



# Senate

General Assembly

**File No. 15**

January Session, 2011

Senate Bill No. 21

*Senate, March 1, 2011*

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

***AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR  
ROUTINE PATIENT CARE COSTS FOR 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 Section 38a-504a of the general statutes is repealed and  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] "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.

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 Section 38a-504b of the general statutes is repealed and the  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

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

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 Section 38a-504c of the general statutes is repealed and the  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

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

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

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

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

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

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

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

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

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

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

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

148 (c) Providers, hospitals or institutions that have contracts with the

149 insurer or health care center to render covered routine patient care  
150 services to insured persons as part of a [cancer] clinical trial [may] shall  
151 not bill the insured person for the cost of any covered routine patient  
152 care service.

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

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

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

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

177 (a) (1) For purposes of cancer clinical trials, the Insurance  
178 Department, in cooperation with the Connecticut Oncology  
179 Association, the American Cancer Society, the Connecticut Association  
180 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a

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

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

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

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

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

225 (d) The Insurance Commissioner shall adopt regulations, in  
226 accordance with chapter 54, to implement the provisions of this  
227 section.

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

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

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

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

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

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

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

273 A clinical trial for the prevention of cancer shall be eligible for  
274 coverage only if it involves a therapeutic intervention, is a phase III  
275 clinical trial approved by one of the entities identified in this section  
276 and is conducted at multiple institutions. In order to be eligible for  
277 coverage of routine patient care costs, as defined in section 38a-542d,  
278 as amended by this act, a [cancer] clinical trial shall be (1) conducted

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

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

297 In order to be eligible for coverage of routine patient care costs, as  
298 defined in section 38a-542d, as amended by this act, the insurer, health  
299 care center or plan administrator may require that the person or entity  
300 seeking coverage for the [cancer] clinical trial provide: (1) Evidence  
301 satisfactory to the insurer, health care center or plan administrator that  
302 the insured person receiving coverage meets all of the patient selection  
303 criteria for the [cancer] clinical trial, including credible evidence in the  
304 form of clinical or pre-clinical data showing that the [cancer] clinical  
305 trial is likely to have a benefit for the insured person that is  
306 commensurate with the risks of participation in the [cancer] clinical  
307 trial to treat the person's condition; [and] (2) evidence that the  
308 appropriate informed consent has been received from the insured  
309 person; [and] (3) copies of any medical records, protocols, test results  
310 or other clinical information used by the physician or institution  
311 seeking to enroll the insured person in the [cancer] clinical trial; [and]  
312 (4) a summary of the anticipated routine patient care costs in excess of

313 the costs for standard treatment; [and] (5) information from the  
314 physician or institution seeking to enroll the insured person in the  
315 clinical trial regarding those items, including any routine patient care  
316 costs, that are eligible for reimbursement by an entity other than the  
317 insurer or health care center, including the entity sponsoring the  
318 clinical trial; and (6) any additional information that may be  
319 reasonably required for the review of a request for coverage of the  
320 [cancer] clinical trial. The health plan or insurer shall request any  
321 additional information about a [cancer] clinical trial [within] not later  
322 than five business days [of] after receiving a request for coverage from  
323 an insured person or a physician seeking to enroll an insured person in  
324 a [cancer] clinical trial. Nothing in sections 38a-542a to 38a-542g,  
325 inclusive, as amended by this act, shall be construed to require the  
326 insurer or health care center to provide coverage for routine patient  
327 care costs that are eligible for reimbursement by an entity other than  
328 the insurer, including the entity sponsoring the [cancer] clinical trial.

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

331 (a) For purposes of sections 38a-542a to 38a-542g, inclusive, as  
332 amended by this act, "routine patient care costs" means: (1) [Coverage  
333 for medically] Medically necessary health care services that are  
334 incurred as a result of the treatment being provided to the insured  
335 person for purposes of the [cancer] clinical trial that would otherwise  
336 be covered if such services were not rendered pursuant to a [cancer]  
337 clinical trial. Such services shall include those rendered by a physician,  
338 diagnostic or laboratory tests, hospitalization or other services  
339 provided to the [patient] insured person during the course of  
340 treatment in the [cancer] clinical trial for a condition, or one of its  
341 complications, that is consistent with the usual and customary  
342 standard of care and would be covered if the insured person were not  
343 enrolled in a [cancer] clinical trial. Such hospitalization shall include  
344 treatment at an out-of-network facility if such treatment is not  
345 available in-network and not eligible for reimbursement by the  
346 sponsors of such clinical trial; and (2) [coverage for routine patient

347 care] costs incurred for drugs provided to the insured person, in  
348 accordance with section 38a-518b, as amended by this act, provided  
349 such drugs have been approved for sale by the federal Food and Drug  
350 Administration.

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

363 (c) Notwithstanding the provisions of subsection (a) of this section,  
364 routine patient care costs shall not include: (1) The cost of an  
365 investigational new drug or device that has not been approved for  
366 market for any indication by the federal Food and Drug  
367 Administration; (2) the cost of a non-health-care service that an insured  
368 person may be required to receive as a result of the treatment being  
369 provided for the purposes of the cancer clinical trial; (3) facility,  
370 ancillary, professional services and drug costs that are paid for by  
371 grants or funding for the [cancer] clinical trial; (4) costs of services that  
372 (A) are inconsistent with widely accepted and established regional or  
373 national standards of care for a particular diagnosis, or (B) are  
374 performed specifically to meet the requirements of the [cancer] clinical  
375 trial; (5) costs that would not be covered under the insured person's  
376 policy for noninvestigational treatments, including, but not limited to,  
377 items excluded from coverage under the insured person's contract  
378 with the insurer or health plan; and (6) transportation, lodging, food or  
379 any other expenses associated with travel to or from a facility  
380 providing the [cancer] clinical trial, for the insured person or any

381 family member or companion.

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

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

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

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

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

409 (e) Nothing in this section shall be construed to prohibit a provider,  
410 hospital or institution from collecting a deductible or copayment as set  
411 forth in the insured person's contract for any covered routine patient

412 care service.

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

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

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

441 (2) For purposes of clinical trials other than cancer clinical trials, the  
442 Insurance Department, in cooperation with at least one state nonprofit  
443 research or advocacy organization pertaining to the subject of the  
444 clinical trial, at least one national nonprofit research or advocacy

445 organization pertaining to the subject of the clinical trial, the  
446 Connecticut Association of Health Plans and Anthem Blue Cross of  
447 Connecticut, shall develop a standardized form that all providers,  
448 hospitals and institutions shall submit to the insurer or health care  
449 center when seeking to enroll an insured person in a clinical trial. An  
450 insurer or health care center shall not substitute any other approval  
451 request form for the form developed by the department, except that  
452 any insurer or health care center that has entered into an agreement to  
453 provide coverage for clinical trials approved pursuant to section 38a-  
454 504g, as amended by this act, may use the form or process established  
455 by such agreement.

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

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

476 (d) The Insurance Commissioner shall adopt regulations, in  
477 accordance with chapter 54, to implement the provisions of this

478 section.

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

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

492 (b) Any such insurer or health care center shall report annually, in  
493 writing, to the department that there have been no changes in the  
494 policy as certified by the department. If there has been any change in  
495 the policy, the insurer or health care center shall resubmit its policy for  
496 certification by the department.

497 (c) Any insurer or health care center coverage policy found by the  
498 department not to be substantially equivalent to the requirements of  
499 sections 38a-542a to 38a-542g, inclusive, as amended by this act, shall  
500 abide by the requirements of sections 38a-542a to 38a-542g, inclusive,  
501 as amended by this act, until the insurer or health care center has  
502 received such certification by the department.

503 Sec. 15. Section 38a-492b of the general statutes is repealed and the  
504 following is substituted in lieu thereof (*Effective January 1, 2012*):

505 (a) Each individual health insurance policy delivered, issued for  
506 delivery, [or] renewed, amended or continued in this state, [on or after  
507 October 1, 1994, which] that provides coverage for prescribed drugs  
508 approved by the federal Food and Drug Administration for treatment

509 of certain types of cancer and other disabling, progressive or life-  
510 threatening medical conditions shall not exclude coverage of any such  
511 drug on the basis that such drug has been prescribed for the treatment  
512 of a type of cancer or other disabling, progressive or life-threatening  
513 medical condition for which the drug has not been approved by the  
514 federal Food and Drug Administration, provided the drug is  
515 recognized for treatment of the specific type of cancer or other  
516 disabling, progressive or life-threatening medical condition for which  
517 the drug has been prescribed in one of the following established  
518 reference compendia: (1) The U.S. Pharmacopoeia Drug Information  
519 Guide for the Health Care Professional (USP DI); (2) The American  
520 Medical Association's Drug Evaluations (AMA DE); or (3) The  
521 American Society of Hospital Pharmacists' American Hospital  
522 Formulary Service Drug Information (AHFS-DI).

523 (b) Nothing in subsection (a) of this section shall be construed to  
524 require coverage for any experimental or investigational drugs or any  
525 drug which the federal Food and Drug Administration has determined  
526 to be contraindicated for treatment of the specific type of cancer or  
527 other disabling, progressive or life-threatening medical condition for  
528 which the drug has been prescribed.

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

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

535 (a) Each group health insurance policy delivered, issued for  
536 delivery, [or] renewed, amended or continued in this state, [on or after  
537 October 1, 1994, which] that provides coverage for prescribed drugs  
538 approved by the federal Food and Drug Administration for treatment  
539 of certain types of cancer and other disabling, progressive or life-  
540 threatening medical conditions shall not exclude coverage of any such  
541 drug on the basis that such drug has been prescribed for the treatment

542 of a type of cancer or other disabling, progressive or life-threatening  
 543 medical condition for which the drug has not been approved by the  
 544 federal Food and Drug Administration, provided the drug is  
 545 recognized for treatment of the specific type of cancer or other  
 546 disabling, progressive or life-threatening medical condition for which  
 547 the drug has been prescribed in one of the following established  
 548 reference compendia: (1) The U.S. Pharmacopoeia Drug Information  
 549 Guide for the Health Care Professional (USP DI); (2) The American  
 550 Medical Association's Drug Evaluations (AMA DE); or (3) The  
 551 American Society of Hospital Pharmacists' American Hospital  
 552 Formulary Service Drug Information (AHFS-DI).

553 (b) Nothing in subsection (a) of this section shall be construed to  
 554 require coverage for any experimental or investigational drugs or any  
 555 drug which the federal Food and Drug Administration has determined  
 556 to be contraindicated for treatment of the specific type of cancer or  
 557 other disabling, progressive or life-threatening medical condition for  
 558 which the drug has been prescribed.

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

This act shall take effect as follows and shall amend the following sections:		
Section 1	January 1, 2012	38a-504a
Sec. 2	January 1, 2012	38a-504b
Sec. 3	January 1, 2012	38a-504c
Sec. 4	January 1, 2012	38a-504d
Sec. 5	January 1, 2012	38a-504e
Sec. 6	January 1, 2012	38a-504f
Sec. 7	January 1, 2012	38a-504g
Sec. 8	January 1, 2012	38a-542a
Sec. 9	January 1, 2012	38a-542b
Sec. 10	January 1, 2012	38a-542c
Sec. 11	January 1, 2012	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

**INS**      *Joint Favorable*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

**OFA Fiscal Note**

**State Impact:**

<b>Agency Affected</b>	<b>Fund-Effect</b>	<b>FY 12 \$</b>	<b>FY 13 \$</b>
State Comptroller - Fringe Benefits	GF - Cost	None	Potential

Note: GF=General Fund, TF = Transportation Fund

**Municipal Impact:**

<b>Municipalities</b>	<b>Effect</b>	<b>FY 12 \$</b>	<b>FY 13 \$</b>
Various Municipalities	STATE MANDATE - Cost	Potential	Potential

**Explanation**

As of July 1, 2010, the State Employees' Health plan went self insured. Pursuant to current federal law the state's self-insured health plan would be exempt from state health insurance benefit mandates however in previous self-funded arrangements the state has traditionally adopted all state mandates. To the extent that the state continues this practice of voluntary mandate adoption the following impacts would be anticipated.

According to the state's employees and retiree health plans, services associated with or as follow-up to use of any experimental or investigational treatment are not covered, unless approved by the plan provider on a case-by-case basis. As it is not possible to determine which routine services may or may not be authorized in each case, the fiscal impact to the state cannot be determined. Any incurred cost as a result of this mandate would not be effective until the contract is renewed on July 1, 2012.

To the extent that municipalities do not provide coverage for

routine care for insured participants in clinical trials, there may be increased costs to provide it. The bill's impact on municipalities depends on how many municipalities provide this coverage and that cannot be determined at this time. The coverage requirements effective January 1, 2012 may result in increased premium costs when municipalities enter into new contracts for health insurance. Due to federal law, municipalities with self-insured health plans are exempt from state health insurance benefit mandates.

The state employee health plan and many municipal health plans are recognized as “grandfathered” health plans under the Patient Protection and Affordability Care Act (PPACA)<sup>1</sup>. It is unclear what effect the adoption of certain health mandates will have on the grandfathered status of the state employee health plan or grandfathered municipal plans PPACA<sup>2</sup>.

### The Out Years

As previously noted, the future fiscal impact to the state cannot be determined as it is not possible to assess which routine services may or may not be authorized under current plan provisions. Those mandated services not being covered will result in a cost to the state health plan upon contract renewal in FY 13. The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

In addition, the federal health care reform act requires that, effective

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<sup>1</sup> Grandfathered plans include most group insurance plans and some individual health plans created or purchased on or before March 23, 2010. Pursuant to the PPACA, all health plans, including those with grandfathered status are required to provide the following as of September 23, 2010: 1) No lifetime limits on coverage, 2) No rescissions of coverage when individual gets sick or has previously made an unintentional error on an application, and 3) Extension of parents’ coverage to young adults until age 26. ([www.healthcare.gov](http://www.healthcare.gov))

<sup>2</sup> According to the PPACA, compared to the plans’ policies as of March 23, 2010, grandfathered plans who make any of the following changes within a certain margin may lose their grandfathered status: 1) Significantly cut or reduce benefits, 2) Raise co-insurance charges, 3) Significantly raise co-payment charges, 4) Significantly raise deductibles, 5) Significantly lower employer contributions, and 5) Add or tighten annual limits on what insurer pays. ([www.healthcare.gov](http://www.healthcare.gov))

January 1, 2014, all states must establish a health benefit exchange, which will offer qualified plans that must include a federally defined essential benefits package. While states are allowed to mandate benefits in excess of the basic package, the federal law appears to require the state to pay the cost of any such additional mandated benefits. The extent of these costs will depend on the mandates included in the federal essential benefit package, which have not yet been determined. Neither the agency nor a mechanism for the state to pay these costs has been established.

**OLR Bill Analysis****SB 21*****AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CLINICAL TRIAL PATIENTS.*****SUMMARY:**

By law, individual and group health insurance policies and HMO contracts must cover (1) medically necessary hospitalization services and other routine patient care costs associated with cancer clinical trials and (2) off-label cancer prescription drugs. This bill expands the coverage requirements to include all disabling, progressive, or life-threatening medical conditions rather than cancer only. (The bill does not define these terms.)

The bill applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; and (4) hospital or medical services, including coverage under an HMO plan. Due to federal law (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

The bill also makes technical and conforming changes.

EFFECTIVE DATE: January 1, 2012

**CLINICAL TRIALS**

The bill defines a “clinical trial” as an organized, systemic, scientific study of interventions for the treatment of disabling, progressive, or life-threatening medical conditions, or therapeutic intervention for prevention. By law, a clinical trial for cancer prevention must be a Phase III trial conducted at multiple institutions. (Phase III clinical

trials compare a new drug or surgical procedure to the current standard of treatment.) The bill does not require this for other types of preventive clinical trials it covers, but maintains it for cancer clinical trials.

### ***Eligibility for Coverage***

By law, to be eligible for coverage, a cancer clinical trial must be conducted under an independent, peer-reviewed protocol approved by one of the National Institutes of Health, a National Cancer Institute-affiliated cooperative group, the federal Food and Drug Administration (FDA) as part of an investigational new drug or device exemption, or the U. S. departments of Defense or Veterans' Affairs. The bill applies this requirement to clinical trials for disabling, progressive, or life-threatening medical conditions. It also makes eligible for coverage clinical trials for disabling, progressive, or life-threatening medical conditions that qualify for Medicare coverage under the Medicare Clinical Trials Policy established under the September 19, 2000 Medicare National Coverage Determination.

The insurer, HMO, or plan administrator may require the person or entity seeking coverage for the clinical trial to provide:

1. evidence that the patient meets all selection criteria for the clinical trial, including credible clinical evidence showing the clinical trial is likely to benefit the person compared to the risks of participation;
2. evidence that the patient has given his or her informed consent;
3. copies of medical records, protocols, test results, or other clinical information used to enroll the patient in the clinical trial;
4. a summary of the anticipated routine patient costs in excess of the standard treatment costs;
5. information regarding items that are eligible for reimbursement from other sources, including the entity sponsoring the clinical

trial; and

6. additional information reasonably required to review the coverage request.

### ***Routine Patient Care Costs***

By law, extended to all clinical trials by the bill, “routine patient care costs” are (1) medically necessary health care services, including physician services, diagnostic or laboratory tests, and hospitalization, incurred as a result of the treatment being provided that would otherwise be covered if they were not rendered as part of a clinical trial and (2) costs incurred for federal FDA-approved drugs. The services must be consistent with the usual and customary standard of care.

Hospitalization must include treatment at an out-of-network facility if such treatment is not available in-network and not eligible for reimbursement by the clinical trial.

Routine patient care costs must be subject to the terms, conditions, restrictions, exclusions, and limitations of the insurance contract or certificate, including limitations on out-of network care. But treatment at an out-of-network hospital must be made available by the out-of-network hospital and the insurer or HMO at no greater cost to the insured person than if such treatment was available in-network. The insurer or HMO may require that any routine tests or services required under the clinical trial be performed by contracted providers.

Routine patient care costs do not include:

1. the cost of an investigational new drug or device that is not FDA-approved;
2. the cost of a non-health-care service that an insured person may be required to receive as a result of the clinical trial;
3. facility, ancillary, professional services, and drug costs that are paid for by grants or funding for the clinical trial;

4. costs of services that are (a) inconsistent with widely accepted and established regional or national standards of care for a particular diagnosis, or (b) performed specifically to meet the requirements of the clinical trials;
5. costs that would not be covered under the insured person's policy for noninvestigational treatments, including items excluded from coverage under the person's insurance contract; and
6. transportation, lodging, food, or any other expenses associated with travel to or from the clinical trial facility.

Health care providers, including hospitals and institutions, that provide routine patient care services that are approved for coverage cannot bill the insurer, HMO, or insured for any (1) services or costs that do not meet the definition of routine patient care services or (2) product or service for which the clinical trial sponsor is paying.

#### ***Payment to Out-of-Network Providers***

An insurer or HMO must pay out-of-network providers the lesser of (1) the lowest contracted daily fee schedule or case rate it pays its Connecticut in-network providers for similar services or (2) billed charges. Out-of-network providers are prohibited from collecting more than the total amount paid by the insurer or HMO and the insured's deductible and copayment.

#### ***Coverage Request Form***

The bill requires the Insurance Department to develop a standardized form that all providers must submit to the insurer or HMO when seeking to enroll an insured patient in a clinical trial for a disabling, progressive, or life-threatening medical condition, excluding cancer. The department must develop the form in consultation with:

1. at least one state nonprofit research or advocacy organization related the clinical trial's subject,

2. at least one national nonprofit research or advocacy organization related to the clinical trial's subject,
3. the Connecticut Association of Health Plans, and
4. Anthem Blue Cross of Connecticut.

An insurer or HMO must use the department's form unless it is exempt because its coverage is certified to be substantially the same as the bill requires and it has the department's approval to use another form.

An insurer or HMO that receives a completed form from a provider requesting coverage for routine patient care costs for clinical trials other than cancer must approve or deny the request within five business days or, if using independent experts to review clinical trial requests, 10 business days. By law, requests for coverage of Phase III cancer clinical trials must be approved or denied within 14 business days.

Under existing law, the Insurance Department has to (1) develop a form for use with cancer clinical trials and (2) adopt regulations to implement the coverage request form requirements, which the bill extends to other clinical trials.

### ***Exemption from Requirements***

Insurers and HMOs must submit their coverage policies for clinical trials to the Insurance Department for evaluation and approval. The department must certify whether the coverage policy is substantially equivalent to the bill's requirements. If it is, the insurer or HMO is exempt from the bill's requirements.

An exempt insurer or HMO must annually report in writing to the department that there have been no changes to the coverage policy. If there have been changes, the insurer or HMO must resubmit the policy for the department's certification.

### **OFF-LABEL DRUGS**

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By law, individual and group health insurance policies that cover a prescription drug that is FDA-approved to treat a certain type of cancer must also cover the drug when it is used for another type of cancer if it is recognized as a cancer treatment in one of three sources (known as “off-label” drugs).

The bill also requires coverage for off-label drug use for FDA-approved drugs to treat other disabling, progressive, or life-threatening medical conditions. The drug must be recognized for the treatment of such a condition in the:

1. U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional,
2. American Medical Association’s Drug Evaluations, or
3. American Society of Hospital Pharmacists’ American Hospital Formulary Service Drug Information.

The bill specifies that it does not require coverage for experimental or investigational drugs or any drug that the FDA has determined to be contraindicated for the treatment of a specific disabling, progressive, or life-threatening medical condition. This is already law with respect to cancer drugs.

### **COMMITTEE ACTION**

Insurance and Real Estate Committee

Joint Favorable

Yea 10 Nay 9 (02/10/2011)