



General Assembly

January Session, 2011

Committee Bill No. 21

LCO No. 2304

02304SB00021INS

Referred to Committee on Insurance and Real Estate

Introduced by:
(INS)

**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 Section 38a-504a of the general statutes is repealed and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 Section 38a-504b of the general statutes is repealed and the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 | January 1, 2012 | 38a-542e |
| Sec. 13 | January 1, 2012 | 38a-542f |
| Sec. 14 | January 1, 2012 | 38a-542g |
| Sec. 15 | January 1, 2012 | 38a-492b |
| Sec. 16 | January 1, 2012 | 38a-518b |

Statement of Purpose:

To require individual and group health insurance coverage of routine patient costs associated with clinical trials for the treatment of disabling, progressive or life-threatening medical conditions.

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

Co-Sponsors: SEN. LOONEY, 11th Dist.

S.B. 21