



House of Representatives

File No. 700

General Assembly

February Session, 2016

(Reprint of File No. 486)

Substitute House Bill No. 5450
As Amended by House Amendment
Schedule "A"

Approved by the Legislative Commissioner
April 21, 2016

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 Section 21a-408 of the general statutes is repealed and the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 (i) under eighteen years of age and not an
67 emancipated minor, or (ii) otherwise lacking legal capacity, such
68 person shall be a parent, guardian or person having legal custody of
69 such qualifying patient, and (B) in the case of a qualifying patient
70 eighteen years of age or older or an emancipated minor, the need for
71 such person shall be evaluated by the qualifying patient's physician
72 and such need shall be documented in the written 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, (ii) is an
77 emancipated minor, or (iii) has written consent from a custodial
78 parent, guardian or other person having legal custody of such person
79 that indicates that such person has permission from such parent,
80 guardian or other person for the palliative use of marijuana for a
81 debilitating medical condition and that such parent, guardian or other
82 person will (I) serve as a primary caregiver for the qualifying patient,
83 and (II) control the acquisition and possession of marijuana and any
84 related paraphernalia for palliative use on behalf of such person.
85 "Qualifying patient" does not include an inmate confined in a
86 correctional institution or facility under the supervision of the
87 Department of Correction;

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

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

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

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

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

107 Sec. 2. Subsection (b) of section 21a-408a of the general statutes is
108 repealed and the following is substituted in lieu thereof (*Effective*
109 *October 1, 2016*):

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

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

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

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

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

139 be responsible for the care of more than one qualifying patient if the
140 primary caregiver and each qualifying patient have a parental,
141 guardianship, conservatorship or sibling relationship.

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

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

171 Sec. 4. Section 21a-408c of the general statutes is repealed and the

172 following is substituted in lieu thereof (*Effective October 1, 2016*):

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

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

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

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

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

204 (3) The written certification issued by the physician is based upon
205 the physician's professional opinion after having completed a
206 medically reasonable assessment of the qualifying patient's medical
207 history and current medical condition made in the course of a bona
208 fide physician-patient relationship; and

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

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

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

223 (a) Each qualifying patient who is issued a written certification for
224 the palliative use of marijuana under subdivision (1) of subsection (a)
225 of section 21a-408a, and the primary caregiver of such qualifying
226 patient, shall register with the Department of Consumer Protection.
227 Such registration shall be effective from the date the Department of
228 Consumer Protection issues a certificate of registration until the
229 expiration of the written certification issued by the physician. The
230 qualifying patient and the primary caregiver shall provide sufficient
231 identifying information, as determined by the department, to establish
232 the personal identity of the qualifying patient and the primary
233 caregiver. If the qualifying patient is under eighteen years of age and
234 not an emancipated minor, the custodial parent, guardian or other
235 person having legal custody of the qualifying patient shall also

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

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

270 action concerning the registration certificate issued by the department.

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

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

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

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

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

305 (a) No licensed dispensary or employee of the dispensary may: (1)
306 Acquire marijuana from a person other than a licensed producer; (2)
307 distribute or dispense marijuana to a person who is not (A) a
308 qualifying patient registered under section 21a-408d, as amended by
309 this act, or 21a-408n, as amended by this act; [or] (B) a primary
310 caregiver of such qualifying patient; (C) a hospice or other inpatient
311 care facility licensed by the Department of Public Health pursuant to
312 chapter 368v that has protocol for the handling and distribution of
313 marijuana that has been approved by the Department of Consumer
314 Protection; (D) a laboratory; and (E) an organization engaged in a
315 research program; or (3) obtain or transport marijuana outside of this
316 state in violation of state or federal law.

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

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

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

327 (a) The Commissioner of Consumer Protection shall establish a
328 Board of Physicians consisting of eight physicians or surgeons who are
329 knowledgeable about the palliative use of marijuana and certified by
330 the appropriate American board [in one of the following specialties:
331 Neurology, pain medicine, pain management, medical oncology,
332 psychiatry, infectious disease, family medicine or gynecology] in the
333 medical specialty in which they practice, at least one of whom shall be

334 a board certified pediatrician appointed in consultation with the
335 Connecticut Chapter of the American Academy of Pediatrics. Four of
336 the members of the board first appointed shall serve for a term of three
337 years and four of the members of the board first appointed shall serve
338 for a term of four years. Thereafter, members of the board shall serve
339 for a term of four years and shall be eligible for reappointment. Any
340 member of the board may serve until a successor is appointed. The
341 Commissioner of Consumer Protection shall serve as an ex-officio
342 member of the board, and shall select a chairperson from among the
343 members of the board.

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

346 (c) The Board of Physicians shall:

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

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

359 ~~[(2)]~~ (3) Accept and review petitions to add medical conditions,
360 medical treatments or diseases to the list of debilitating medical
361 conditions that qualify for the palliative use of marijuana;

362 ~~[(3)]~~ (4) Convene at least twice per year to conduct public hearings
363 and to evaluate petitions, which shall be maintained as confidential
364 pursuant to subsection ~~[(d)]~~ (e) of this section, for the purpose of

365 adding medical conditions, medical treatments or diseases to the list of
366 debilitating medical conditions that qualify for the palliative use of
367 marijuana;

368 [(4)] (5) Review and recommend to the Department of Consumer
369 Protection protocols for determining the amounts of marijuana that
370 may be reasonably necessary to ensure uninterrupted availability for a
371 period of one month for qualifying patients, including amounts for
372 topical treatments; and

373 [(5)] (6) Perform other duties related to the palliative use of
374 marijuana upon the request of the Commissioner of Consumer
375 Protection.

376 (d) The Board of Physicians may review the list of debilitating
377 medical conditions that qualify for the palliative use of marijuana and
378 make recommendations to the joint standing committees of the
379 General Assembly having cognizance of matters relating to general
380 law and public health for the removal of a debilitating medical
381 condition, medical treatment or disease from such list.

382 [(d)] (e) Any individually identifiable health information contained
383 in a petition received under this section shall be confidential and shall
384 not be subject to disclosure under the Freedom of Information Act, as
385 defined in section 1-200.

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

391 (b) Prior to the effective date of regulations adopted under this
392 section, the Commissioner of Consumer Protection may issue a
393 temporary certificate of registration to a laboratory employee. The
394 commissioner shall prescribe the standards, procedures and fees for
395 obtaining a temporary certificate of registration as a laboratory

396 employee.

397 (c) The Commissioner of Consumer Protection shall adopt
398 regulations, in accordance with chapter 54 of the general statutes, to (1)
399 provide for the licensure of laboratories and laboratory employees, (2)
400 establish standards and procedures for the revocation, suspension,
401 summary suspension and nonrenewal of laboratory and laboratory
402 employee licenses, provided such standards and procedures are
403 consistent with the provisions of subsection (c) of section 4-182 of the
404 general statutes, (3) establish a license and renewal fee for each
405 licensed laboratory and licensed laboratory employee, provided the
406 aggregate amount of such license and renewal fees shall not be less
407 than the amount necessary to cover the direct and indirect cost of
408 licensing and regulating laboratories and laboratory employees in
409 accordance with the provisions of chapter 420f of the general statutes,
410 and (4) establish other licensing, renewal and operational standards
411 deemed necessary by the commissioner.

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

415 Sec. 11. (NEW) (*Effective October 1, 2016*) (a) No laboratory employee
416 may (1) acquire marijuana from a person other than a licensed
417 producer, licensed dispensary or organization engaged in a research
418 program, (2) deliver, transport or distribute marijuana to (A) a person
419 who is not a licensed dispensary, (B) a person who is not a licensed
420 producer, or (C) an organization not engaged in a research program, or
421 (3) obtain or transport marijuana outside of this state in violation of
422 state or federal law.

423 (b) (1) No laboratory employee acting within the scope of his or her
424 employment shall be subject to arrest or prosecution, penalized in any
425 manner, including, but not limited to, being subject to any civil
426 penalty, or denied any right or privilege, including, but not limited to,
427 being subject to any disciplinary action by a professional licensing

428 board, for acquiring, possessing, delivering, transporting or
429 distributing marijuana to a licensed dispensary, a licensed producer or
430 an organization engaged in an approved research program under the
431 provisions of chapter 420f of the general statutes.

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

438 Sec. 12. (NEW) (*Effective October 1, 2016*) (a) The Commissioner of
439 Consumer Protection may approve a research program if such research
440 program will (1) be administered or overseen by (A) a hospital or
441 health care facility licensed by the Connecticut Department of Public
442 Health pursuant to chapter 368v of the general statutes, (B) an
443 institution of higher education, as defined in section 10a-55 of the
444 general statutes, (C) a licensed producer, or (D) a licensed dispensary,
445 and (2) have institutional review board oversight and, if the research
446 program involves the use of animals, have an institutional animal care
447 and use committee.

448 (b) Except as provided in subsection (c) of this section, no person
449 may act as a research program employee or represent that such person
450 is a licensed research program employee unless such person has
451 obtained a license from the Commissioner of Consumer Protection
452 pursuant to this section.

453 (c) Prior to the effective date of regulations adopted under this
454 section, the Commissioner of Consumer Protection may issue a
455 temporary certificate of registration to a research program employee.
456 The commissioner shall prescribe the standards, procedures and fees
457 for obtaining a temporary certificate of registration as a research
458 program employee.

459 (d) The Commissioner of Consumer Protection shall adopt

460 regulations, in accordance with chapter 54 of the general statutes, to (1)
461 provide for the approval of research programs and licensure of
462 research program employees, (2) establish standards and procedures
463 for the termination or suspension of a research program, (3) establish
464 standards and procedures for the revocation, suspension, summary
465 suspension and nonrenewal of a research program employee license,
466 provided such standards and procedures are consistent with the
467 provisions of subsection (c) of section 4-182 of the general statutes, (4)
468 establish a (A) fee for research program review and approval, and (B)
469 license and renewal fee for each research program employee, provided
470 the aggregate amount of such fees shall not be less than the amount
471 necessary to cover the direct and indirect cost of approving research
472 programs and licensing and regulating research program employees
473 pursuant to the provisions of chapter 420f of the general statutes, and
474 (5) establish other licensing, renewal and operational standards
475 deemed necessary by the commissioner.

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

479 Sec. 13. (NEW) (*Effective October 1, 2016*) (a) No research program or
480 research program employee may (1) acquire marijuana from a person
481 other than a licensed producer, licensed dispensary or laboratory, (2)
482 deliver, transport or distribute marijuana to a person who is not (A) a
483 licensed dispensary, (B) a licensed producer, or (C) a research program
484 subject, (3) distribute or administer marijuana to an animal unless such
485 animal is an animal research subject, or (4) obtain or transport
486 marijuana outside of this state in violation of state or federal law.

487 (b) No research program employee acting within the scope of his or
488 her employment shall be subject to arrest or prosecution, penalized in
489 any manner, including, but not limited to, being subject to any civil
490 penalty, or denied any right or privilege, including, but not limited to,
491 being subject to any disciplinary action by a professional licensing
492 board, for acquiring, possessing, delivering, transporting or

493 distributing marijuana to a licensed dispensary, a licensed producer or
494 a research program subject or distributing or administering marijuana
495 to an animal research subject under the provisions of chapter 420f of
496 the general statutes.

497 Sec. 14. (NEW) (*Effective October 1, 2016*) (a) Any person seeking to
498 participate as a research program subject shall register with the
499 Department of Consumer Protection prior to participating in an
500 approved research program. The Commissioner of Consumer
501 Protection shall prescribe the standards and procedures for obtaining a
502 certificate of registration as a research program subject.

503 (b) A research program subject who has a valid registration
504 certificate from the Department of Consumer Protection and is acting
505 within the scope of his or her involvement in an approved research
506 program shall not be subject to arrest or prosecution, penalized in any
507 manner, including, but not limited to, being subject to any civil penalty
508 or denied any right or privilege, including, but not limited to, being
509 subject to any disciplinary action by a professional licensing board, for
510 the use of marijuana.

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

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

515 (2) The ingestion of marijuana (A) in a motor bus or a school bus or
516 in any other moving vehicle, (B) in the workplace, (C) on any school
517 grounds or any public or private school, dormitory, college or
518 university property unless such college or university is participating in
519 a research program and such use is pursuant to the terms of the
520 research program, (D) in any public place, or (E) in the presence of a
521 person under eighteen years of age unless such person is a qualifying
522 patient or research program subject. For purposes of this subdivision,
523 (i) "presence" means within the direct line of sight of the palliative use
524 of marijuana or exposure to second-hand marijuana smoke, or both; (ii)

525 "public place" means any area that is used or held out for use by the
526 public, whether owned or operated by public or private interests; (iii)
527 "vehicle" means a vehicle, as defined in section 14-1 of the general
528 statutes; (iv) "motor bus" means a motor bus, as defined in section 14-1
529 of the general statutes; and (v) "school bus" means a school bus, as
530 defined in section 14-1 of the general statutes.

531 (d) Information obtained under this section shall be confidential and
532 shall not be subject to disclosure under the Freedom of Information
533 Act, as defined in section 1-200 of the general statutes, except that
534 reasonable access to registry information obtained under this section
535 shall be provided to (1) state agencies, federal agencies and local law
536 enforcement agencies for the purpose of investigating or prosecuting a
537 violation of law, (2) physicians and pharmacists for the purpose of
538 providing patient care and drug therapy management and monitoring
539 controlled substances obtained by the research program subject, (3)
540 public or private entities for research or educational purposes,
541 provided no individually identifiable health information may be
542 disclosed, (4) a licensed dispensary for the purpose of complying with
543 sections 21a-408 to 21a-408n, inclusive, of the general statutes, as
544 amended by this act, or (5) a research program subject, but only with
545 respect to information related to such research program subject.

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

549 (a) During the period beginning on October 1, 2012, and ending
550 thirty calendar days after the effective date of regulations adopted
551 pursuant to section 21a-408m, a qualifying patient who would be
552 determined to be eligible for a registration certificate pursuant to
553 subsection (a) of section 21a-408d, as amended by this act, except for
554 the lack of effective regulations concerning licensed dispensaries,
555 licensed producers, distribution systems and amounts of marijuana,
556 may obtain a written certification from a physician and upon
557 presenting the written certification to the Department of Consumer

558 Protection, the department shall issue a temporary registration
 559 certificate for the palliative use of marijuana. The department shall
 560 indicate on such temporary registration certificate the amount of
 561 usable marijuana that constitutes a one month supply which may be
 562 possessed pursuant to such temporary registration certificate. The
 563 department shall maintain a list of all temporary registration
 564 certificates issued pursuant to this section and the information on such
 565 list shall be confidential and shall not be subject to disclosure under the
 566 Freedom of Information Act, as defined in section 1-200, except that
 567 such information may be disclosed in the manner set forth in
 568 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	<i>October 1, 2016</i>	21a-408a(b)
Sec. 3	<i>October 1, 2016</i>	21a-408b
Sec. 4	<i>October 1, 2016</i>	21a-408c
Sec. 5	<i>October 1, 2016</i>	21a-408d
Sec. 6	<i>October 1, 2016</i>	21a-408h
Sec. 7	<i>October 1, 2016</i>	21a-408j(a)
Sec. 8	<i>October 1, 2016</i>	21a-408k(a)
Sec. 9	<i>October 1, 2016</i>	21a-408l
Sec. 10	<i>October 1, 2016</i>	New section
Sec. 11	<i>October 1, 2016</i>	New section
Sec. 12	<i>October 1, 2016</i>	New section
Sec. 13	<i>October 1, 2016</i>	New section
Sec. 14	<i>October 1, 2016</i>	New section
Sec. 15	<i>October 1, 2016</i>	21a-408n(a)

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.

House "A" (LCO 4338) is technical and results in no fiscal impact.

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 (as amended by House "A")******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, including allowing the board to recommend that a medical condition, treatment, or disease be removed from the list of qualifying debilitating conditions; and
9. requires dispensaries to report annually to DCP.

The bill also makes technical and conforming changes.

*House Amendment "A" adds provisions (1) allowing the medical marijuana board to recommend that conditions be removed from the qualifying list, (2) specifying that certain requirements for minors apply only to unemancipated minors, and (3) making clarifying 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 unemancipated 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 and Agreement to Serve as Primary Caregiver

Under the bill, to qualify for medical marijuana use, an unemancipated 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).

Under current law, an adult medical marijuana patient's physician must evaluate the patient's need for a primary caregiver and document the need in the certification of palliative use. The bill also requires this for patients who are emancipated minors. (As noted above, for unemancipated minors, the bill requires a parent or other person with legal custody to serve as the primary caregiver.)

Letter from Two Physicians

Under the bill, if the qualifying patient is an unemancipated 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 an unemancipated minor, the requirement instead applies to the custodial parent, guardian, or other person with legal custody.

After registering, patients (or the person with legal custody of the patient) 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 person with legal custody 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 action 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. It also allows laboratory employees to deliver or 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.

The bill allows the board to review the list of qualifying debilitating medical conditions and make recommendations to the General Law and Public Health Committees for removing conditions, treatments, or diseases from the list.

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 (File 391), 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)

General Law Committee

Joint Favorable

Yea 10 Nay 3 (04/15/2016)