



General Assembly

Amendment

January Session, 2001

LCO No. **6127**

Offered by:
SEN. HARP, 10th Dist.

To: Subst. Senate Bill No. **325**

File No. 153

Cal. No. 175

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

-
- 1 In line 27, after "institution" and before the period insert ", or any
2 trial that is no longer approved by an entity identified in subdivision
3 (1), (2), (3) or (4) of this section"
- 4 In line 71, strike out "and devices"
- 5 In line 73, strike out "or devices"
- 6 In line 76, after "contract" insert "or certificate of insurance"
- 7 In line 150, after "agreement" insert "to provide coverage for cancer
8 clinical trials"
- 9 In line 164, strike out "Providers" and insert "The insured, or the
10 provider with the insured's written consent," in lieu thereof
- 11 In line 170, strike out "may" and insert "shall" in lieu thereof

12 After line 192, insert the following:

13 "Sec. 8. (NEW) Each individual health insurance policy providing
14 coverage of the type specified in subdivisions (1), (2), (4), (11) and (12)
15 of section 38a-469 of the general statutes delivered, issued for delivery
16 or renewed in this state on or after January 1, 2002, shall provide
17 coverage for the routine patient care costs, as defined in section 11 of
18 this act, associated with cancer clinical trials, in accordance with
19 sections 9 to 14, inclusive, of this act. As used in this section and
20 sections 9 to 14, inclusive, of this act, "cancer clinical trial" means an
21 organized, systematic, scientific study of therapies, tests or other
22 clinical interventions for purposes of treatment or palliation or
23 therapeutic intervention for the prevention of cancer in human beings,
24 except that a clinical trial for the prevention of cancer is eligible for
25 coverage only if it involves a therapeutic intervention and is a phase III
26 clinical trial approved by one of the entities identified in section 9 of
27 this act and is conducted at multiple institutions.

28 Sec. 9. (NEW) In order to be eligible for coverage of routine patient
29 care costs, as defined in section 11 of this act, a cancer clinical trial shall
30 be conducted under the auspices of an independent peer-reviewed
31 protocol that has been reviewed and approved by: (1) One of the
32 National Institutes of Health; or (2) a National Cancer Institute
33 affiliated cooperative group; or (3) the federal Food and Drug
34 Administration as part of an investigational new drug or device
35 exemption; or (4) the federal Department of Defense or Veterans
36 Affairs. Nothing in sections 8 to 14, inclusive, of this act shall be
37 construed to require coverage for any single institution cancer clinical
38 trial conducted solely under the approval of the institutional review
39 board of an institution, or any trial that is no longer approved by an
40 entity identified in subdivision (1), (2), (3) or (4) of this section.

41 Sec. 10. (NEW) In order to be eligible for coverage of routine patient
42 care costs, as defined in section 11 of this act, the insurer, health care
43 center or plan administrator may require that the person or entity
44 seeking coverage for the cancer clinical trial provide: (1) Evidence

45 satisfactory to the insurer, health care center or plan administrator that
46 the insured person receiving coverage meets all of the patient selection
47 criteria for the cancer clinical trial, including credible evidence in the
48 form of clinical or pre-clinical data showing that the cancer clinical trial
49 is likely to have a benefit for the insured person that is commensurate
50 with the risks of participation in the cancer clinical trial to treat the
51 person's condition; and (2) evidence that the appropriate informed
52 consent has been received from the insured person; and (3) copies of
53 any medical records, protocols, test results or other clinical information
54 used by the physician or institution seeking to enroll the insured
55 person in the cancer clinical trial; and (4) a summary of the anticipated
56 routine patient care costs in excess of the costs for standard treatment;
57 and (5) information from the physician or institution seeking to enroll
58 the insured person in the clinical trial regarding those items, including
59 any routine patient care costs, that are eligible for reimbursement by
60 an entity other than the insurer or health care center, including the
61 entity sponsoring the clinical trial; and (6) any additional information
62 that may be reasonably required for the review of a request for
63 coverage of the cancer clinical trial. The health plan or insurer shall
64 request any additional information about a cancer clinical trial within
65 five business days of receiving a request for coverage from an insured
66 person or a physician seeking to enroll an insured person in a cancer
67 clinical trial. Nothing in sections 8 to 14, inclusive, of this act shall be
68 construed to require the insurer or health care center to provide
69 coverage for routine patient care costs that are eligible for
70 reimbursement by an entity other than the insurer, including the entity
71 sponsoring the cancer clinical trial.

72 Sec. 11. (NEW) (a) For purposes of sections 8 to 14, inclusive, of this
73 act, "routine patient care costs" means: (1) Coverage for medically
74 necessary health care services that are incurred as a result of the
75 treatment being provided to the insured person for purposes of the
76 cancer clinical trial that would otherwise be covered if such services
77 were not rendered pursuant to a cancer clinical trial. Such services
78 shall include those rendered by a physician, diagnostic or laboratory

79 tests, hospitalization or other services provided to the patient during
80 the course of treatment in the cancer clinical trial for a condition, or
81 one of its complications, that is consistent with the usual and
82 customary standard of care and would be covered if the insured
83 person were not enrolled in a cancer clinical trial; and (2) coverage for
84 routine patient care costs incurred for drugs provided to the insured
85 person, in accordance with section 38a-518b of the general statutes,
86 provided such drugs have been approved for sale by the federal Food
87 and Drug Administration.

88 (b) Routine patient care costs shall be subject to the terms,
89 conditions, restrictions, exclusions and limitations of the contract or
90 certificate of insurance between the subscriber and the insurer or
91 health plan, including limitations on out-of-network care. The insurer
92 or health care center may require that any routine tests or services
93 required under the cancer clinical trial protocol be performed by
94 providers or institutions under contract with the insurer or health care
95 center.

96 (c) Notwithstanding the provisions of subsection (a) of this section,
97 routine patient care costs shall not include: (1) The cost of an
98 investigational new drug or device that has not been approved for
99 market for any indication by the federal Food and Drug
100 Administration; (2) the cost of a nonhealth care service that an insured
101 person may be required to receive as a result of the treatment being
102 provided for the purposes of the cancer clinical trial; (3) facility,
103 ancillary, professional services and drug costs that are paid for by
104 grants or funding for the cancer clinical trial; (4) costs of services that
105 (A) are inconsistent with widely accepted and established regional or
106 national standards of care for a particular diagnosis, or (B) are
107 performed specifically to meet the requirements of the cancer clinical
108 trial; (5) costs that would not be covered under the insured person's
109 policy for noninvestigational treatments, including, but not limited to,
110 items excluded from coverage under the insured person's contract
111 with the insurer or health plan; and (6) transportation, lodging, food or
112 any other expenses associated with travel to or from a facility

113 providing the cancer clinical trial, for the insured person or any family
114 member or companion.

115 Sec. 12. (NEW) (a) Providers, hospitals and institutions that provide
116 routine patient care services as set forth in subsection (a) of section 11
117 of this act as part of a cancer clinical trial that meets the requirements
118 of sections 8 to 14, inclusive, of this act and is approved for coverage
119 by the insurer or health care center shall not bill the insurer or health
120 care center or the insured person for any facility, ancillary or
121 professional services or costs that are not routine patient care services
122 as set forth in subsection (a) of section 11 of this act or for any product
123 or service that is paid by the entity sponsoring or funding the cancer
124 clinical trial.

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

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

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

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

143 (f) Pursuant to subsection (b) of section 11 of this act, insurers or

144 health care centers shall be required to pay providers, hospitals and
145 institutions that do not have a contract with the insurer or health care
146 center to render covered routine patient care services to insured
147 persons the lesser of (1) the lowest contracted per diem, fee schedule
148 rate or case rate that the insurer or health care center pays to any
149 participating provider in the state of Connecticut for similar in-
150 network services, or (2) the billed charges. Providers, hospitals or
151 institutions may not collect any amount more than the total amount
152 paid by the insurer or health care center and the insured person in the
153 form of a deductible or copayment set forth in the insured person's
154 contract. Such amount shall be deemed by the provider, hospital or
155 institution to be payment in full.

156 Sec. 13. (NEW) (a) For purposes of cancer clinical trials, the
157 Insurance Department, in cooperation with the Connecticut Oncology
158 Association, the American Cancer Society, the Connecticut Association
159 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a
160 standardized form that all providers, hospitals and institutions shall
161 submit to the insurer or health care center when seeking to enroll an
162 insured person in a cancer clinical trial. An insurer or health care
163 center may not substitute any other approval request form for the form
164 developed by the department, except that any insurer or health care
165 center that has entered into an agreement to provide coverage for
166 cancer clinical trials approved pursuant to section 14 of this act may
167 use the form or process established by such agreement.

168 (b) Any insurer or health care center that receives the department
169 form from a provider, hospital or institution seeking coverage for the
170 routine patient care costs of an insured person in a cancer clinical trial
171 shall approve or deny coverage for such services within five business
172 days of receiving such request and any other reasonable supporting
173 materials requested by the insurer or health plan pursuant to section
174 10 of this act, except that an insurer or health care center that utilizes
175 independent experts to review such requests shall respond within ten
176 business days. Requests for coverage of phase III clinical trials for the
177 prevention of cancer pursuant to section 8 of this act shall be approved

178 or denied within fourteen business days.

179 (c) The insured, or the provider with the insured's written consent,
180 may appeal any denial of coverage for medical necessity to an external,
181 independent review pursuant to section 38a-478n of the general
182 statutes. Such external review shall be conducted by a properly
183 qualified review agent whom the department has determined does not
184 have a conflict of interest regarding the cancer clinical trial.

185 (d) The Insurance Commissioner shall adopt regulations, in
186 accordance with chapter 54 of the general statutes, to implement the
187 provisions of this section.

188 Sec. 14. (NEW) (a) Any insurer or health care center with coverage
189 policies for care in cancer clinical trials shall submit such policies to the
190 Insurance Department for evaluation and approval. The department
191 shall certify whether the insurer's or health care center's coverage
192 policy for routine patient care costs associated with cancer clinical
193 trials is substantially equivalent to the requirements of sections 8 to 14,
194 inclusive, of this act. If the department finds that such coverage is
195 substantially equivalent to the requirements of sections 8 to 14,
196 inclusive, of this act, the insurer or health care center shall be exempt
197 from the provisions of sections 8 to 14, inclusive, of this act.

198 (b) Any such insurer or health care center shall report annually, in
199 writing, to the department that there have been no changes in the
200 policy as certified by the department. If there has been any change in
201 the policy, the insurer or health care center shall resubmit its policy for
202 certification by the department.

203 (c) Any insurer or health care center coverage policy found by the
204 department not to be substantially equivalent to the requirements of
205 sections 8 to 14, inclusive, of this act shall abide by the requirements of
206 sections 8 to 14, inclusive, of this act until the insurer or health care
207 center has received such certification by the department."