



General Assembly

**Substitute Bill No. 21**

January Session, 2011

\* \_\_\_\_\_SB00021APP\_\_050511\_\_\_\_\_\*

**AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR  
ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL  
PATIENTS.**

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

1 Section 1. Section 38a-504a of the general statutes is repealed and  
2 the following is substituted in lieu thereof (*Effective January 1, 2012*):

3 Each individual health insurance policy providing coverage of the  
4 type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-  
5 469 delivered, issued for delivery, [or] renewed, amended or continued  
6 in this state, [on or after January 1, 2002,] shall provide coverage for the  
7 routine patient care costs, as defined in section 38a-504d, as amended  
8 by this act, associated with [cancer] clinical trials, in accordance with  
9 sections 38a-504b to 38a-504g, inclusive, as amended by this act. As  
10 used in this section and sections 38a-504b to 38a-504g, inclusive, as  
11 amended by this act: ["cancer clinical"] (1) "Clinical trial" means an  
12 organized, systematic, scientific study of therapies, tests or other  
13 clinical interventions for purposes of treatment or palliation or  
14 therapeutic intervention for the prevention of [cancer in human beings,  
15 except that a clinical trial for the prevention of cancer is eligible for  
16 coverage only if it involves a therapeutic intervention and is a phase III  
17 clinical trial approved by one of the entities identified in section 38a-  
18 504b and is conducted at multiple institutions] disabling, progressive  
19 or life-threatening medical conditions in human beings, and (2)

20 "disabling, progressive or life threatening medical conditions" means  
21 cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral  
22 sclerosis, acquired immunodeficiency syndrome or muscular  
23 dystrophy.

24 Sec. 2. Section 38a-504b of the general statutes is repealed and the  
25 following is substituted in lieu thereof (*Effective January 1, 2012*):

26 A clinical trial for the prevention of cancer shall be eligible for  
27 coverage only if it involves a therapeutic intervention, is a phase III  
28 clinical trial approved by one of the entities identified in this section  
29 and is conducted at multiple institutions. In order to be eligible for  
30 coverage of routine patient care costs, as defined in section 38a-504d,  
31 as amended by this act, a [cancer] clinical trial shall be (1) conducted  
32 under the auspices of an independent peer-reviewed protocol that has  
33 been reviewed and approved by: [(1)] (A) One of the National  
34 Institutes of Health; [or (2)] (B) a National Cancer Institute affiliated  
35 cooperative group; [or (3)] (C) the federal Food and Drug  
36 Administration as part of an investigational new drug or device  
37 exemption; or [(4)] (D) the federal Department of Defense or Veterans  
38 Affairs; or (2) qualified to receive Medicare coverage of its routine  
39 costs under the Medicare Clinical Trial Policy established under the  
40 September 19, 2000, Medicare National Coverage Determination, as  
41 amended from time to time. Nothing in sections 38a-504a to 38a-504g,  
42 inclusive, as amended by this act, shall be construed to require  
43 coverage for any single institution [cancer] clinical trial conducted  
44 solely under the approval of the institutional review board of an  
45 institution, or any trial that is no longer approved by an entity  
46 identified in [subdivision (1), (2), (3) or (4) of this section]  
47 subparagraph (A), (B), (C) or (D) of subdivision (1) of this subsection.

48 Sec. 3. Section 38a-504c of the general statutes is repealed and the  
49 following is substituted in lieu thereof (*Effective January 1, 2012*):

50 In order to be eligible for coverage of routine patient care costs, as  
51 defined in section 38a-504d, as amended by this act, the insurer, health

52 care center or plan administrator may require that the person or entity  
53 seeking coverage for the [cancer] clinical trial provide: (1) Evidence  
54 satisfactory to the insurer, health care center or plan administrator that  
55 the insured person receiving coverage meets all of the patient selection  
56 criteria for the [cancer] clinical trial, including credible evidence in the  
57 form of clinical or preclinical data showing that the [cancer] clinical  
58 trial is likely to have a benefit for the insured person that is  
59 commensurate with the risks of participation in the [cancer] clinical  
60 trial to treat the person's condition; [and] (2) evidence that the  
61 appropriate informed consent has been received from the insured  
62 person; [and] (3) copies of any medical records, protocols, test results  
63 or other clinical information used by the physician or institution  
64 seeking to enroll the insured person in the [cancer] clinical trial; [and]  
65 (4) a summary of the anticipated routine patient care costs in excess of  
66 the costs for standard treatment; [and] (5) information from the  
67 physician or institution seeking to enroll the insured person in the  
68 clinical trial regarding those items, including any routine patient care  
69 costs, that are eligible for reimbursement by an entity other than the  
70 insurer or health care center, including the entity sponsoring the  
71 clinical trial; and (6) any additional information that may be  
72 reasonably required for the review of a request for coverage of the  
73 [cancer] clinical trial. The health plan or insurer shall request any  
74 additional information about a [cancer] clinical trial [within] not later  
75 than five business days [of] after receiving a request for coverage from  
76 an insured person or a physician seeking to enroll an insured person in  
77 a [cancer] clinical trial. Nothing in sections 38a-504a to 38a-504g,  
78 inclusive, as amended by this act, shall be construed to require the  
79 insurer or health care center to provide coverage for routine patient  
80 care costs that are eligible for reimbursement by an entity other than  
81 the insurer, including the entity sponsoring the [cancer] clinical trial.

82 Sec. 4. Section 38a-504d of the general statutes is repealed and the  
83 following is substituted in lieu thereof (*Effective January 1, 2012*):

84 (a) For purposes of sections 38a-504a to 38a-504g, inclusive, as  
85 amended by this act, "routine patient care costs" means: (1) [Coverage

86 for medically] Medically necessary health care services that are  
87 incurred as a result of the treatment being provided to the insured  
88 person for purposes of the [cancer] clinical trial that would otherwise  
89 be covered if such services were not rendered pursuant to a [cancer]  
90 clinical trial. Such services shall include those rendered by a physician,  
91 diagnostic or laboratory tests, hospitalization or other services  
92 provided to the [patient] insured person during the course of  
93 treatment in the [cancer] clinical trial for a condition, or one of its  
94 complications, that is consistent with the usual and customary  
95 standard of care and would be covered if the insured person were not  
96 enrolled in a [cancer] clinical trial. Such hospitalization shall include  
97 treatment at an out-of-network facility if such treatment is not  
98 available in-network and not eligible for reimbursement by the  
99 sponsors of such clinical trial, [;] and (2) [coverage for routine patient  
100 care] costs incurred for drugs provided to the insured person, in  
101 accordance with section [38a-518b] 38a-492b, as amended by this act,  
102 provided such drugs have been approved for sale by the federal Food  
103 and Drug Administration.

104 (b) Routine patient care costs shall be subject to the terms,  
105 conditions, restrictions, exclusions and limitations of the contract or  
106 certificate of insurance between the subscriber and the insurer or  
107 health plan, including limitations on out-of-network care, except that  
108 treatment at an out-of-network hospital as provided in subdivision (1)  
109 of subsection (a) of this section shall be made available by the out-of-  
110 network hospital and the insurer or health care center at no greater  
111 cost to the insured person than if such treatment was available in-  
112 network. The insurer or health care center may require that any  
113 routine tests or services required under the [cancer] clinical trial  
114 protocol be performed by providers or institutions under contract with  
115 the insurer or health care center.

116 (c) Notwithstanding the provisions of subsection (a) of this section,  
117 routine patient care costs shall not include: (1) The cost of an  
118 investigational new drug or device that has not been approved for  
119 market for any indication by the federal Food and Drug

120 Administration; (2) the cost of a non-health-care service that an insured  
121 person may be required to receive as a result of the treatment being  
122 provided for the purposes of the [cancer] clinical trial; (3) facility,  
123 ancillary, professional services and drug costs that are paid for by  
124 grants or funding for the [cancer] clinical trial; (4) costs of services that  
125 (A) are inconsistent with widely accepted and established regional or  
126 national standards of care for a particular diagnosis, or (B) are  
127 performed specifically to meet the requirements of the [cancer] clinical  
128 trial; (5) costs that would not be covered under the insured person's  
129 policy for noninvestigational treatments, including, but not limited to,  
130 items excluded from coverage under the insured person's contract  
131 with the insurer or health plan; and (6) transportation, lodging, food or  
132 any other expenses associated with travel to or from a facility  
133 providing the [cancer] clinical trial, for the insured person or any  
134 family member or companion.

135 Sec. 5. Section 38a-504e of the general statutes is repealed and the  
136 following is substituted in lieu thereof (*Effective January 1, 2012*):

137 (a) Providers, hospitals and institutions that provide routine patient  
138 care services as set forth in subsection (a) of section 38a-504d, as  
139 amended by this act, as part of a [cancer] clinical trial that meets the  
140 requirements of sections 38a-504a to 38a-504g, inclusive, as amended  
141 by this act, and is approved for coverage by the insurer or health care  
142 center shall not bill the insurer or health care center or the insured  
143 person for any facility, ancillary or professional services or costs that  
144 are not routine patient care services as set forth in subsection (a) of  
145 section 38a-504d, as amended by this act, or for any product or service  
146 that is paid by the entity sponsoring or funding the [cancer] clinical  
147 trial.

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

152 (c) Providers, hospitals or institutions that have contracts with the  
153 insurer or health care center to render covered routine patient care  
154 services to insured persons as part of a [cancer] clinical trial [may] shall  
155 not bill the insured person for the cost of any covered routine patient  
156 care service.

157 (d) Providers, hospitals or institutions that do not have a contract  
158 with the insurer or health care center to render covered routine patient  
159 care services to insured persons as part of a [cancer] clinical trial [may]  
160 shall not bill the insured person for the cost of any covered routine  
161 patient care service.

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

166 (f) Pursuant to subsection (b) of section 38a-504d, as amended by  
167 this act, insurers or health care centers shall be required to pay  
168 providers, hospitals and institutions that do not have a contract with  
169 the insurer or health care center to render covered routine patient care  
170 services to insured persons the lesser of (1) the lowest contracted per  
171 diem, fee schedule rate or case rate that the insurer or health care  
172 center pays to any participating provider in the state of Connecticut for  
173 similar in-network services, or (2) the billed charges. Providers,  
174 hospitals or institutions [may] shall not collect any amount more than  
175 the total amount paid by the insurer or health care center and the  
176 insured person in the form of a deductible or copayment set forth in  
177 the insured person's contract. Such amount shall be deemed by the  
178 provider, hospital or institution to be payment in full.

179 Sec. 6. Section 38a-504f of the general statutes is repealed and the  
180 following is substituted in lieu thereof (*Effective January 1, 2012*):

181 (a) (1) For purposes of cancer clinical trials, the Insurance  
182 Department, in cooperation with the Connecticut Oncology  
183 Association, the American Cancer Society, the Connecticut Association

184 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a  
185 standardized form that all providers, hospitals and institutions shall  
186 submit to the insurer or health care center when seeking to enroll an  
187 insured person in a cancer clinical trial. An insurer or health care  
188 center [may] shall not substitute any other approval request form for  
189 the form developed by the department, except that any insurer or  
190 health care center that has entered into an agreement to provide  
191 coverage for cancer clinical trials approved pursuant to section 38a-  
192 504g, as amended by this act, may use the form or process established  
193 by such agreement.

194 (2) For purposes of clinical trials other than cancer clinical trials, the  
195 Insurance Department, in cooperation with at least one state nonprofit  
196 research or advocacy organization concerned with the subject of the  
197 clinical trial, at least one national nonprofit research or advocacy  
198 organization concerned with the subject of the clinical trial, the  
199 Connecticut Association of Health Plans and Anthem Blue Cross of  
200 Connecticut, shall develop a standardized form that all providers,  
201 hospitals and institutions shall submit to the insurer or health care  
202 center when seeking to enroll an insured person in a clinical trial. An  
203 insurer or health care center shall not substitute any other approval  
204 request form for the form developed by the department, except that  
205 any insurer or health care center that has entered into an agreement to  
206 provide coverage for clinical trials approved pursuant to section 38a-  
207 504g, as amended by this act, may use the form or process established  
208 by such agreement.

209 (b) Any insurer or health care center that receives the department  
210 form from a provider, hospital or institution seeking coverage for the  
211 routine patient care costs of an insured person in a [cancer] clinical  
212 trial shall approve or deny coverage for such services [within] not later  
213 than five business days [of] after receiving such request and any other  
214 reasonable supporting materials requested by the insurer or health  
215 plan pursuant to section 38a-504c, as amended by this act, except that  
216 an insurer or health care center that utilizes independent experts to  
217 review such requests shall respond [within] not later than ten business

218 days after receiving such request and supporting materials. Requests  
219 for coverage of phase III clinical trials for the prevention of cancer  
220 pursuant to section [38a-504a] 38a-504b, as amended by this act, shall  
221 be approved or denied [within] not later than fourteen business days  
222 after receiving such request and supporting materials.

223 (c) The insured, or the provider with the insured's written consent,  
224 may appeal any denial of coverage for medical necessity to an external,  
225 independent review pursuant to section 38a-478n. Such external  
226 review shall be conducted by a properly qualified review agent whom  
227 the department has determined does not have a conflict of interest  
228 regarding the [cancer] clinical trial.

229 (d) The Insurance Commissioner shall adopt regulations, in  
230 accordance with chapter 54, to implement the provisions of this  
231 section.

232 Sec. 7. Section 38a-504g of the general statutes is repealed and the  
233 following is substituted in lieu thereof (*Effective January 1, 2012*):

234 (a) Any insurer or health care center with coverage policies for care  
235 in [cancer] clinical trials shall submit such policies to the Insurance  
236 Department for evaluation and approval. The department shall certify  
237 whether the insurer's or health care center's coverage policy for routine  
238 patient care costs associated with [cancer] clinical trials is substantially  
239 equivalent to the requirements of sections 38a-504a to 38a-504g,  
240 inclusive, as amended by this act. If the department finds that such  
241 coverage is substantially equivalent to the requirements of sections  
242 38a-504a to 38a-504g, inclusive, as amended by this act, the insurer or  
243 health care center shall be exempt from the provisions of sections 38a-  
244 504a to 38a-504g, inclusive, as amended by this act.

245 (b) Any such insurer or health care center shall report annually, in  
246 writing, to the department that there have been no changes in the  
247 policy as certified by the department. If there has been any change in  
248 the policy, the insurer or health care center shall resubmit its policy for  
249 certification by the department.

250 (c) Any insurer or health care center coverage policy found by the  
251 department not to be substantially equivalent to the requirements of  
252 sections 38a-504a to 38a-504g, inclusive, as amended by this act, shall  
253 abide by the requirements of sections 38a-504a to 38a-504g, inclusive,  
254 as amended by this act, until the insurer or health care center has  
255 received such certification by the department.

256 Sec. 8. Section 38a-542a of the general statutes is repealed and the  
257 following is substituted in lieu thereof (*Effective January 1, 2012*):

258 Each group health insurance policy providing coverage of the type  
259 specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469  
260 delivered, issued for delivery, [or] renewed, amended or continued in  
261 this state, [on or after January 1, 2002,] shall provide coverage for the  
262 routine patient care costs, as defined in section 38a-542d, as amended  
263 by this act, associated with [cancer] clinical trials, in accordance with  
264 sections 38a-542b to 38a-542g, inclusive, as amended by this act. As  
265 used in this section and sections 38a-542b to 38a-542g, inclusive, as  
266 amended by this act: ["cancer clinical] (1) "Clinical" trial" means an  
267 organized, systematic, scientific study of therapies, tests or other  
268 clinical interventions for purposes of treatment or palliation or  
269 therapeutic intervention for the prevention of [cancer in human beings,  
270 except that a clinical trial for the prevention of cancer is eligible for  
271 coverage only if it involves a therapeutic intervention and is a phase III  
272 clinical trial approved by one of the entities identified in section 38a-  
273 542b and is conducted at multiple institutions] disabling, progressive  
274 or life-threatening medical conditions in human beings, and (2)  
275 "disabling, progressive or life threatening medical conditions" means  
276 cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral  
277 sclerosis, acquired immunodeficiency syndrome or muscular  
278 dystrophy.

279 Sec. 9. Section 38a-542b of the general statutes is repealed and the  
280 following is substituted in lieu thereof (*Effective January 1, 2012*):

281 A clinical trial for the prevention of cancer shall be eligible for

282 coverage only if it involves a therapeutic intervention, is a phase III  
283 clinical trial approved by one of the entities identified in this section  
284 and is conducted at multiple institutions. In order to be eligible for  
285 coverage of routine patient care costs, as defined in section 38a-542d,  
286 as amended by this act, a [cancer] clinical trial shall be (1) conducted  
287 under the auspices of an independent peer-reviewed protocol that has  
288 been reviewed and approved by: [(1)] (A) One of the National  
289 Institutes of Health; [or (2)] (B) a National Cancer Institute affiliated  
290 cooperative group; [or (3)] (C) the federal Food and Drug  
291 Administration as part of an investigational new drug or device  
292 exemption; or [(4)] (D) the federal Department of Defense or Veterans  
293 Affairs; or (2) qualified to receive Medicare coverage of its routine  
294 costs under the Medicare Clinical Trial Policy established under the  
295 September 19, 2000, Medicare National Coverage Determination, as  
296 amended from time to time. Nothing in sections 38a-542a to 38a-542g,  
297 inclusive, as amended by this act, shall be construed to require  
298 coverage for any single institution [cancer] clinical trial conducted  
299 solely under the approval of the institutional review board of an  
300 institution, or any trial that is no longer approved by an entity  
301 identified in [subdivision (1), (2), (3) or (4) of this section]  
302 subparagraph (A), (B), (C) or (D) of subdivision (1) of this subsection.

303 Sec. 10. Section 38a-542c of the general statutes is repealed and the  
304 following is substituted in lieu thereof (*Effective January 1, 2012*):

305 In order to be eligible for coverage of routine patient care costs, as  
306 defined in section 38a-542d, as amended by this act, the insurer, health  
307 care center or plan administrator may require that the person or entity  
308 seeking coverage for the [cancer] clinical trial provide: (1) Evidence  
309 satisfactory to the insurer, health care center or plan administrator that  
310 the insured person receiving coverage meets all of the patient selection  
311 criteria for the [cancer] clinical trial, including credible evidence in the  
312 form of clinical or pre-clinical data showing that the [cancer] clinical  
313 trial is likely to have a benefit for the insured person that is  
314 commensurate with the risks of participation in the [cancer] clinical  
315 trial to treat the person's condition; [and] (2) evidence that the

316 appropriate informed consent has been received from the insured  
317 person; [and] (3) copies of any medical records, protocols, test results  
318 or other clinical information used by the physician or institution  
319 seeking to enroll the insured person in the [cancer] clinical trial; [and]  
320 (4) a summary of the anticipated routine patient care costs in excess of  
321 the costs for standard treatment; [and] (5) information from the  
322 physician or institution seeking to enroll the insured person in the  
323 clinical trial regarding those items, including any routine patient care  
324 costs, that are eligible for reimbursement by an entity other than the  
325 insurer or health care center, including the entity sponsoring the  
326 clinical trial; and (6) any additional information that may be  
327 reasonably required for the review of a request for coverage of the  
328 [cancer] clinical trial. The health plan or insurer shall request any  
329 additional information about a [cancer] clinical trial [within] not later  
330 than five business days [of] after receiving a request for coverage from  
331 an insured person or a physician seeking to enroll an insured person in  
332 a [cancer] clinical trial. Nothing in sections 38a-542a to 38a-542g,  
333 inclusive, as amended by this act, shall be construed to require the  
334 insurer or health care center to provide coverage for routine patient  
335 care costs that are eligible for reimbursement by an entity other than  
336 the insurer, including the entity sponsoring the [cancer] clinical trial.

337 Sec. 11. Section 38a-542d of the general statutes is repealed and the  
338 following is substituted in lieu thereof (*Effective January 1, 2012*):

339 (a) For purposes of sections 38a-542a to 38a-542g, inclusive, as  
340 amended by this act, "routine patient care costs" means: (1) [Coverage  
341 for medically] Medically necessary health care services that are  
342 incurred as a result of the treatment being provided to the insured  
343 person for purposes of the [cancer] clinical trial that would otherwise  
344 be covered if such services were not rendered pursuant to a [cancer]  
345 clinical trial. Such services shall include those rendered by a physician,  
346 diagnostic or laboratory tests, hospitalization or other services  
347 provided to the [patient] insured person during the course of  
348 treatment in the [cancer] clinical trial for a condition, or one of its  
349 complications, that is consistent with the usual and customary

350 standard of care and would be covered if the insured person were not  
351 enrolled in a [cancer] clinical trial. Such hospitalization shall include  
352 treatment at an out-of-network facility if such treatment is not  
353 available in-network and not eligible for reimbursement by the  
354 sponsors of such clinical trial; and (2) [coverage for routine patient  
355 care] costs incurred for drugs provided to the insured person, in  
356 accordance with section 38a-518b, as amended by this act, provided  
357 such drugs have been approved for sale by the federal Food and Drug  
358 Administration.

359 (b) Routine patient care costs shall be subject to the terms,  
360 conditions, restrictions, exclusions and limitations of the contract or  
361 certificate of insurance between the subscriber and the insurer or  
362 health plan, including limitations on out-of-network care, except that  
363 treatment at an out-of-network hospital as provided in subdivision (1)  
364 of subsection (a) of this section shall be made available by the out-of-  
365 network hospital and the insurer or health care center at no greater  
366 cost to the insured person than if such treatment was available in-  
367 network. The insurer or health care center may require that any  
368 routine tests or services required under the [cancer] clinical trial  
369 protocol be performed by providers or institutions under contract with  
370 the insurer or health care center.

371 (c) Notwithstanding the provisions of subsection (a) of this section,  
372 routine patient care costs shall not include: (1) The cost of an  
373 investigational new drug or device that has not been approved for  
374 market for any indication by the federal Food and Drug  
375 Administration; (2) the cost of a non-health-care service that an insured  
376 person may be required to receive as a result of the treatment being  
377 provided for the purposes of the cancer clinical trial; (3) facility,  
378 ancillary, professional services and drug costs that are paid for by  
379 grants or funding for the [cancer] clinical trial; (4) costs of services that  
380 (A) are inconsistent with widely accepted and established regional or  
381 national standards of care for a particular diagnosis, or (B) are  
382 performed specifically to meet the requirements of the [cancer] clinical  
383 trial; (5) costs that would not be covered under the insured person's

384 policy for noninvestigational treatments, including, but not limited to,  
385 items excluded from coverage under the insured person's contract  
386 with the insurer or health plan; and (6) transportation, lodging, food or  
387 any other expenses associated with travel to or from a facility  
388 providing the [cancer] clinical trial, for the insured person or any  
389 family member or companion.

390 Sec. 12. Section 38a-542e of the general statutes is repealed and the  
391 following is substituted in lieu thereof (*Effective January 1, 2012*):

392 (a) Providers, hospitals and institutions that provide routine patient  
393 care services as set forth in subsection (a) of section 38a-542d, as  
394 amended by this act, as part of a [cancer] clinical trial that meets the  
395 requirements of sections 38a-542a to 38a-542g, inclusive, as amended  
396 by this act, and is approved for coverage by the insurer or health care  
397 center shall not bill the insurer or health care center or the insured  
398 person for any facility, ancillary or professional services or costs that  
399 are not routine patient care services as set forth in subsection (a) of  
400 section 38a-542d, as amended by this act, or for any product or service  
401 that is paid by the entity sponsoring or funding the [cancer] clinical  
402 trial.

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

407 (c) Providers, hospitals or institutions that have contracts with the  
408 insurer or health care center to render covered routine patient care  
409 services to insured persons as part of a [cancer] clinical trial [may] shall  
410 not bill the insured person for the cost of any covered routine patient  
411 care service.

412 (d) Providers, hospitals or institutions that do not have a contract  
413 with the insurer or health care center to render covered routine patient  
414 care services to insured persons as part of a [cancer] clinical trial [may]  
415 shall not bill the insured person for the cost of any covered routine

416 patient care service.

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

421 (f) Pursuant to subsection (b) of section 38a-542d, as amended by  
422 this act, insurers or health care centers shall be required to pay  
423 providers, hospitals and institutions that do not have a contract with  
424 the insurer or health care center to render covered routine patient care  
425 services to insured persons the lesser of (1) the lowest contracted per  
426 diem, fee schedule rate or case rate that the insurer or health care  
427 center pays to any participating provider in the state of Connecticut for  
428 similar in-network services, or (2) the billed charges. Providers,  
429 hospitals or institutions [may] shall not collect any amount more than  
430 the total amount paid by the insurer or health care center and the  
431 insured person in the form of a deductible or copayment set forth in  
432 the insured person's contract. Such amount shall be deemed by the  
433 provider, hospital or institution to be payment in full.

434 Sec. 13. Section 38a-542f of the general statutes is repealed and the  
435 following is substituted in lieu thereof (*Effective January 1, 2012*):

436 (a) (1) For purposes of cancer clinical trials, the Insurance  
437 Department, in cooperation with the Connecticut Oncology  
438 Association, the American Cancer Society, the Connecticut Association  
439 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a  
440 standardized form that all providers, hospitals and institutions shall  
441 submit to the insurer or health care center when seeking to enroll an  
442 insured person in a cancer clinical trial. An insurer or health care  
443 center [may] shall not substitute any other approval request form for  
444 the form developed by the department, except that any insurer or  
445 health care center that has entered into an agreement to provide  
446 coverage for cancer clinical trials approved pursuant to section 38a-  
447 542g, as amended by this act, may use the form or process established

448 by such agreement.

449 (2) For purposes of clinical trials other than cancer clinical trials, the  
450 Insurance Department, in cooperation with at least one state nonprofit  
451 research or advocacy organization concerned with the subject of the  
452 clinical trial, at least one national nonprofit research or advocacy  
453 organization concerned with the subject of the clinical trial, the  
454 Connecticut Association of Health Plans and Anthem Blue Cross of  
455 Connecticut, shall develop a standardized form that all providers,  
456 hospitals and institutions shall submit to the insurer or health care  
457 center when seeking to enroll an insured person in a clinical trial. An  
458 insurer or health care center shall not substitute any other approval  
459 request form for the form developed by the department, except that  
460 any insurer or health care center that has entered into an agreement to  
461 provide coverage for clinical trials approved pursuant to section 38a-  
462 504g, as amended by this act, may use the form or process established  
463 by such agreement.

464 (b) Any insurer or health care center that receives the department  
465 form from a provider, hospital or institution seeking coverage for the  
466 routine patient care costs of an insured person in a [cancer] clinical  
467 trial shall approve or deny coverage for such services [within] not later  
468 than five business days [of] after receiving such request and any other  
469 reasonable supporting materials requested by the insurer or health  
470 plan pursuant to section 38a-542c, as amended by this act, except that  
471 an insurer or health care center that utilizes independent experts to  
472 review such requests shall respond [within] not later than ten business  
473 days after receiving such request and supporting materials. Requests  
474 for coverage of phase III clinical trials for the prevention of cancer  
475 pursuant to section [38a-542a] 38-542b, as amended by this act, shall be  
476 approved or denied [within] not later than fourteen business days after  
477 receiving such request and supporting materials.

478 (c) The insured, or the provider with the insured's written consent,  
479 may appeal any denial of coverage for medical necessity to an external,  
480 independent review pursuant to section 38a-478n. Such external

481 review shall be conducted by a properly qualified review agent whom  
482 the department has determined does not have a conflict of interest  
483 regarding the [cancer] clinical trial.

484 (d) The Insurance Commissioner shall adopt regulations, in  
485 accordance with chapter 54, to implement the provisions of this  
486 section.

487 Sec. 14. Section 38a-542g of the general statutes is repealed and the  
488 following is substituted in lieu thereof (*Effective January 1, 2012*):

489 (a) Any insurer or health care center with coverage policies for care  
490 in [cancer] clinical trials shall submit such policies to the Insurance  
491 Department for evaluation and approval. The department shall certify  
492 whether the insurer's or health care center's coverage policy for routine  
493 patient care costs associated with [cancer] clinical trials is substantially  
494 equivalent to the requirements of sections 38a-542a to 38a-542g,  
495 inclusive, as amended by this act. If the department finds that such  
496 coverage is substantially equivalent to the requirements of sections  
497 38a-542a to 38a-542g, inclusive, as amended by this act, the insurer or  
498 health care center shall be exempt from the provisions of sections 38a-  
499 542a to 38a-542g, inclusive, as amended by this act.

500 (b) Any such insurer or health care center shall report annually, in  
501 writing, to the department that there have been no changes in the  
502 policy as certified by the department. If there has been any change in  
503 the policy, the insurer or health care center shall resubmit its policy for  
504 certification by the department.

505 (c) Any insurer or health care center coverage policy found by the  
506 department not to be substantially equivalent to the requirements of  
507 sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall  
508 abide by the requirements of sections 38a-542a to 38a-542g, inclusive,  
509 as amended by this act, until the insurer or health care center has  
510 received such certification by the department.

511 Sec. 15. Section 38a-492b of the general statutes is repealed and the

512 following is substituted in lieu thereof (*Effective January 1, 2012*):

513 (a) Each individual health insurance policy delivered, issued for  
514 delivery, [or] renewed, amended or continued in this state, [on or after  
515 October 1, 1994, which] that provides coverage for prescribed drugs  
516 approved by the federal Food and Drug Administration for treatment  
517 of certain types of cancer and disabling, progressive or life-threatening  
518 medical conditions, as defined in section 38a-504a, as amended by this  
519 act, shall not exclude coverage of any such drug on the basis that such  
520 drug has been prescribed for the treatment of a type of cancer or a  
521 disabling, progressive or life-threatening medical condition for which  
522 the drug has not been approved by the federal Food and Drug  
523 Administration, provided the drug is recognized for treatment of the  
524 specific type of cancer or a disabling, progressive or life-threatening  
525 medical condition for which the drug has been prescribed in one of the  
526 following established reference compendia: (1) The U.S.  
527 Pharmacopoeia Drug Information Guide for the Health Care  
528 Professional (USP DI); (2) The American Medical Association's Drug  
529 Evaluations (AMA DE); or (3) The American Society of Hospital  
530 Pharmacists' American Hospital Formulary Service Drug Information  
531 (AHFS-DI).

532 (b) Nothing in subsection (a) of this section shall be construed to  
533 require coverage for any experimental or investigational drugs or any  
534 drug which the federal Food and Drug Administration has determined  
535 to be contraindicated for treatment of the specific type of cancer or  
536 disabling, progressive or life-threatening medical condition for which  
537 the drug has been prescribed.

538 (c) [Nothing] Except as specified, nothing in this section shall be  
539 construed to create, impair, limit or modify authority to provide  
540 reimbursement for drugs used in the treatment of any other disease or  
541 condition.

542 Sec. 16. Section 38a-518b of the general statutes is repealed and the  
543 following is substituted in lieu thereof (*Effective January 1, 2012*):

544 (a) Each group health insurance policy delivered, issued for  
545 delivery, ~~[or] renewed,~~ amended or continued in this state, ~~[on or after~~  
546 ~~October 1, 1994, which]~~ that provides coverage for prescribed drugs  
547 approved by the federal Food and Drug Administration for treatment  
548 of certain types of cancer and disabling, progressive or life-threatening  
549 medical conditions, as defined in section 38a-542a, as amended by this  
550 act, shall not exclude coverage of any such drug on the basis that such  
551 drug has been prescribed for the treatment of a type of cancer or a  
552 disabling, progressive or life-threatening medical condition for which  
553 the drug has not been approved by the federal Food and Drug  
554 Administration, provided the drug is recognized for treatment of the  
555 specific type of cancer or a disabling, progressive or life-threatening  
556 medical condition for which the drug has been prescribed in one of the  
557 following established reference compendia: (1) The U.S.  
558 Pharmacopoeia Drug Information Guide for the Health Care  
559 Professional (USP DI); (2) The American Medical Association's Drug  
560 Evaluations (AMA DE); or (3) The American Society of Hospital  
561 Pharmacists' American Hospital Formulary Service Drug Information  
562 (AHFS-DI).

563 (b) Nothing in subsection (a) of this section shall be construed to  
564 require coverage for any experimental or investigational drugs or any  
565 drug which the federal Food and Drug Administration has determined  
566 to be contraindicated for treatment of the specific type of cancer or a  
567 disabling, progressive or life-threatening medical condition for which  
568 the drug has been prescribed.

569 (c) ~~[Nothing]~~ Except as specified, ~~nothing~~ in this section shall be  
570 construed to create, impair, limit or modify authority to provide  
571 reimbursement for drugs used in the treatment of any other disease or  
572 condition.

This act shall take effect as follows and shall amend the following sections:		
Section 1	January 1, 2012	38a-504a

Sec. 2	<i>January 1, 2012</i>	38a-504b
Sec. 3	<i>January 1, 2012</i>	38a-504c
Sec. 4	<i>January 1, 2012</i>	38a-504d
Sec. 5	<i>January 1, 2012</i>	38a-504e
Sec. 6	<i>January 1, 2012</i>	38a-504f
Sec. 7	<i>January 1, 2012</i>	38a-504g
Sec. 8	<i>January 1, 2012</i>	38a-542a
Sec. 9	<i>January 1, 2012</i>	38a-542b
Sec. 10	<i>January 1, 2012</i>	38a-542c
Sec. 11	<i>January 1, 2012</i>	38a-542d
Sec. 12	<i>January 1, 2012</i>	38a-542e
Sec. 13	<i>January 1, 2012</i>	38a-542f
Sec. 14	<i>January 1, 2012</i>	38a-542g
Sec. 15	<i>January 1, 2012</i>	38a-492b
Sec. 16	<i>January 1, 2012</i>	38a-518b

**APP**      *Joint Favorable Subst.*