



General Assembly

January Session, 2001

**Committee Bill No. 325**

LCO No. 3961

Referred to Committee on Public Health

Introduced by:  
(PH)

**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) (a) As used in this section, unless the context  
2 otherwise requires:

3 (1) "Cancer clinical trial" means an organized, systematic and  
4 scientific study of therapies, tests or other clinical interventions, for the  
5 purpose of treatment, palliation or therapeutic intervention for the  
6 prevention of cancer in human beings, that seeks to answer a credible  
7 and specific medical or scientific question that has the potential to  
8 advance cancer care;

9 (2) "Insurer" means each insurer, health care center, hospital and  
10 medical service corporation, or other entity delivering, issuing for  
11 delivery, renewing or amending any individual health insurance  
12 policy in this state on or after October 1, 2001, providing coverage of  
13 the type specified in subdivisions (1), (2), (4), (11) and (12) of section  
14 38a-469 of the general statutes; and

15 (3) "Routine patient care services" means medically necessary health  
16 care services that are provided in the course of treatment in a cancer  
17 clinical trial. (A) For purposes of this subdivision, "routine patient care  
18 services" includes (i) any physician service, diagnostic or laboratory  
19 test, hospitalization or other service provided in the course of  
20 treatment in such cancer clinical trial for a condition, or a complication  
21 of such condition, that is consistent with the usual and customary  
22 standard of care and would be covered if the insured were not enrolled  
23 in a cancer clinical trial, (ii) drugs and devices provided to the insured  
24 during the cancer clinical trial, provided such drugs or devices have  
25 been approved for sale by the federal Food and Drug Administration,  
26 whether or not the federal Food and Drug Administration has  
27 approved such drug or device for use in treating the insured's  
28 particular condition, and to the extent such drugs or devices are not  
29 paid for by the entity sponsoring or funding such cancer clinical trial  
30 or the manufacturer, distributor or provider of such drug or device,  
31 and (iii) reasonable and medically necessary services required to  
32 administer any such drug or use any such device under evaluation in  
33 the cancer clinical trial. (B) For purposes of this subdivision, "routine  
34 patient care services" does not include (i) an investigational new drug  
35 that has not been approved for market for any indication by the federal  
36 Food and Drug Administration, (ii) a nonhealth care service that an  
37 insured may be required to receive as a result of the course of  
38 treatment in the cancer clinical trial, (iii) facility, ancillary or  
39 professional services or drugs or devices that are paid for by a grant or  
40 other funding source for the cancer clinical trial, (iv) services that are  
41 inconsistent with widely accepted and established regional or national  
42 standards of care for a particular diagnosis or are performed  
43 specifically to meet the requirements of the cancer clinical trial, (v)  
44 services associated with managing the research for the cancer clinical  
45 trial, (vi) services that would not be covered under the policy for  
46 noninvestigational treatments, and (vii) transportation, lodging, food  
47 or any other expenses associated with travel to or from a facility  
48 providing the cancer clinical trial.

49 (b) Each individual health insurance policy providing coverage of  
50 the type specified in subdivisions (1), (2), (4), (11) and (12) of section  
51 38a-469 of the general statutes delivered, issued for delivery, amended,  
52 renewed or continued in this state on or after October 1, 2001, shall  
53 provide coverage for routine patient care services in a cancer clinical  
54 trial in accordance with the provisions of this section.

55 (c) In order to be eligible for coverage pursuant to subsection (b) of  
56 this section, a cancer clinical trial shall be conducted under the  
57 auspices of an independent peer-reviewed protocol that has been  
58 approved by at least one of the following entities: (1) One of the  
59 National Institutes of Health; (2) a cooperative group affiliated with  
60 the National Cancer Institute; (3) the federal Food and Drug  
61 Administration as part of an investigational new drug or device  
62 exemption; (4) the federal Department of Veterans Affairs; or (5) the  
63 federal Department of Defense. A cancer clinical trial for the  
64 prevention of cancer shall be eligible for coverage pursuant to  
65 subsection (b) of this section only if such cancer clinical trial involves a  
66 therapeutic intervention and is a phase III clinical trial of the federal  
67 Food and Drug Administration that is approved by an entity set forth  
68 in subdivisions (1) to (5), inclusive, of this subsection and is conducted  
69 at multiple institutions. Nothing in this section shall be construed to  
70 require coverage for any single institution cancer clinical trial  
71 conducted solely under the approval of the institutional review board  
72 of such institution.

73 (d) Before providing coverage pursuant to subsection (b) of this  
74 section, the following shall be provided to the insurer at the insurer's  
75 request: (1) Evidence satisfactory to the insurer that the insured meets  
76 all patient selection criteria for the cancer clinical trial, including  
77 credible evidence in the form of clinical or pre-clinical data showing  
78 that the proposed cancer clinical trial is likely to benefit the insured in  
79 the treatment of the insured's condition; (2) evidence that the  
80 appropriate informed consent has been received from the insured; (3)  
81 medical records, test results, protocols and other relevant information

82 from the physician or institution seeking to enroll the insured in the  
83 cancer clinical trial; (4) a summary of the anticipated costs for services  
84 in excess of costs for standard treatment; and (5) information from the  
85 institution conducting the cancer clinical trial regarding components of  
86 such cancer clinical trial that are eligible for reimbursement by any  
87 other entity, including the entity sponsoring such cancer clinical trial.

88 (e) (1) No provider that renders routine patient care services as part  
89 of a cancer clinical trial covered pursuant to subsection (b) of this  
90 section may charge the insurer or the insured for any facility, ancillary  
91 or professional services or other cost that is not a routine patient care  
92 service or for any product or service that is paid by the entity  
93 sponsoring or funding the cancer clinical trial. Such provider may  
94 charge and collect any copayment or deductible for which the insured  
95 may be obligated to pay under the policy.

96 (2) No provider that, pursuant to any contract entered into with the  
97 insurer, renders routine patient care services or administrative services  
98 as part of a cancer clinical trial covered pursuant to subsection (b) of  
99 this section may charge the insured for the cost of any such routine  
100 patient care services or administrative services. Such provider may  
101 appeal the denial of reimbursement by the insurer only to the extent  
102 allowed under such contract.

103 (3) A provider that renders routine patient care services as part of a  
104 cancer clinical trial covered pursuant to subsection (b) of this section  
105 and is not a party to a contract with the insurer shall not charge the  
106 insured for the cost of any such routine patient care services. The  
107 insurer shall pay any such provider for such routine patient care  
108 services the lesser of (1) the lowest contracted per diem or fee schedule  
109 rate that the insurer pays to a provider for similar routine patient care  
110 services pursuant to a contract between such provider and the insurer,  
111 or (2) the amount charged for such routine patient care services. No  
112 such provider may charge any amount for such routine patient care  
113 services that is greater than the total amount paid by the insurer for

114 such routine patient care services plus any amount paid by the insured  
115 as a copayment or deductible pursuant to the policy. Such amount  
116 shall be deemed payment in full for such routine patient care services.

117 (f) Routine patient care services in a cancer clinical trial for which  
118 coverage is provided pursuant to subsection (b) of this section shall be  
119 subject to the terms, conditions, restrictions, exclusions and limitations  
120 set forth in the policy. The insurer may require that the cancer clinical  
121 trial protocol, including tests or services required under such protocol,  
122 be performed in accordance with the policy and any contract between  
123 the insurer and the provider.

124 (g) The Insurance Commissioner, in cooperation with one or more  
125 organizations or associations promoting cancer research or  
126 representing health care providers in this state, and one or more  
127 organizations or associations representing insurers or health care  
128 centers in this state, shall develop a standard form that all providers  
129 rendering routine patient care services in a cancer clinical trial shall  
130 submit to insurers in this state when seeking approval for care in a  
131 cancer clinical trial. On and after the date that the commissioner  
132 develops such form, no other approval request form may be  
133 substituted for such submission. Any insurer receiving a request from  
134 a provider on such form shall approve or deny coverage for such  
135 routine patient care services within three business days of receiving  
136 such form, together with any other reasonable supporting materials  
137 requested by the insurer.

138 Sec. 2. (NEW) (a) As used in this section, unless the context  
139 otherwise requires:

140 (1) "Cancer clinical trial" means an organized, systematic and  
141 scientific study of therapies, tests or other clinical interventions, for the  
142 purpose of treatment, palliation or therapeutic intervention for the  
143 prevention of cancer in human beings, that seeks to answer a credible  
144 and specific medical or scientific question that has the potential to  
145 advance cancer care;

146 (2) "Insurer" means each insurer, health care center, hospital and  
147 medical service corporation, or other entity delivering, issuing for  
148 delivery, renewing or amending any group health insurance policy in  
149 this state on or after October 1, 2001, providing coverage of the type  
150 specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of  
151 the general statutes; and

152 (3) "Routine patient care services" means medically necessary health  
153 care services that are provided in the course of treatment in a cancer  
154 clinical trial. (A) For purposes of this subdivision, "routine patient care  
155 services" includes (i) any physician service, diagnostic or laboratory  
156 test, hospitalization or other service provided in the course of  
157 treatment in such cancer clinical trial for a condition, or a complication  
158 of such condition, that is consistent with the usual and customary  
159 standard of care and would be covered if the insured were not enrolled  
160 in a cancer clinical trial, (ii) drugs and devices provided to the insured  
161 during the cancer clinical trial, provided such drugs or devices have  
162 been approved for sale by the federal Food and Drug Administration,  
163 whether or not the federal Food and Drug Administration has  
164 approved such drug or device for use in treating the insured's  
165 particular condition, and to the extent such drugs or devices are not  
166 paid for by the entity sponsoring or funding such cancer clinical trial  
167 or the manufacturer, distributor or provider of such drug or device,  
168 and (iii) reasonable and medically necessary services required to  
169 administer any such drug or use any such device under evaluation in  
170 the cancer clinical trial. (B) For purposes of this subdivision, "routine  
171 patient care services" does not include (i) an investigational new drug  
172 that has not been approved for market for any indication by the federal  
173 Food and Drug Administration, (ii) a nonhealth care service that an  
174 insured may be required to receive as a result of the course of  
175 treatment in the cancer clinical trial, (iii) facility, ancillary or  
176 professional services or drugs or devices that are paid for by a grant or  
177 other funding source for the cancer clinical trial, (iv) services that are  
178 inconsistent with widely accepted and established regional or national  
179 standards of care for a particular diagnosis or are performed

180 specifically to meet the requirements of the cancer clinical trial, (v)  
181 services associated with managing the research for the cancer clinical  
182 trial, (vi) services that would not be covered under the policy for  
183 noninvestigational treatments, and (vii) transportation, lodging, food  
184 or any other expenses associated with travel to or from a facility  
185 providing the cancer clinical trial.

186 (b) Each group health insurance policy providing coverage of the  
187 type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-  
188 469 of the general statutes delivered, issued for delivery, amended,  
189 renewed or continued in this state on or after October 1, 2001, shall  
190 provide coverage for routine patient care services in a cancer clinical  
191 trial in accordance with the provisions of this section.

192 (c) In order to be eligible for coverage pursuant to subsection (b) of  
193 this section, a cancer clinical trial shall be conducted under the  
194 auspices of an independent peer-reviewed protocol that has been  
195 approved by at least one of the following entities: (1) One of the  
196 National Institutes of Health; (2) a cooperative group affiliated with  
197 the National Cancer Institute; (3) the federal Food and Drug  
198 Administration as part of an investigational new drug or device  
199 exemption; (4) the federal Department of Veterans Affairs; or (5) the  
200 federal Department of Defense. A cancer clinical trial for the  
201 prevention of cancer shall be eligible for coverage pursuant to  
202 subsection (b) of this section only if such cancer clinical trial involves a  
203 therapeutic intervention and is a phase III clinical trial of the federal  
204 Food and Drug Administration that is approved by an entity set forth  
205 in subdivisions (1) to (5), inclusive, of this subsection and is conducted  
206 at multiple institutions. Nothing in this section shall be construed to  
207 require coverage for any single institution cancer clinical trial  
208 conducted solely under the approval of the institutional review board  
209 of such institution.

210 (d) Before providing coverage pursuant to subsection (b) of this  
211 section, the following shall be provided to the insurer at the insurer's

212 request: (1) Evidence satisfactory to the insurer that the insured meets  
213 all patient selection criteria for the cancer clinical trial, including  
214 credible evidence in the form of clinical or pre-clinical data showing  
215 that the proposed cancer clinical trial is likely to benefit the insured in  
216 the treatment of the insured's condition; (2) evidence that the  
217 appropriate informed consent has been received from the insured; (3)  
218 medical records, test results, protocols and other relevant information  
219 from the physician or institution seeking to enroll the insured in the  
220 cancer clinical trial; (4) a summary of the anticipated costs for services  
221 in excess of costs for standard treatment; and (5) information from the  
222 institution conducting the cancer clinical trial regarding components of  
223 such cancer clinical trial that are eligible for reimbursement by any  
224 other entity, including the entity sponsoring such cancer clinical trial.

225 (e) (1) No provider that renders routine patient care services as part  
226 of a cancer clinical trial covered pursuant to subsection (b) of this  
227 section may charge the insurer or the insured for any facility, ancillary  
228 or professional services or other cost that is not a routine patient care  
229 service or for any product or service that is paid by the entity  
230 sponsoring or funding the cancer clinical trial. Such provider may  
231 charge and collect any copayment or deductible for which the insured  
232 may be obligated to pay under the policy.

233 (2) No provider that, pursuant to any contract entered into with the  
234 insurer, renders routine patient care services or administrative services  
235 as part of a cancer clinical trial covered pursuant to subsection (b) of  
236 this section may charge the insured for the cost of any such routine  
237 patient care services or administrative services. Such provider may  
238 appeal the denial of reimbursement by the insurer only to the extent  
239 allowed under such contract.

240 (3) A provider that renders routine patient care services as part of a  
241 cancer clinical trial covered pursuant to subsection (b) of this section  
242 and is not a party to a contract with the insurer shall not charge the  
243 insured for the cost of any such routine patient care services. The

244 insurer shall pay any such provider for such routine patient care  
245 services the lesser of (1) the lowest contracted per diem or fee schedule  
246 rate that the insurer pays to a provider for similar routine patient care  
247 services pursuant to a contract between such provider and the insurer,  
248 or (2) the amount charged for such routine patient care services. No  
249 such provider may charge any amount for such routine patient care  
250 services that is greater than the total amount paid by the insurer for  
251 such routine patient care services plus any amount paid by the insured  
252 as a copayment or deductible pursuant to the policy. Such amount  
253 shall be deemed payment in full for such routine patient care services.

254 (f) Routine patient care services in a cancer clinical trial for which  
255 coverage is provided pursuant to subsection (b) of this section shall be  
256 subject to the terms, conditions, restrictions, exclusions and limitations  
257 set forth in the policy. The insurer may require that the cancer clinical  
258 trial protocol, including tests or services required under such protocol,  
259 be performed in accordance with the policy and any contract between  
260 the insurer and the provider.

261 (g) The Insurance Commissioner, in cooperation with one or more  
262 organizations or associations promoting cancer research or  
263 representing health care providers in this state, and one or more  
264 organizations or associations representing insurers or health care  
265 centers in this state, shall develop a standard form that all providers  
266 rendering routine patient care services in a cancer clinical trial shall  
267 submit to insurers in this state when seeking approval for care in a  
268 cancer clinical trial. On and after the date that the commissioner  
269 develops such form, no other approval request form may be  
270 substituted for such submission. Any insurer receiving a request from  
271 a provider on such form shall approve or deny coverage for such  
272 routine patient care services within three business days of receiving  
273 such form, together with any other reasonable supporting materials  
274 requested by the insurer.

275 Sec. 3. Subsection (b) of section 38a-483c of the general statutes is

276 repealed and the following is substituted in lieu thereof:

277 (b) No such health insurance policy may deny a procedure,  
278 treatment or the use of any drug as experimental if such procedure,  
279 treatment or drug, for the illness or condition being treated, or for the  
280 diagnosis for which it is being prescribed [,] (1) has successfully  
281 completed a phase III clinical trial of the federal Food and Drug  
282 Administration, or (2) is provided pursuant to a cancer clinical trial in  
283 accordance with section 1 of this act.

284 Sec. 4. Subsection (b) of section 38a-513b of the general statutes is  
285 repealed and the following is substituted in lieu thereof:

286 (b) No such health insurance policy may deny a procedure,  
287 treatment or the use of any drug as experimental if such procedure,  
288 treatment or drug, for the illness or condition being treated, or for the  
289 diagnosis for which it is being prescribed [,] (1) has successfully  
290 completed a phase III clinical trial of the federal Food and Drug  
291 Administration, or (2) is provided pursuant to a cancer clinical trial in  
292 accordance with section 2 of this act.

**Statement of Purpose:**

To mandate individual and group health insurance coverage for routine health care services during phase I, II and III clinical trials.

*[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]*

Co-Sponsors: SEN. PRAGUE, 19th Dist.; SEN. HARP, 10th Dist.  
SEN. BOZEK, 6th Dist.; SEN. SULLIVAN, 5th Dist.  
REP. FRITZ, 90th Dist.; SEN. PETERS, 20th Dist.  
SEN. HANDLEY, 4th Dist.