



Senate

General Assembly

File No. 801

January Session, 2011

Substitute Senate Bill No. 21

Senate, May 16, 2011

The Committee on Appropriations reported through SEN. HARP of the 10th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

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

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

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 Section 38a-504a of the general statutes is repealed and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

3 Each individual health insurance policy providing coverage of the
4 type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-
5 469 delivered, issued for delivery, [or] renewed, amended or continued
6 in this state, [on or after January 1, 2002,] shall provide coverage for the
7 routine patient care costs, as defined in section 38a-504d, as amended
8 by this act, associated with [cancer] clinical trials, in accordance with
9 sections 38a-504b to 38a-504g, inclusive, as amended by this act. As
10 used in this section and sections 38a-504b to 38a-504g, inclusive, as
11 amended by this act: ["cancer clinical"] (1) "Clinical trial" means an
12 organized, systematic, scientific study of therapies, tests or other
13 clinical interventions for purposes of treatment or palliation or

14 therapeutic intervention for the prevention of [cancer in human beings,
15 except that a clinical trial for the prevention of cancer is eligible for
16 coverage only if it involves a therapeutic intervention and is a phase III
17 clinical trial approved by one of the entities identified in section 38a-
18 504b and is conducted at multiple institutions] disabling, progressive
19 or life-threatening medical conditions in human beings, and (2)
20 "disabling, progressive or life threatening medical conditions" means
21 cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral
22 sclerosis, acquired immunodeficiency syndrome or muscular
23 dystrophy.

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 Section 38a-504b of the general statutes is repealed and the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

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

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

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

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

84 (a) For purposes of sections 38a-504a to 38a-504g, inclusive, as
85 amended by this act, "routine patient care costs" means: (1) [Coverage
86 for medically] Medically necessary health care services that are
87 incurred as a result of the treatment being provided to the insured
88 person for purposes of the [cancer] clinical trial that would otherwise
89 be covered if such services were not rendered pursuant to a [cancer]
90 clinical trial. Such services shall include those rendered by a physician,
91 diagnostic or laboratory tests, hospitalization or other services
92 provided to the [patient] insured person during the course of
93 treatment in the [cancer] clinical trial for a condition, or one of its
94 complications, that is consistent with the usual and customary
95 standard of care and would be covered if the insured person were not
96 enrolled in a [cancer] clinical trial. Such hospitalization shall include
97 treatment at an out-of-network facility if such treatment is not
98 available in-network and not eligible for reimbursement by the
99 sponsors of such clinical trial, [;] and (2) [coverage for routine patient
100 care] costs incurred for drugs provided to the insured person, in
101 accordance with section [38a-518b] 38a-492b, as amended by this act,
102 provided such drugs have been approved for sale by the federal Food
103 and Drug Administration.

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

116 (c) Notwithstanding the provisions of subsection (a) of this section,
117 routine patient care costs shall not include: (1) The cost of an
118 investigational new drug or device that has not been approved for
119 market for any indication by the federal Food and Drug
120 Administration; (2) the cost of a non-health-care service that an insured
121 person may be required to receive as a result of the treatment being
122 provided for the purposes of the [cancer] clinical trial; (3) facility,
123 ancillary, professional services and drug costs that are paid for by
124 grants or funding for the [cancer] clinical trial; (4) costs of services that
125 (A) are inconsistent with widely accepted and established regional or
126 national standards of care for a particular diagnosis, or (B) are
127 performed specifically to meet the requirements of the [cancer] clinical
128 trial; (5) costs that would not be covered under the insured person's
129 policy for noninvestigational treatments, including, but not limited to,
130 items excluded from coverage under the insured person's contract
131 with the insurer or health plan; and (6) transportation, lodging, food or
132 any other expenses associated with travel to or from a facility
133 providing the [cancer] clinical trial, for the insured person or any
134 family member or companion.

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

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

148 (b) Providers, hospitals, institutions and insured persons may

149 appeal a health plan's denials of payment for services only to the
150 extent permitted by the contract between the insurer or health care
151 center and the provider, hospital or institution.

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

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

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

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

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

181 (a) (1) For purposes of cancer clinical trials, the Insurance
182 Department, in cooperation with the Connecticut Oncology
183 Association, the American Cancer Society, the Connecticut Association
184 of Health Plans and Anthem Blue Cross of Connecticut, shall develop a
185 standardized form that all providers, hospitals and institutions shall
186 submit to the insurer or health care center when seeking to enroll an
187 insured person in a cancer clinical trial. An insurer or health care
188 center [may] shall not substitute any other approval request form for
189 the form developed by the department, except that any insurer or
190 health care center that has entered into an agreement to provide
191 coverage for cancer clinical trials approved pursuant to section 38a-
192 504g, as amended by this act, may use the form or process established
193 by such agreement.

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

209 (b) Any insurer or health care center that receives the department
210 form from a provider, hospital or institution seeking coverage for the
211 routine patient care costs of an insured person in a [cancer] clinical
212 trial shall approve or deny coverage for such services [within] not later
213 than five business days [of] after receiving such request and any other
214 reasonable supporting materials requested by the insurer or health

215 plan pursuant to section 38a-504c, as amended by this act, except that
216 an insurer or health care center that utilizes independent experts to
217 review such requests shall respond [within] not later than ten business
218 days after receiving such request and supporting materials. Requests
219 for coverage of phase III clinical trials for the prevention of cancer
220 pursuant to section [38a-504a] 38a-504b, as amended by this act, shall
221 be approved or denied [within] not later than fourteen business days
222 after receiving such request and supporting materials.

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

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

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

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

245 (b) Any such insurer or health care center shall report annually, in
246 writing, to the department that there have been no changes in the

247 policy as certified by the department. If there has been any change in
248 the policy, the insurer or health care center shall resubmit its policy for
249 certification by the department.

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

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

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

279 Sec. 9. Section 38a-542b of the general statutes is repealed and the

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

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

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

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

313 trial is likely to have a benefit for the insured person that is
314 commensurate with the risks of participation in the [cancer] clinical
315 trial to treat the person's condition; [and] (2) evidence that the
316 appropriate informed consent has been received from the insured
317 person; [and] (3) copies of any medical records, protocols, test results
318 or other clinical information used by the physician or institution
319 seeking to enroll the insured person in the [cancer] clinical trial; [and]
320 (4) a summary of the anticipated routine patient care costs in excess of
321 the costs for standard treatment; [and] (5) information from the
322 physician or institution seeking to enroll the insured person in the
323 clinical trial regarding those items, including any routine patient care
324 costs, that are eligible for reimbursement by an entity other than the
325 insurer or health care center, including the entity sponsoring the
326 clinical trial; and (6) any additional information that may be
327 reasonably required for the review of a request for coverage of the
328 [cancer] clinical trial. The health plan or insurer shall request any
329 additional information about a [cancer] clinical trial [within] not later
330 than five business days [of] after receiving a request for coverage from
331 an insured person or a physician seeking to enroll an insured person in
332 a [cancer] clinical trial. Nothing in sections 38a-542a to 38a-542g,
333 inclusive, as amended by this act, shall be construed to require the
334 insurer or health care center to provide coverage for routine patient
335 care costs that are eligible for reimbursement by an entity other than
336 the insurer, including the entity sponsoring the [cancer] clinical trial.

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

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

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

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

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

381 national standards of care for a particular diagnosis, or (B) are
382 performed specifically to meet the requirements of the [cancer] clinical
383 trial; (5) costs that would not be covered under the insured person's
384 policy for noninvestigational treatments, including, but not limited to,
385 items excluded from coverage under the insured person's contract
386 with the insurer or health plan; and (6) transportation, lodging, food or
387 any other expenses associated with travel to or from a facility
388 providing the [cancer] clinical trial, for the insured person or any
389 family member or companion.

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

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

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

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

412 (d) Providers, hospitals or institutions that do not have a contract

413 with the insurer or health care center to render covered routine patient
414 care services to insured persons as part of a [cancer] clinical trial [may]
415 shall not bill the insured person for the cost of any covered routine
416 patient care service.

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

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

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

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

446 coverage for cancer clinical trials approved pursuant to section 38a-
447 542g, as amended by this act, may use the form or process established
448 by such agreement.

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

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

478 (c) The insured, or the provider with the insured's written consent,

479 may appeal any denial of coverage for medical necessity to an external,
480 independent review pursuant to section 38a-478n. Such external
481 review shall be conducted by a properly qualified review agent whom
482 the department has determined does not have a conflict of interest
483 regarding the [cancer] clinical trial.

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

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

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

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

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

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

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

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

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

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

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

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

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

This act shall take effect as follows and shall amend the following sections:		
Section 1	January 1, 2012	38a-504a
Sec. 2	January 1, 2012	38a-504b

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

APP *Joint Favorable Subst.*

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:

Agency Affected	Fund-Effect	FY 12 \$	FY 13 \$
Comptroller Misc. Accounts (Fringe Benefits)	GF & TF- Cost	Potential	Potential

Note: GF=General Fund and TF= Transportation Fund

Municipal Impact:

Municipalities	Effect	FY 12 \$	FY 13 \$
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, self-insured health plans are exempt from state health mandates, however in previous self-funded arrangements the state has traditionally adopted all state mandates. To the extent the state continues this practice of voluntary mandate adoption, the following impacts are anticipated.

According to the state employee and retiree health plan, 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. The state employee and retiree health plan currently provides coverage for routine patient costs in association with cancer clinical trials. The bill expands this coverage to include multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, AIDS and muscular dystrophy. As it is not possible to determine which routine services or off label prescription drugs may or may not be provided and authorized for the diseases specified, the

fiscal impact to the state cannot be determined.

To the extent that fully insured municipalities do not provide coverage for routine care or off label prescriptions for insured participants in clinical trials for the diseases specified, there may be an increased cost to provide the coverage mandated. The coverage requirements may result in increased premium costs when municipalities enter into new health insurance contracts after January 1, 2012. Due to current federal law, municipalities with self-insured plans are exempt from state health insurance mandates.

The state employee health plan and many municipal health plans are recognized as “grandfathered” health plans under the Patient Protection and Affordable Care Act (PPACA)¹. 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 PPACA².

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 and off label prescriptions may or may not be provided and authorized for the diseases included in the bill. Those mandated services not currently covered will result in a cost to the state employee and retiree health plan and municipalities. The annualized ongoing fiscal impact

¹ 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)

² 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)

identified above would continue into the future subject to inflation.

The federal health care reform act requires that, effective 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 mechanism for the state to pay these costs has been established.

OLR Bill Analysis**sSB 21*****AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR ROUTINE PATIENT CARE COSTS FOR CERTAIN 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 certain disabling, progressive, or life-threatening medical conditions rather than cancer only.

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. Under the bill, “disabling, progressive, or life-threatening medical conditions” includes cancer, multiple sclerosis, Parkinson’s disease, amyotrophic lateral sclerosis, acquired immunodeficiency

syndrome (AIDS), and muscular dystrophy.

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 designated by the bill. It also makes eligible for coverage clinical trials for the designated 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, and 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 is 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 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 the designated 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 to 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

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 (known as "off-label" drugs) if it is recognized as a cancer treatment in one of three sources.

The bill also requires coverage for off-label drug use for FDA-approved drugs to treat the designated 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 covered by the bill. This is already law with respect to cancer drugs.

BACKGROUND

Legislative History

On April 27, the Senate referred the bill (File 15) to the Appropriations Committee, which favorably reported a substitute that limits insurance coverage for clinical trials to those for cancer, multiple sclerosis, Parkinson's disease, amyotrophic lateral sclerosis, AIDS, and muscular dystrophy, instead of all disabling, progressive, or life threatening conditions.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable

Yea 10 Nay 9 (02/10/2011)

Insurance and Real Estate Committee

Joint Favorable

Yea 19 Nay 0 (02/10/2011)

Appropriations Committee

Joint Favorable Substitute

Yea 34 Nay 20 (05/04/2011)