



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.*

INS *JOINT FAVORABLE*