory mechanism when an insurer or HMO denies coverage on grounds of medical necessity. This mechanism requires the commissioner to assign the appeal to an independent entity. The bill requires her to insure this entity does not have a conflict of interest regarding the clinical trial.

The bill allows the commissioner to adopt regulations implementing its requirements for forms, timelines for reviewing applications, and appeals of coverage denials.

### **COVERED COSTS**

The bill defines "routine patient care costs" as coverage (1) for medically necessary services resulting from the treatment provided in the trial that would be covered even if they were not provided in a trial

and (2) as “routine patient care costs” incurred in providing FDA-approved “off-label use” drugs and devices (see COMMENT). Medically necessary services include physicians’ services, diagnostic and lab tests, hospitalization, or other services provided during the trials for a condition or a complication related to the condition, that are consistent with the usual and customary standard of care and would be covered if the person were not in the trial. An “off-label use” drug is one the FDA has approved to treat a cancer other than the type for which it is being prescribed. It must be recognized by one of several national groups for treatment of the specific cancer for which it is being prescribed.

The bill specifically excludes the following from routine care costs:

1. investigational drugs and devices the FDA has not approved for any use;
2. non-healthcare services participant may need because of the trial;
3. facility, ancillary, and professional services and drugs for which the clinical trial receives funding;
4. services that are inconsistent with widely accepted and established national or regional standards of care for a particular diagnosis or that are performed specifically to meet the trial’s requirements;
5. costs that would not be covered by the trial participant’s insurance policy for noninvestigational treatment, including items excluded under the policy; and
6. transportation, lodging, food, and other expenses connected with the participant or the participant’s family traveling to and from a trial facility.

The bill subjects eligible routine care costs to the terms, conditions, restrictions, exclusions, and limitations (including limitations on out-of-network care) of the insured's health care contract. It permits the insurer or HMO to require that network providers and institutions perform routine tests or services conducted under the trial protocol.

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**PROVIDER BILLING AND PAYMENT**

Under the bill, providers, hospitals, and institutions that provide services as part of a clinical trial approved for coverage may not bill the insurer, HMO, or patient for any facility, ancillary, or professional services or costs that are not routine patient care costs or for any other service or product paid for by the trial sponsor. They cannot bill the insured person for any routine patient care service whether or not they are part of the insurer's or HMO's network. But the bill does not prohibit them from charging a deductible or copayment if that is part of the insured's policy.

The bill requires an insurer or HMO that covers out-of-network care to pay these providers, hospitals, and institutions the lesser of (1) the lowest contracted daily, fee schedule, or case rate it pays its Connecticut network providers for similar services or (2) the billed charges. (This requirement appears to supersede the bill's provision that routine patient care costs are subject to contract limitations on out-of-network care). These providers cannot collect more than the total paid by these payers and the insured through his deductible and copayment. They must deem this amount to be payment in full.

Providers, hospitals, and institutions can appeal a "health plan's" denial of payment for services only to the extent permitted by the insurer's or HMO's contract with them. (The meaning of health plan in this context is unclear.)

**EXEMPTION FOR COVERAGE EQUIVALENCY**

An insurer or HMO that covers care in cancer clinical trials are exempt from the bill's requirements if the Insurance Department certifies that its routine patient care cost coverage is substantially equivalent to those requirements. If it is exempted, it must submit annual written reports to the department that it has not changed a certified policy. If it changes a policy, it must resubmit it for recertification.

If the department finds a policy not to be substantially equivalent, the insurer or HMO must follow the bill's requirements until the department certifies the policy.

## **BACKGROUND**

### ***Clinical Trials***

The National Cancer Institute identifies four types of clinical trials and three phases. Treatment trials test new drugs, approaches to surgery, methods (like gene therapy), and combinations of these. Prevention trials test new approaches to prevent cancer in the first place or its reoccurrence. Quality of life or supportive care trials (probably what the bill refers to as palliation trials) explore ways to improve comfort and quality of life for cancer patients. Screening trials test ways to find cancer, especially in its early stages.

Phase I trials are small and evaluate how a new drug should be given (e.g., orally or by injection). Phase II trials test a new drug's safety and begin to evaluate how well it works. Phase III trials compare a new drug or surgical procedure to the current standard of treatment. They usually enroll large numbers of people who are assigned randomly to treatment and control groups.

## **COMMENT**

### ***Use of Substitute Enrollment Form***

The bill allows an insurer or HMO that enters "into an agreement approved pursuant to section 7" to use an enrollment form other than the one the insurance commissioner develops. Section 7 calls for the insurance commissioner to certify that an insurer's or HMO's policy is substantially equivalent to the bill's requirements. It does not speak to an agreement.

### ***Definition of Routine Patient Care Costs***

The bill defines this term in two ways, one of which is unclear. The first definition is as medically necessary services resulting from the clinical trial. The second is tied to drug and device prescription but, because it uses the term "routine patient care cost" as part of the definition, it is not clear whether the costs are for the drugs and devices themselves or the medically necessary services incurred in providing them.

**COMMITTEE ACTION**

Public Health Committee

Joint Favorable Substitute

Yea 24 Nay 0