



House of Representatives

General Assembly

File No. 486

February Session, 2016

Substitute House Bill No. 5450

House of Representatives, April 6, 2016

The Committee on Public Health reported through REP. RITTER of the 1st Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING THE PALLIATIVE USE OF MARIJUANA.

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

1 Section 1. Section 21a-408 of the general statutes is repealed and the
2 following is substituted in lieu thereof (*Effective October 1, 2016*):

3 As used in [sections 21a-408] this section, sections 21a-408a to 21a-
4 408o, inclusive, as amended by this act, and sections 10 to 14, inclusive,
5 of this act, unless the context otherwise requires:

6 (1) "Cultivation" includes planting, propagating, cultivating,
7 growing and harvesting;

8 (2) "Debilitating medical condition" means (A) cancer, glaucoma,
9 positive status for human immunodeficiency virus or acquired
10 immune deficiency syndrome, Parkinson's disease, multiple sclerosis,
11 damage to the nervous tissue of the spinal cord with objective
12 neurological indication of intractable spasticity, epilepsy or
13 uncontrolled intractable seizure disorder, cachexia, wasting syndrome,

14 Crohn's disease, posttraumatic stress disorder, irreversible spinal cord
15 injury with objective neurological indication of intractable spasticity,
16 cerebral palsy, cystic fibrosis or terminal illness requiring end-of-life
17 care, except, if the qualifying patient is under eighteen years of age,
18 "debilitating medical condition" means terminal illness requiring end-
19 of-life care, irreversible spinal cord injury with objective neurological
20 indication of intractable spasticity, cerebral palsy, cystic fibrosis, severe
21 epilepsy or uncontrolled intractable seizure disorder, or (B) any
22 medical condition, medical treatment or disease approved for
23 qualifying patients by the Department of Consumer Protection
24 pursuant to regulations adopted under section 21a-408m;

25 (3) "Institutional animal care and use committee" means a
26 committee that oversees an organization's animal program, facilities
27 and procedures to ensure compliance with federal policies, guidelines
28 and principles related to the care and use of animals in research;

29 (4) "Institutional review board" means a specifically constituted
30 review body established or designated by an organization to protect
31 the rights and welfare of persons recruited to participate in biomedical,
32 behavioral or social science research;

33 (5) "Laboratory" means a laboratory located in the state that is
34 licensed to provide analysis of controlled substances pursuant to
35 section 21a-246 and section 10 of this act;

36 (6) "Laboratory employee" means a person who is (A) licensed as a
37 laboratory employee pursuant to section 10 of this act, or (B) holds a
38 temporary certificate of registration issued pursuant to section 10 of
39 this act;

40 [(3)] (7) "Licensed dispensary" or "dispensary" means a person who
41 is licensed as a dispensary pursuant to section 21a-408h, as amended
42 by this act;

43 [(4)] (8) "Licensed producer" or "producer" means a person who is
44 licensed as a producer pursuant to section 21a-408i;

45 [(5)] (9) "Marijuana" means marijuana, as defined in section 21a-240;

46 (10) "Nurse" means a person who is licensed as a nurse under
47 chapter 378;

48 [(6)] (11) "Palliative use" means the acquisition, distribution,
49 transfer, possession, use or transportation of marijuana or
50 paraphernalia relating to marijuana, including the transfer of
51 marijuana and paraphernalia relating to marijuana from the patient's
52 primary caregiver to the qualifying patient, to alleviate a qualifying
53 patient's symptoms of a debilitating medical condition or the effects of
54 such symptoms, but does not include any such use of marijuana by
55 any person other than the qualifying patient;

56 [(7)] (12) "Paraphernalia" means drug paraphernalia, as defined in
57 section 21a-240;

58 [(8)] (13) "Physician" means a person who is licensed as a physician
59 under chapter 370, but does not include a physician assistant, as
60 defined in section 20-12a;

61 [(9)] (14) "Primary caregiver" means a person, other than the
62 qualifying patient and the qualifying patient's physician, who is
63 eighteen years of age or older and has agreed to undertake
64 responsibility for managing the well-being of the qualifying patient
65 with respect to the palliative use of marijuana, provided (A) in the case
66 of a qualifying patient under eighteen years of age or otherwise
67 lacking legal capacity, such person shall be a parent, guardian or
68 person having legal custody of such qualifying patient, and (B) in the
69 case of a qualifying patient eighteen years of age or older lacking legal
70 capacity, the need for such person shall be evaluated by the qualifying
71 patient's physician and such need shall be documented in the written
72 certification;

73 [(10)] (15) "Qualifying patient" means a person who: [is eighteen
74 years of age or older, is] (A) Is a resident of Connecticut, [and] (B) has
75 been diagnosed by a physician as having a debilitating medical

76 condition, and (C) (i) is eighteen years of age or older, or (ii) has
77 written consent from a custodial parent, guardian or other person
78 having legal custody of such person that indicates that such person has
79 permission from such parent, guardian or other person for the
80 palliative use of marijuana for a debilitating medical condition and
81 that such parent, guardian or other person will (I) serve as a primary
82 caregiver for the qualifying patient, and (II) control the acquisition and
83 possession of marijuana and any related paraphernalia for palliative
84 use on behalf of such person. "Qualifying patient" does not include an
85 inmate confined in a correctional institution or facility under the
86 supervision of the Department of Correction;

87 (16) "Research program" means a study approved by the
88 Department of Consumer Protection in accordance with this chapter
89 and undertaken to increase information or knowledge regarding the
90 growth, processing, medical attributes, dosage forms, administration
91 or use of marijuana to treat or alleviate symptoms of any medical
92 conditions or the effects of such symptoms;

93 (17) "Research program employee" means a person who (A) is
94 licensed as a research program employee under section 12 of this act,
95 or (B) holds a temporary certificate of registration issued pursuant to
96 section 12 of this act;

97 (18) "Research program subject" means a person registered as a
98 research program subject pursuant to section 14 of this act;

99 [(11)] (19) "Usable marijuana" means the dried leaves and flowers of
100 the marijuana plant, and any mixtures or preparations of such leaves
101 and flowers, that are appropriate for the palliative use of marijuana,
102 but does not include the seeds, stalks and roots of the marijuana plant;
103 and

104 [(12)] (20) "Written certification" means a written certification issued
105 by a physician pursuant to section 21a-408c, as amended by this act.

106 Sec. 2. Subsection (b) of section 21a-408a of the general statutes is

107 repealed and the following is substituted in lieu thereof (*Effective*
108 *October 1, 2016*):

109 (b) The provisions of subsection (a) of this section do not apply to:

110 (1) Any palliative use of marijuana that endangers the health or
111 well-being of a person other than the qualifying patient or the primary
112 caregiver; or

113 (2) The ingestion of marijuana (A) in a motor bus or a school bus or
114 in any other moving vehicle, (B) in the workplace, (C) on any school
115 grounds or any public or private school, dormitory, college or
116 university property, unless such college or university is participating
117 in a research program and such use is pursuant to the terms of the
118 research program, (D) in any public place, or (E) in the presence of a
119 person under the age of eighteen, unless such person is a qualifying
120 patient or research program subject. For the purposes of this
121 subdivision, (i) "presence" means within the direct line of sight of the
122 palliative use of marijuana or exposure to second-hand marijuana
123 smoke, or both; (ii) "public place" means any area that is used or held
124 out for use by the public whether owned or operated by public or
125 private interests; (iii) "vehicle" means a vehicle, as defined in section
126 14-1; (iv) "motor bus" means a motor bus, as defined in section 14-1;
127 and (v) "school bus" means a school bus, as defined in section 14-1.

128 Sec. 3. Section 21a-408b of the general statutes is repealed and the
129 following is substituted in lieu thereof (*Effective October 1, 2016*):

130 (a) No person may serve as a primary caregiver for a qualifying
131 patient (1) unless such qualifying patient has a valid registration
132 certificate from the Department of Consumer Protection pursuant to
133 subsection (a) of section 21a-408d, as amended by this act, and (2) if
134 such person has been convicted of a violation of any law pertaining to
135 the illegal manufacture, sale or distribution of a controlled substance.
136 A primary caregiver may not be responsible for the care of more than
137 one qualifying patient at any time, except that a primary caregiver may
138 be responsible for the care of more than one qualifying patient if the

139 primary caregiver and each qualifying patient have a parental,
140 guardianship, conservatorship or sibling relationship.

141 (b) A primary caregiver who has a valid registration certificate from
142 the Department of Consumer Protection pursuant to subsection (a) of
143 section 21a-408d, as amended by this act, and complies with the
144 requirements of sections 21a-408 to 21a-408n, inclusive, as amended by
145 this act, shall not be subject to arrest or prosecution, penalized in any
146 manner, including, but not limited to, being subject to any civil
147 penalty, or denied any right or privilege, including, but not limited to,
148 being subject to any disciplinary action by a professional licensing
149 board, for the acquisition, distribution, possession or transportation of
150 marijuana or paraphernalia related to marijuana on behalf of such
151 primary caregiver's qualifying patient, provided (1) the amount of any
152 marijuana so acquired, distributed, possessed or transported, together
153 with the combined amount of usable marijuana possessed by the
154 qualifying patient and the primary caregiver, does not exceed an
155 amount reasonably necessary to ensure uninterrupted availability for a
156 period of one month, as determined by the Department of Consumer
157 Protection pursuant to regulations adopted under section 21a-408m,
158 and (2) such amount is obtained solely within this state from a licensed
159 dispensary. Any person with a valid registration certificate who is
160 found to be in possession of marijuana that did not originate from the
161 selected dispensary may be subject to a hearing before the
162 commissioner for possible enforcement action concerning the
163 registration certificate issued by the department. For the purposes of
164 this subsection, "distribution" or "distributed" means the transfer of
165 marijuana and paraphernalia related to marijuana from the primary
166 caregiver to the qualifying patient.

167 (c) A dispensary shall not dispense any marijuana product in a
168 smokable, inhalable or vaporizable form to a primary caregiver for a
169 qualifying patient who is under eighteen years of age.

170 Sec. 4. Section 21a-408c of the general statutes is repealed and the
171 following is substituted in lieu thereof (*Effective October 1, 2016*):

172 (a) A physician may issue a written certification to a qualifying
173 patient that authorizes the palliative use of marijuana by the qualifying
174 patient. Such written certification shall be in the form prescribed by the
175 Department of Consumer Protection and shall include a statement
176 signed and dated by the qualifying patient's physician stating that, in
177 such physician's professional opinion, the qualifying patient has a
178 debilitating medical condition and the potential benefits of the
179 palliative use of marijuana would likely outweigh the health risks of
180 such use to the qualifying patient.

181 (b) Any written certification for the palliative use of marijuana
182 issued by a physician under subsection (a) of this section shall be valid
183 for a period not to exceed one year from the date such written
184 certification is signed and dated by the physician. Not later than ten
185 calendar days after the expiration of such period, or at any time before
186 the expiration of such period should the qualifying patient no longer
187 wish to possess marijuana for palliative use, the qualifying patient or
188 the primary caregiver shall destroy all usable marijuana possessed by
189 the qualifying patient and the primary caregiver for palliative use.

190 (c) A physician shall not be subject to arrest or prosecution,
191 penalized in any manner, including, but not limited to, being subject to
192 any civil penalty, or denied any right or privilege, including, but not
193 limited to, being subject to any disciplinary action by the Connecticut
194 Medical Examining Board or other professional licensing board, for
195 providing a written certification for the palliative use of marijuana
196 under subdivision (1) of subsection (a) of section 21a-408a if:

197 (1) The physician has diagnosed the qualifying patient as having a
198 debilitating medical condition;

199 (2) The physician has explained the potential risks and benefits of
200 the palliative use of marijuana to the qualifying patient and, if the
201 qualifying patient lacks legal capacity, to a parent, guardian or person
202 having legal custody of the qualifying patient;

203 (3) The written certification issued by the physician is based upon

204 the physician's professional opinion after having completed a
205 medically reasonable assessment of the qualifying patient's medical
206 history and current medical condition made in the course of a bona
207 fide physician-patient relationship; and

208 (4) The physician has no financial interest in a dispensary licensed
209 under section 21a-408h, as amended by this act, or a producer licensed
210 under section 21a-408i.

211 (d) A nurse shall not be subject to arrest or prosecution, penalized in
212 any manner, including, but not limited to, being subject to any civil
213 penalty, or denied any right or privilege, including, but not limited to,
214 being subject to any disciplinary action by the Board of Examiners for
215 Nursing, or other professional licensing board, for administering
216 marijuana to a qualifying patient or research program subject in a
217 hospital or health care facility licensed by the Department of Public
218 Health.

219 Sec. 5. Section 21a-408d of the 2016 supplement to the general
220 statutes is repealed and the following is substituted in lieu thereof
221 (*Effective October 1, 2016*):

222 (a) Each qualifying patient who is issued a written certification for
223 the palliative use of marijuana under subdivision (1) of subsection (a)
224 of section 21a-408a, and the primary caregiver of such qualifying
225 patient, shall register with the Department of Consumer Protection.
226 Such registration shall be effective from the date the Department of
227 Consumer Protection issues a certificate of registration until the
228 expiration of the written certification issued by the physician. The
229 qualifying patient and the primary caregiver shall provide sufficient
230 identifying information, as determined by the department, to establish
231 the personal identity of the qualifying patient and the primary
232 caregiver. If the qualifying patient is under eighteen years of age, the
233 custodial parent, guardian or other person having legal custody of the
234 qualifying patient shall also provide a letter from both the qualifying
235 patient's primary care provider and a physician who is board certified
236 in an area of medicine involved in the treatment of the debilitating

237 condition for which the qualifying patient was certified that confirms
238 that the palliative use of marijuana is in the best interest of the
239 qualifying patient. A physician may issue a written certification for the
240 palliative use of marijuana by a qualifying patient who is under
241 eighteen years of age, provided such written certification shall not be
242 for marijuana in a dosage form that requires that the marijuana be
243 smoked, inhaled or vaporized. The qualifying patient or the primary
244 caregiver shall report any change in [such] the identifying information
245 to the department not later than five business days after such change.
246 The department shall issue a registration certificate to the qualifying
247 patient and to the primary caregiver and may charge a reasonable fee,
248 not to exceed twenty-five dollars, for each registration certificate
249 issued under this subsection. Any registration fees collected by the
250 department under this subsection shall be paid to the State Treasurer
251 and credited to the General Fund.

252 (b) The qualifying patient, or, if the qualifying patient is under
253 eighteen years of age, the custodial parent, guardian or other person
254 having legal custody of the qualifying patient, shall select a licensed,
255 in-state dispensary to obtain the palliative marijuana products at the
256 time of registration. Upon the issuance of the certificate of registration
257 by the department, the qualifying patient, or the qualifying patient's
258 custodial parent, guardian or other person having legal custody of the
259 qualifying patient, shall purchase such palliative marijuana products
260 from such dispensary, except that the qualifying patient, or the
261 qualifying patient's custodial parent, guardian or other person having
262 legal custody of the qualifying patient, may change such dispensary in
263 accordance with regulations adopted by the department. Any person
264 with a valid registration certificate who is found to be in possession of
265 marijuana that did not originate from the selected dispensary may be
266 subject to hearing before the commissioner for possible enforcement
267 action concerning the registration certificate issued by the department.

268 (c) A dispensary shall not dispense any marijuana products in a
269 smokable, inhalable or vaporizable form to a qualifying patient who is
270 under eighteen years of age.

271 [(b)] (d) Information obtained under this section shall be
272 confidential and shall not be subject to disclosure under the Freedom
273 of Information Act, as defined in section 1-200, except that reasonable
274 access to registry information obtained under this section and
275 temporary registration information obtained under section 21a-408n,
276 as amended by this act, shall be provided to: (1) State agencies, federal
277 agencies and local law enforcement agencies for the purpose of
278 investigating or prosecuting a violation of law; (2) physicians and
279 pharmacists for the purpose of providing patient care and drug
280 therapy management and monitoring controlled substances obtained
281 by the qualifying patient; (3) public or private entities for research or
282 educational purposes, provided no individually identifiable health
283 information may be disclosed; (4) a licensed dispensary for the
284 purpose of complying with sections 21a-408 to 21a-408n, inclusive, as
285 amended by this act; (5) a qualifying patient, but only with respect to
286 information related to such qualifying patient or such qualifying
287 patient's primary caregiver; or (6) a primary caregiver, but only with
288 respect to information related to such primary caregiver's qualifying
289 patient.

290 Sec. 6. Section 21a-408h of the 2016 supplement to the general
291 statutes is amended by adding subsection (d) as follows (*Effective*
292 *October 1, 2016*):

293 (NEW) (d) On or before January 1, 2017, and annually thereafter,
294 each licensed dispensary shall report data to the Department of
295 Consumer Protection relating to the types, mixtures and dosages of
296 palliative marijuana dispensed by such dispensary. A report prepared
297 pursuant to this subsection shall be in such form as may be prescribed
298 by the Commissioner of Consumer Protection.

299 Sec. 7. Subsection (a) of section 21a-408j of the general statutes is
300 repealed and the following is substituted in lieu thereof (*Effective*
301 *October 1, 2016*):

302 (a) No licensed dispensary or employee of the dispensary may: (1)
303 Acquire marijuana from a person other than a licensed producer; (2)

304 distribute or dispense marijuana to a person who is not (A) a
305 qualifying patient registered under section 21a-408d, as amended by
306 this act, or 21a-408n, as amended by this act; [or] (B) a primary
307 caregiver of such qualifying patient; (C) a hospice or other inpatient
308 care facility licensed by the Department of Public Health pursuant to
309 chapter 368v that has protocol for the handling and distribution of
310 marijuana that has been approved by the Department of Consumer
311 Protection; (D) a laboratory; and (E) an organization engaged in a
312 research program; or (3) obtain or transport marijuana outside of this
313 state in violation of state or federal law.

314 Sec. 8. Subsection (a) of section 21a-408k of the general statutes is
315 repealed and the following is substituted in lieu thereof (*Effective*
316 *October 1, 2016*):

317 (a) No licensed producer or employee of the producer may: (1) Sell,
318 deliver, transport or distribute marijuana to a person who is not (A) a
319 licensed dispensary, (B) a laboratory, or (C) an organization engaged in
320 a research program, or (2) obtain or transport marijuana outside of this
321 state in violation of state or federal law.

322 Sec. 9. Section 21a-408l of the general statutes is repealed and the
323 following is substituted in lieu thereof (*Effective October 1, 2016*):

324 (a) The Commissioner of Consumer Protection shall establish a
325 Board of Physicians consisting of eight physicians or surgeons who are
326 knowledgeable about the palliative use of marijuana and certified by
327 the appropriate American board [in one of the following specialties:
328 Neurology, pain medicine, pain management, medical oncology,
329 psychiatry, infectious disease, family medicine or gynecology] in the
330 medical specialty in which they practice, at least one of whom shall be
331 a board certified pediatrician appointed in consultation with the
332 Connecticut Chapter of the American Academy of Pediatrics. Four of
333 the members of the board first appointed shall serve for a term of three
334 years and four of the members of the board first appointed shall serve
335 for a term of four years. Thereafter, members of the board shall serve
336 for a term of four years and shall be eligible for reappointment. Any

337 member of the board may serve until a successor is appointed. The
338 Commissioner of Consumer Protection shall serve as an ex-officio
339 member of the board, and shall select a chairperson from among the
340 members of the board.

341 (b) A quorum of the Board of Physicians shall consist of [~~three~~] four
342 members.

343 (c) The Board of Physicians shall:

344 (1) Review and recommend to the Department of Consumer
345 Protection for approval the debilitating medical conditions, medical
346 treatments or diseases to be added to the list of debilitating medical
347 conditions that qualify for the palliative use of marijuana for
348 qualifying patients eighteen years of age or older;

349 (2) Review and recommend to the Department of Consumer
350 Protection for approval any illnesses that are severely debilitating, as
351 defined in 21 CFR 312.81(b), to be added to the list of debilitating
352 medical conditions that qualify for the palliative use of marijuana for
353 qualifying patients under eighteen years of age, taking into account,
354 among other things, the effect of the palliative use of marijuana on the
355 brain development of such patients;

356 ~~[(2)]~~ (3) Accept and review petitions to add medical conditions,
357 medical treatments or diseases to the list of debilitating medical
358 conditions that qualify for the palliative use of marijuana;

359 ~~[(3)]~~ (4) Convene at least twice per year to conduct public hearings
360 and to evaluate petitions, which shall be maintained as confidential
361 pursuant to subsection (d) of this section, for the purpose of adding
362 medical conditions, medical treatments or diseases to the list of
363 debilitating medical conditions that qualify for the palliative use of
364 marijuana;

365 ~~[(4)]~~ (5) Review and recommend to the Department of Consumer
366 Protection protocols for determining the amounts of marijuana that
367 may be reasonably necessary to ensure uninterrupted availability for a

368 period of one month for qualifying patients, including amounts for
369 topical treatments; and

370 [(5)] (6) Perform other duties related to the palliative use of
371 marijuana upon the request of the Commissioner of Consumer
372 Protection.

373 (d) Any individually identifiable health information contained in a
374 petition received under this section shall be confidential and shall not
375 be subject to disclosure under the Freedom of Information Act, as
376 defined in section 1-200.

377 Sec. 10. (NEW) (*Effective October 1, 2016*) (a) Except as provided in
378 subsection (b) of this section, no person may act as a laboratory
379 employee or represent that such person is a licensed laboratory
380 employee unless such person has obtained a license from the
381 Commissioner of Consumer Protection pursuant to this section.

382 (b) Prior to the effective date of regulations adopted under this
383 section, the Commissioner of Consumer Protection may issue a
384 temporary certificate of registration to a laboratory employee. The
385 commissioner shall prescribe the standards, procedures and fees for
386 obtaining a temporary certificate of registration as a laboratory
387 employee.

388 (c) The Commissioner of Consumer Protection shall adopt
389 regulations, in accordance with chapter 54 of the general statutes, to (1)
390 provide for the licensure of laboratories and laboratory employees, (2)
391 establish standards and procedures for the revocation, suspension,
392 summary suspension and nonrenewal of laboratory and laboratory
393 employee licenses, provided such standards and procedures are
394 consistent with the provisions of subsection (c) of section 4-182 of the
395 general statutes, (3) establish a license and renewal fee for each
396 licensed laboratory and licensed laboratory employee, provided the
397 aggregate amount of such license and renewal fees shall not be less
398 than the amount necessary to cover the direct and indirect cost of
399 licensing and regulating laboratories and laboratory employees in

400 accordance with the provisions of chapter 420f of the general statutes,
401 and (4) establish other licensing, renewal and operational standards
402 deemed necessary by the commissioner.

403 (d) Any fees collected by the Department of Consumer Protection
404 under this section shall be paid to the State Treasurer and credited to
405 the General Fund.

406 Sec. 11. (NEW) (*Effective October 1, 2016*) (a) No laboratory employee
407 may (1) acquire marijuana from a person other than a licensed
408 producer, licensed dispensary or organization engaged in a research
409 program, (2) deliver, transport or distribute marijuana to (A) a person
410 who is not a licensed dispensary, (B) a person who is not a licensed
411 producer, or (C) an organization not engaged in a research program, or
412 (3) obtain or transport marijuana outside of this state in violation of
413 state or federal law.

414 (b) (1) No laboratory employee acting within the scope of his or her
415 employment shall be subject to arrest or prosecution, penalized in any
416 manner, including, but not limited to, being subject to any civil
417 penalty, or denied any right or privilege, including, but not limited to,
418 being subject to any disciplinary action by a professional licensing
419 board, for acquiring, possessing, delivering, transporting or
420 distributing marijuana to a licensed dispensary, a licensed producer or
421 an organization engaged in an approved research program under the
422 provisions of chapter 420f of the general statutes.

423 (2) No laboratory shall be subject to prosecution, penalized in any
424 manner, including, but not limited to, being subject to any civil penalty
425 or denied any right or privilege, for acquiring, possessing, delivering,
426 transporting or distributing marijuana to a licensed dispensary, a
427 licensed producer or an organization engaged in an approved research
428 program under the provisions of chapter 420f of the general statutes.

429 Sec. 12. (NEW) (*Effective October 1, 2016*) (a) The Commissioner of
430 Consumer Protection may approve a research program if such research
431 program will (1) be administered or overseen by (A) a hospital or

432 health care facility licensed by the Connecticut Department of Public
433 Health pursuant to chapter 368v of the general statutes, (B) an
434 institution of higher education, as defined in section 10a-55 of the
435 general statutes, (C) a licensed producer, or (D) a licensed dispensary,
436 and (2) have institutional review board oversight and, if the research
437 program involves the use of animals, have an institutional animal care
438 and use committee.

439 (b) Except as provided in subsection (c) of this section, no person
440 may act as a research program employee or represent that such person
441 is a licensed research program employee unless such person has
442 obtained a license from the Commissioner of Consumer Protection
443 pursuant to this section.

444 (c) Prior to the effective date of regulations adopted under this
445 section, the Commissioner of Consumer Protection may issue a
446 temporary certificate of registration to a research program employee.
447 The commissioner shall prescribe the standards, procedures and fees
448 for obtaining a temporary certificate of registration as a research
449 program employee.

450 (d) The Commissioner of Consumer Protection shall adopt
451 regulations, in accordance with chapter 54 of the general statutes, to (1)
452 provide for the approval of research programs and licensure of
453 research program employees, (2) establish standards and procedures
454 for the termination or suspension of a research program, (3) establish
455 standards and procedures for the revocation, suspension, summary
456 suspension and nonrenewal of a research program employee license,
457 provided such standards and procedures are consistent with the
458 provisions of subsection (c) of section 4-182 of the general statutes, (4)
459 establish a (A) fee for research program review and approval, and (B)
460 license and renewal fee for each research program employee, provided
461 the aggregate amount of such fees shall not be less than the amount
462 necessary to cover the direct and indirect cost of approving research
463 programs and licensing and regulating research program employees
464 pursuant to the provisions of chapter 420f of the general statutes, and

465 (5) establish other licensing, renewal and operational standards
466 deemed necessary by the commissioner.

467 (e) Any fees collected by the Department of Consumer Protection
468 under this section shall be paid to the State Treasurer and credited to
469 the General Fund.

470 Sec. 13. (NEW) (*Effective October 1, 2016*) (a) No research program or
471 research program employee may (1) acquire marijuana from a person
472 other than a licensed producer, licensed dispensary or laboratory, (2)
473 deliver, transport or distribute marijuana to a person who is not (A) a
474 licensed dispensary, (B) a licensed producer, or (C) a research program
475 subject, (3) distribute or administer marijuana to an animal unless such
476 animal is an animal research subject, or (4) obtain or transport
477 marijuana outside of this state in violation of state or federal law.

478 (b) No research program employee acting within the scope of his or
479 her employment shall be subject to arrest or prosecution, penalized in
480 any manner, including, but not limited to, being subject to any civil
481 penalty, or denied any right or privilege, including, but not limited to,
482 being subject to any disciplinary action by a professional licensing
483 board, for acquiring, possessing, delivering, transporting or
484 distributing marijuana to a licensed dispensary, a licensed producer or
485 a research program subject or distributing or administering marijuana
486 to an animal research subject under the provisions of chapter 420f of
487 the general statutes.

488 Sec. 14. (NEW) (*Effective October 1, 2016*) (a) Any person seeking to
489 participate as a research program subject shall register with the
490 Department of Consumer Protection prior to participating in an
491 approved research program. The Commissioner of Consumer
492 Protection shall prescribe the standards and procedures for obtaining a
493 certificate of registration as a research program subject.

494 (b) A research program subject who has a valid registration
495 certificate from the Department of Consumer Protection and is acting
496 within the scope of his or her involvement in an approved research

497 program shall not be subject to arrest or prosecution, penalized in any
498 manner, including, but not limited to, being subject to any civil penalty
499 or denied any right or privilege, including, but not limited to, being
500 subject to any disciplinary action by a professional licensing board, for
501 the use of marijuana.

502 (c) The provisions of subsection (b) of this section do not apply to:

503 (1) Any use of marijuana that endangers the health or well-being of
504 a person other than the research program subject or a research
505 program employee; or

506 (2) The ingestion of marijuana (A) in a motor bus or a school bus or
507 in any other moving vehicle, (B) in the workplace, (C) on any school
508 grounds or any public or private school, dormitory, college or
509 university property unless such college or university is participating in
510 a research program and such use is pursuant to the terms of the
511 research program, (D) in any public place, or (E) in the presence of a
512 person under eighteen years of age unless such person is a qualifying
513 patient or research program subject. For purposes of this subdivision,
514 (i) "presence" means within the direct line of sight of the palliative use
515 of marijuana or exposure to second-hand marijuana smoke, or both; (ii)
516 "public place" means any area that is used or held out for use by the
517 public, whether owned or operated by public or private interests; (iii)
518 "vehicle" means a vehicle, as defined in section 14-1 of the general
519 statutes; (iv) "motor bus" means a motor bus, as defined in section 14-1
520 of the general statutes; and (v) "school bus" means a school bus, as
521 defined in section 14-1 of the general statutes.

522 (d) Information obtained under this section shall be confidential and
523 shall not be subject to disclosure under the Freedom of Information
524 Act, as defined in section 1-200 of the general statutes, except that
525 reasonable access to registry information obtained under this section
526 shall be provided to (1) state agencies, federal agencies and local law
527 enforcement agencies for the purpose of investigating or prosecuting a
528 violation of law, (2) physicians and pharmacists for the purpose of
529 providing patient care and drug therapy management and monitoring

530 controlled substances obtained by the research program subject, (3)
 531 public or private entities for research or educational purposes,
 532 provided no individually identifiable health information may be
 533 disclosed, (4) a licensed dispensary for the purpose of complying with
 534 sections 21a-408 to 21a-408n, inclusive, of the general statutes, as
 535 amended by this act, or (5) a research program subject, but only with
 536 respect to information related to such research program subject.

537 Sec. 15. Subsection (a) of section 21a-408n of the general statutes is
 538 repealed and the following is substituted in lieu thereof (*Effective*
 539 *October 1, 2016*):

540 (a) During the period beginning on October 1, 2012, and ending
 541 thirty calendar days after the effective date of regulations adopted
 542 pursuant to section 21a-408m, a qualifying patient who would be
 543 determined to be eligible for a registration certificate pursuant to
 544 subsection (a) of section 21a-408d, as amended by this act, except for
 545 the lack of effective regulations concerning licensed dispensaries,
 546 licensed producers, distribution systems and amounts of marijuana,
 547 may obtain a written certification from a physician and upon
 548 presenting the written certification to the Department of Consumer
 549 Protection, the department shall issue a temporary registration
 550 certificate for the palliative use of marijuana. The department shall
 551 indicate on such temporary registration certificate the amount of
 552 usable marijuana that constitutes a one month supply which may be
 553 possessed pursuant to such temporary registration certificate. The
 554 department shall maintain a list of all temporary registration
 555 certificates issued pursuant to this section and the information on such
 556 list shall be confidential and shall not be subject to disclosure under the
 557 Freedom of Information Act, as defined in section 1-200, except that
 558 such information may be disclosed in the manner set forth in
 559 subsection [(b)] (d) of section 21a-408d, as amended by this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2016</i>	21a-408

Sec. 2	October 1, 2016	21a-408a(b)
Sec. 3	October 1, 2016	21a-408b
Sec. 4	October 1, 2016	21a-408c
Sec. 5	October 1, 2016	21a-408d
Sec. 6	October 1, 2016	21a-408h
Sec. 7	October 1, 2016	21a-408j(a)
Sec. 8	October 1, 2016	21a-408k(a)
Sec. 9	October 1, 2016	21a-408l
Sec. 10	October 1, 2016	New section
Sec. 11	October 1, 2016	New section
Sec. 12	October 1, 2016	New section
Sec. 13	October 1, 2016	New section
Sec. 14	October 1, 2016	New section
Sec. 15	October 1, 2016	21a-408n(a)

Statement of Legislative Commissioners:

In Sections 3(b) and (c) and 5(b) and (c), "facility" was deleted after "dispensary" for consistency with the defined term in Section 1; in Sections 5(b) and 9(c), "qualifying" was inserted before "patient" for consistency with other provisions of the section and the defined term in Section 1; and Section 11(b) was divided into two subdivisions for clarity and accuracy.

PH *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 17 \$	FY 18 \$
Resources of the General Fund	GF - Revenue Gain	Less than 10,000	Less than 10,000

Note: GF=General Fund

Municipal Impact: None

Explanation

The bill results in a revenue gain of less than \$10,000 in FY 17 and FY 18 by allowing minors to be qualifying patients for the palliative marijuana program. It is estimated that fewer than 100 minors would participate in the program.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to the number of minors participating in the program.

OLR Bill Analysis

sHB 5450

AN ACT CONCERNING THE PALLIATIVE USE OF MARIJUANA.

SUMMARY:

This bill makes various changes to the state's medical marijuana program, which the Department of Consumer Protection (DCP) administers. Among other things, the bill:

1. allows minors to be qualifying patients, subject to certain additional requirements and limitations beyond those that apply for adults;
2. adds to the list of qualifying debilitating conditions for adults;
3. requires patients to select a dispensary from which they will purchase marijuana, and subjects patients to a possible enforcement hearing if they possess marijuana obtained from another source;
4. allows dispensaries to distribute marijuana to hospices and other inpatient care facilities that have protocols for handling and distributing marijuana;
5. specifically allows nurses to administer marijuana in licensed health care facilities;
6. allows the DCP commissioner to approve medical marijuana research programs, requires him to adopt regulations on licensing research program employees and related matters, and requires research program subjects to register with the department;
7. requires the DCP commissioner to adopt regulations on

licensing marijuana laboratories and laboratory employees;

8. makes changes to qualifications of and other matters concerning the medical marijuana board; and
9. requires dispensaries to report annually to DCP.

The bill also makes technical and conforming changes.

EFFECTIVE DATE: October 1, 2016

§§ 1-3 & 5 — MINORS AS QUALIFYING PATIENTS

Under current law, only state residents age 18 or older may be qualifying medical marijuana patients. The bill extends the program to state residents under age 18. As under current law, inmates are ineligible. (While the law refers to “palliative” rather than “medical” marijuana use, the program is generally referred to as the medical marijuana program.)

As is the case for adult patients under existing law, before using marijuana for medical purposes, minors must have a written certification by a physician who determined, among other things, that the patient has a qualifying debilitating medical condition (see below). Patients, and their primary caregivers, must register with DCP and pay certain fees.

The bill creates additional requirements that must be met for minors to qualify (see below).

Current law prohibits the use of medical marijuana in the presence of minors. The bill creates an exception if the minor is a qualifying patient or research program subject.

Written Consent by Parent or Person with Legal Custody

To qualify for medical marijuana use, a minor must have written consent from a custodial parent, guardian, or other person with legal custody, indicating that the person has given permission for the minor to use marijuana for a debilitating condition.

The written consent must also state that the person will (1) serve as the minor's primary caregiver and (2) control the acquisition and possession of marijuana and any related paraphernalia on the minor's behalf.

By law, a medical marijuana patient's primary caregiver is someone at least age 18, other than the patient or the patient's physician, who agrees to take responsibility for managing the patient's well-being with respect to palliative marijuana use. Someone convicted of illegally making, selling, or distributing controlled substances cannot serve as a primary caregiver (CGS § 21a-408b).

Letter from Two Physicians

Under the bill, if the qualifying patient is a minor, the person with legal custody must provide DCP with a letter from the minor's primary care provider and a physician board certified in an area involved in the treatment of the minor's debilitating condition. The letter must confirm that the palliative use of marijuana is in the patient's best interest.

Qualifying Debilitating Conditions and Form of Marijuana

The bill allows a minor to use marijuana for:

1. a terminal illness requiring end-of-life care;
2. an irreversible spinal cord injury with objective neurological indication of intractable spasticity;
3. cerebral palsy;
4. cystic fibrosis;
5. severe epilepsy or uncontrolled intractable seizure disorder; or
6. any other medical condition, treatment, or disease that DCP approves through regulations.

The bill prohibits a dispensary from dispensing any marijuana

product in a smokable, inhalable, or vaporizable form to a (1) patient who is a minor or (2) primary caregiver of such a patient. It similarly prohibits a physician from issuing a written certification for a minor's marijuana use in a dosage form requiring that the marijuana be smoked, inhaled, or vaporized.

Other Existing Provisions

Otherwise, the bill applies the same program requirements and prohibitions when minors are patients as for adults under existing law and the bill. For example:

1. patients who comply with the law may not be arrested, prosecuted, or otherwise penalized, including being subject to civil penalties, or denied any right or privilege, including being disciplined by a professional licensing board, for the medical use of marijuana;
2. these protections do not apply if the patient ingests marijuana in certain settings, such as at work, at school, or in public;
3. schools, landlords, and employers are prohibited from taking certain actions against a medical marijuana patient or caregiver if solely based on the person's status as such, unless the actions are required by federal law or to obtain federal funding; and
4. health insurers are not required to cover medical marijuana use.

§ 1 — DEBILITATING CONDITIONS FOR ADULTS

The bill adds the following to the list of qualifying debilitating conditions for adult medical marijuana patients:

1. uncontrolled intractable seizure disorder (epilepsy is already a qualifying condition),
2. irreversible spinal cord injury with objective neurological indication of intractable spasticity,
3. cerebral palsy,

4. cystic fibrosis, and
5. terminal illness requiring end-of-life care.

§§ 3 & 5 — SOURCE OF MARIJUANA

Under the bill, when a qualifying medical marijuana patient registers with DCP, he or she must select a licensed, in-state dispensary from which to obtain his or her marijuana. If the patient is a minor, the requirement instead applies to the person with legal custody (presumably the “primary caregiver”).

After registering, patients (or primary caregivers of minors) may purchase marijuana only from the selected dispensary, unless they change their selection in accordance with DCP regulations.

If a registered medical marijuana patient or primary caregiver is found to possess marijuana that did not originate from the selected dispensary, he or she may be subject to a hearing before the DCP commissioner, on possible enforcement against the person’s registration certificate.

§§ 4 & 7 — MARIJUANA USE AT LICENSED HEALTH CARE FACILITIES

The bill allows licensed marijuana dispensaries or their employees to distribute or dispense marijuana to a hospice or other inpatient care facility licensed by the Department of Public Health (DPH). This applies only if the facility has a DCP-approved protocol for handling and distributing marijuana.

The bill extends legal protections to nurses who administer marijuana to qualifying patients or research program subjects in hospitals or health care facilities licensed by DPH. The protections are similar to those under existing law for physicians who issue written certifications for marijuana use as allowed by law.

Thus, under the bill, these nurses cannot be arrested, prosecuted, or otherwise penalized, including being subject to civil penalties, or denied any right or privilege, including being disciplined by the Board

of Examiners for Nursing or another professional licensing board, for administering marijuana as set forth above.

§§ 1-2, 7-8, & 12-14 — RESEARCH PROGRAMS

Under specified conditions, the bill allows the DCP commissioner to approve medical marijuana research programs (i.e., studies intended to increase knowledge of the growth, processing, medical attributes, dosage forms, administration, or use of marijuana to treat or alleviate symptoms of any medical condition or the symptoms' effects). As described below, it requires research program employees to be licensed by, and research program subjects to register with, DCP.

Program Approval

The bill allows the DCP commissioner to approve a marijuana research program if it will:

1. be administered or overseen by a DPH-licensed hospital or health care facility, a higher education institution, or a licensed producer or dispensary and
2. have institutional review board oversight.

Under the bill, an institutional review board is a specifically constituted review body established or designated by an organization to protect the rights and welfare of people recruited to participate in biomedical, behavioral, or social science research.

If the research will involve animals, the program also must have an institutional animal care and use committee. This is a committee overseeing an organization's animal program, facilities, and procedures to ensure compliance with federal policies, guidelines, and principles on animal research.

Research Programs, Employees, and Related Regulations

The bill requires the DCP commissioner to adopt regulations to:

1. provide for the approval of research programs and licensure of research program employees;

2. set standards and procedures for terminating or suspending research programs;
3. set standards and procedures for employee license revocation, suspension, summary suspension, and nonrenewal, consistent with Uniform Administrative Procedure Act provisions requiring agencies to give notice and an opportunity to show compliance before revoking or suspending a license, except for summary suspensions when emergency action is needed;
4. set fees for research program review and approval and employee licenses and license renewal, with the aggregate amount of fees at least covering the costs of program approval and the licensing and regulating of research employees under the medical marijuana law; and
5. establish other licensing, renewal, and operational standards the commissioner deems necessary.

Before the regulations take effect, the commissioner may issue temporary registration certificates to research program employees, and he must prescribe the standards, procedures, and fees for obtaining them. After the regulations take effect, no unlicensed person may act as a research program employee or represent that he or she is licensed as such.

The bill requires any such program approval, employee licensing, or temporary certificate fees to be paid to the state treasurer for deposit in the General Fund.

It allows licensed dispensaries or their employees to distribute or dispense marijuana to organizations engaged in approved research programs. It allows licensed producers or their employees to sell or otherwise distribute marijuana to these organizations.

Current law does not allow qualifying patients to ingest marijuana on college or university property. The bill creates an exception if the institution is participating in an approved research program and the

marijuana is used under the terms of that program.

Prohibited Acts and Legal Protections for Research Programs and Employees

The bill prohibits research programs, or their licensed or temporarily certified employees, from:

1. acquiring marijuana from anyone other than a licensed dispensary, producer, or laboratory;
2. delivering, transporting, or distributing marijuana to anyone other than licensed dispensaries or producers or research program subjects;
3. distributing or administering marijuana to animals who are not research subjects; and
4. obtaining or transporting marijuana outside of the state in violation of state or federal law.

The bill extends legal protections to licensed or temporarily certified research program employees who, when acting within the scope of their employment, (1) acquire, possess, deliver, transport, or distribute marijuana to a licensed dispensary or producer or research program subject or (2) distribute or administer marijuana to an animal research subject, under the medical marijuana law. They may not be arrested, prosecuted, or otherwise penalized, including being subject to civil penalties, or denied any right or privilege, including being disciplined by a professional licensing board, for these actions.

Research Program Subjects

The bill requires anyone seeking to participate as a research program subject to first register with DCP. The commissioner must prescribe registration standards and procedures.

The bill generally extends the legal protections noted above to a research program subject with a valid registration certificate, for the use of marijuana while acting within the scope of an approved

research program.

However, these protections do not apply to marijuana use in certain settings, similar to the restrictions on other medical marijuana users under existing law and the bill. Thus, the protections for research subjects do not apply if the person's marijuana use endangers the health or well-being of someone else, other than a research program employee. The protections also do not apply if the person ingests marijuana:

1. in a motor bus, school bus, or other moving vehicle;
2. at work;
3. on school grounds or any public or private school, dormitory, college, or university property, unless the college or university is participating in a research program and the marijuana use is part of that program;
4. in any public place; or
5. in the presence of a person under age 18 who is not a qualifying patient or research program subject.

Similar to existing law for qualifying patients, the bill provides that:

1. information on research program subject registration is generally confidential and not subject to disclosure under the Freedom of Information Act, but
2. DCP must give reasonable access to this information to certain people for specified purposes (e.g., local, state, and federal agencies for law enforcement purposes or physicians and pharmacists for treatment and monitoring purposes).

§§ 1, 7-8, & 10-11 — LABORATORIES AND LABORATORY EMPLOYEES

Existing law generally requires anyone operating a laboratory providing analysis of controlled substances to be licensed by DCP

(CGS § 21a-246). The bill requires the DCP commissioner to adopt regulations providing for the licensure of marijuana laboratories and laboratory employees.

The regulations must cover similar topics as those noted above for research programs and employees, such as (1) standards and procedures for disciplinary actions against licensees and (2) licensure and renewal fees that cover the cost of licensing and regulating laboratories and employees.

Under the bill, as with research programs and employees:

1. after the regulations take effect, no unlicensed person may act as a laboratory employee or represent that he or she is licensed as such;
2. before then, the commissioner may issue temporary registration certificates to laboratory employees, and must prescribe related standards, procedures, and fees; and
3. any fees for laboratory or laboratory employee licensing or renewal and temporary certificates must be paid to the state treasurer and be deposited in the General Fund.

The bill allows licensed marijuana dispensaries or their employees to distribute or dispense marijuana to these laboratories. It also allows licensed marijuana producers or their employees to sell or otherwise distribute marijuana to these laboratories.

Prohibited Acts and Legal Protections

The bill prohibits licensed or temporarily certified laboratory employees from acquiring marijuana from, or delivering, transporting, or distributing marijuana to, anyone other than licensed producers or dispensaries or organizations engaged in approved research programs. They also must not obtain or transport marijuana outside of the state in violation of state or federal law.

The bill extends the legal protections noted above for research

program employees to licensed or temporarily certified laboratory employees acting within the scope of their employment, when acquiring, possessing, delivering, transporting, or distributing marijuana to licensed dispensaries or producers or organizations engaged in an approved research program. It extends similar protections to licensed laboratories as applicable.

§ 9 — BOARD OF PHYSICIANS

By law, the DCP commissioner must establish a board of eight physicians knowledgeable about palliative marijuana use. The bill eliminates the requirement that physicians on the board be certified in one of certain listed specialties. It instead requires that (1) at least one member be a board certified pediatrician, appointed in consultation with the state chapter of the American Academy of Pediatrics, and (2) the other members be board certified in the medical specialty in which they practice.

One of the board's existing duties is to review and recommend to DCP additions to the list of debilitating conditions that qualify for medical marijuana use for adults. The bill additionally requires the board to review and recommend to DCP for approval any illnesses defined as severely debilitating in specified federal regulations, to be added to the list of qualifying debilitating conditions for minors. When doing so, the board must consider the effect of medical marijuana use on the brain development of patients who are minors. Under the federal regulation, a disease or condition is "severely debilitating" if it causes major irreversible morbidity (21 C.F.R. § 312.81(b)).

The bill also increases the members needed for a quorum, from three to four.

§ 6 — DISPENSARY ANNUAL REPORTING

The bill requires licensed dispensaries to annually report to DCP on the types, mixtures, and dosages of palliative marijuana they dispense. The first report is due by January 1, 2017. The DCP commissioner may prescribe the form for the reporting.

BACKGROUND

Related Bill

sSB 67, reported favorably by the Public Health Committee, extends to advanced practice registered nurses the same authority as physicians to certify patients for medical marijuana use, except for glaucoma.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea 22 Nay 6 (03/21/2016)