STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

August 7, 2018

Legislative Regulations Review Committee
Attn: Kirstin L. Breiner
Capitol Building, Room 011
Connecticut General Assembly
Hartford, Connecticut 06106

RE: Resubmittal of Proposed Regulation
2017-29 Department of Consumer Protection
Palliative Use of Marijuana

Dear Honorable Members of the Legislative Regulations Review Committee:

Pursuant to Section 4-170 of the Connecticut General Statutes, I resubmit for the Legislative Regulations Review Committee's ("LRRC") consideration and approval proposed regulation revisions concerning the Palliative Use of Marijuana. This is a resubmission of a package that was rejected without prejudice on July 24, 2018.

The proposed amendments to the regulations, authorized by Section 21a-408m of the Connecticut General Statutes, are being proposed to update the medical marijuana laws in accordance with legislative changes to Chapter 420f of the Connecticut General Statutes and add new debilitating conditions recommended by the Connecticut Board of Physicians and the Commissioner of Consumer Protection. Additionally, this revised regulation streamlines and provides additional public health safeguards for the medical marijuana program. In addition, pursuant to CGS Section 4-168(g) several technical amendments to the regulations were included to correct clerical errors in the existing regulations.

The attachment is a list of all of the Legislative Commissioner's Office comments to the regulation as proposed to the LRRC on July 24, 2018. The Department of Consumer Protection has made all of the changes that were indicated as technical and substantive changes recommended to the Department.

If you have any questions, please contact me via e- mail at Leslie.Obrien@ct.gov or by telephone at (860) 713-6208. I thank you in advance for your consideration.

Sincerely,

Leslie O'Brien
Legislative Director

Enclosures
cc: Commissioner Michelle Seagull

450 Columbus Boulevard, Suite 901, Hartford, Connecticut 06103-1840
General Information (860) 713-6100
Website: ct.gov/dcp

The Connecticut General Assembly

Legislative Commissioners' Office

Edwin J. Maley, Jr.
Commissioner
William A. Hamzy
Commissioner

Louise M. Nadeau
Director

Legislative Office Building
Suite 5500
Hartford, Connecticut
06106-1591
(860) 240-8410
fax (860) 240-8414
e-mail: lco@cga.ct.gov

Memorandum

To: Legislative Regulation Review Committee
From: Legislative Commissioners' Office
Committee Meeting Date: July 24, 2018

Regulation No:	2018-11
Agency:	Department of Consumer Protection
Subject Matter:	Palliative Use of Marijuana
Statutory Authority: (copy attached)	21a-408m, 21a-408r, 21a-408t

	Yes or No
Mandatory	Y
Federal Requirement	N
Permissive	N

For the Committee's Information:

Substantive Concerns:

1. On page 43, in section 21a-408-36(i), the agency is authorizing "members of the department, local law enforcement or other federal, state of Connecticut or local government officials" to enter any area of a dispensary facility "if necessary to perform their governmental duties." This provision is overly vague and it is beyond the authority of the agency to authorize other governmental agencies that do not already have that authority under some other provision of law to enter dispensary facilities. The current provision

appears to be a new authorization of authority, which is not within the authority of the agency to grant. Also, on page 63, in section 21a-408-55(f) and on page 76, in section 21a-408-63(i), the agency is using almost identical language regarding production facilities which present the same issues.

2. Throughout the proposed regulation, the agency refers to the "Act" as authority for various provisions, which is defined as sections 21a-408 to 21a-408q of the Connecticut General Statutes. Additional provisions have been added to the chapter concerning the palliative marijuana program regarding the licensing of laboratory and research program employees and the approval of research programs in sections 21a-408r to 21a-408t of the general statutes. The agency should determine which sections of the proposed regulation should be amended to incorporate the appropriate references to the newer statutory sections. For example, on page 34, in section 21a-408-32(b)(2), in the third line, it appears that "Act", should be "Act, sections 21a-408r and 21a-408t of the Connecticut General Statutes," and in the next to last line, "Act", should be "Act, sections 21a-408r to 21a-408v, inclusive, of the Connecticut General Statutes,".

Technical Corrections:

1. The introductory language used by the agency is inaccurate. The proposed regulation should be divided into three sections and rephrased as follows: For the first section, the introductory language should reference amending sections 21a-408-1 to 21a-480-18, inclusive, of the Regulations of Connecticut State Agencies, the second section should begin on page 21 and should cite to amending sections 21a-408-20 to 21a-480-70 of said regulations and the third section should begin on page 85 and cite to the addition of sections 21a-408-71 and 21a-408-72 to said regulations, for accuracy and proper form.

2. Throughout the proposed regulation, the text that is proposed to be deleted should be enclosed in brackets and the subsection or subdivision designators should not be bracketed separately. For example, on page 8, in section 21a-408-6(a), all of the brackets could be replaced with one opening bracket before "For" and one closing bracket after "safety.", in former subsection (a)(14), for proper form.

3. On page 1, in section 21a-408-1, "[As] Except as otherwise provided in this section, defined terms" should be "As" for clarity and ", shall have the meaning prescribed in section 21a-408 of the Connecticut General Statutes" should be deleted as unnecessary.

4. On page 2, in section 21a-408-1(13), the agency is redefining "commissioner" to include the commissioner's designee. Throughout the proposed regulation, the agency has used the phrase "the commissioner or the commissioner's authorized representative". The agency should either delete the reference to designee in the definition of commissioner or delete the references throughout the regulation to the commissioner's authorized representative as duplicative.

5. Throughout the proposed regulation, additional references to "APRN" or "APRN's" should be added for consistency in the following instances: On page 1, in section 21a-408-1(12), "or APRN" should be inserted after the two references to "physician", for consistency. The same change should be made on pages 11 and 12, in sections 21a-408-8(a)(2), (a)(11) and (b)(2); on page 12, in the catchline for section 21a-408-9; on page 43, in section 21a-408-36(g); on page 46, in section 21a-408-40(a)(2); on page 47, in section 21a-408-41(b)(5) and (6); on page 50, in section 21a-408-44(a)(2), (4) and (5) and in subsection (b); on page 54, in section 21a-408-48(c)(1) and section 21a-408-49(c)(3); on page 68, in section 21a-408-59(a)(2); on page 71, in section 21a-408-60(h) and on page 82, in section 21a-408-68(a)(iv).

6. Throughout the proposed regulation, "commissioner" and "department" should not be capitalized. For example, on page 40, in section 21a-408-35(c)(5), "Department" should be "department". The same changes should be made on page 43, in section 21a-408-36(h); on page 65, in section 21a-408-57(a)(8); on page 69, in section 21a-408-59(a) in subdivisions (4), (4)(ii) and (4)(iv), and in subsections (a)(4)(i), (4)(iii) and (b) and on page 83, in section 21a-408-68(c).

7. On page 5, in section 21a-408-1, subdivisions "(50)" to "(59)", inclusive, should be "(59)" to "(67)", inclusive, for accuracy.

8. On page 5, in section 21a-408-2(a)(1), "[chapter] chapters" should be "chapter", for proper form.

9. On page 6, in section 21a-408-2(a)(4), spaces should be inserted before the opening brackets and the second opening bracket should not be underlined, for proper form.

10. On page 7, in section 21a-408-4(a) and (b), "or APRN that" should be "[that] or APRN who", for proper form.

11. On page 7, in section 21a-408-5(b), "or APRN" should be capitalized, for proper form.

12. On page 8, in section 21a-408-6(b)(1), "determine" and "department" should be capitalized and "and" should be inserted after "Correction,", for proper form.

13. On page 9, in section 21a-408-6(b)(2), (c)(1) to (3), inclusive and (c)(1)(A) and (B), inclusive, the first letter in each first word after the subdivision or subparagraph designator should be capitalized, for consistency and proper form. Also, in (b)(2), the semicolon after "substance" should be a period, for proper form.

14. On page 9, in section 21a-408-6(c)(3), "made" should be "that a written certification has been issued", for clarity.

15. On page 9, in section 21a-408-6(e), "their second" should be "[their] such applicant's second", for proper form.

16. On page 9, in section 21a-408-6(g), in the sixth line, "the" should be inserted before "primary caregiver", for proper form and in the tenth line, "21a-408-28" should be "[21a-408-28] 21a-408-29", for accuracy.

17. On page 9, in section 21a-408-6(h)(1), "subsection (e)" should be "subsection [(e)] (g)", for accuracy.

18. On page 10, in section 21a-408-7(a)(6), "21a-408-28" should be "[21a-408-28] 21a-408-29", for accuracy.

19. On page 11, in section 21a-408-8(a)(7), "[21a-408-72]" should be "21a-408-72", to accurately reflect the text of the existing regulation.

20. On page 11, in section 21a-408-8(a)(11), "bona-fide relationship" should be "bona-fide healthcare professional-patient relationship", for consistency.

21. On page 12, in section 21a-408-9(b), "Corrections" should be "[Corrections] Correction", for accuracy.

22. On page 13, in section 21a-408-9(c), the period after "department" should not be underlined, for proper form.

23. On page 13, in section 21a-408-10(a), "Qualifying" should be underlined, for proper form.

24. On page 14, in section 21a-408-12(a), "(k)" should be "[(k)] "(i)", for accuracy.

25. On page 16, in section 21a-408-12a(a)(9), an underlined semicolon should be inserted after "Neuralgia" and in subdivision (12), the "and" after "Syndromes;" should be deleted, for proper form.

26. On page 19, in section 21a-408-16(f), "(1)" should be inserted before "Only" and "Notwithstanding the above" should be "(2) Notwithstanding the provisions of subdivision (1) of this subsection", for proper form and clarity.

27. On page 20, in section 21a-408-18(a), "(a)" should be bracketed and "notify [report to]" should be "[report to] notify", for proper form.

28. On page 23, in section 21a-408-21(b)(7), an underlined comma should be inserted after "if any", for proper form and in (b)(10) of sais section, "licensee" should be "[licensee] applicant", for consistency.

29. On page 26, in section 21a-408-25, in subsections (a), (b) and (c),"sections 21a-408-13 to 21a-408-25" should be "this section and sections 21a-408-13 to 21a-408-24,", for proper form.

30. On page 29, in section 21a-408-29, the underlined periods in subdivisions (1), (3) to (5), inclusive and (15) should be semicolons, for consistency. In subdivision (5), "program"

should be "program under section 21a-408t of the Connecticut General Statutes", for clarity.

31. On page 30, in section 21a-408-29(11), "fee of" should be inserted before "one thousand five hundred", for proper form.

32. On page 33, in section 21a-408-31(a), an underlined comma should be inserted after "laboratory license", for proper form.

33. On pages 33 and 34, in section 21a-408-32, subdivision designators (1) to (6), inclusive, should be included in the brackets, for proper form.

34. On page 35, in section 21a-408-32(b)(18), "mental illness," should be "mental illness or" and an underlined comma should be inserted before "provided", for proper form.

35. On page 38, in section 21a-408-34(a)(1), "agencies" should be inserted after "enforcement", for proper form.

36. On page 39, in section 21a-408-34(a)(3), a comma should be inserted after "subject", for proper form.

37. On page 39, in section 21a-408-34(d), "(d)" should be underlined for proper form.

38. On page 40, in section 21a-408-35(c)(3) and (4), "an approved research program" should be "a research program approved by the commissioner under section 21a-408t of the Connecticut General Statutes", for clarity.

39. On page 41, in section 21a-408-35(d) "section" should be inserted before "20-617a", for proper form, in subsection (e)(1) and (e)(2) of said section, "a dispensary" should be "A dispensary" and in subsection (e)(1), "Section" should be "section", for proper form.

40. On page 42, in section 21a-408-36(a), "[on the premises]" should be deleted, for proper form.

41. On page 43, in section 21a-408-36(d), a space should be inserted after "section" and in subsection (f)(4), "subsection (f)(1) of this section" should be "subdivision (1) of this subsection", for proper form.

42. On page 47, in section 21a-408-41(d), an underlined period should be inserted after "affixed", for proper form.

43. On page 54, in section 21a-408-50, "(a)" should be deleted, for proper form.

44. On page 55, in section 21a-408-49(c)(3), "21a-408-47" should be "21a-408-48", for accuracy.

45. On page 58, in section 21a-408-52(c)(2), "of" should be inserted after "outside", for proper form.

46. On page 61, in section 21a-408-54(b)(7), "herein" should be "in this subdivision", for clarity and in subsection (c) of said section, "21a-408-20 to" should be "21a-408-20 and", for proper form.

47. On page 62, in section 21a-408-55(b), the two references to "Connecticut General Statutes" should be changed to "of the Connecticut General Statutes" and moved to after "inclusive,", for proper form.

48. On page 65, in section 21a-408-56(8), "picked-up" should be "picked up" for proper form.

49. On page 65, in section 21a-408-57(b)(1), "this provision" should be "this subdivision", for clarity.

50. On page 66, in section 21a-408-57(b)(5), "USP" should be "United States Pharmacopeia", for clarity and consistency.

51. On page 67, in section 21a-408-58(c)(7)(E), "constitute" should be "constitutes", for proper form.

52. On page 68, in section 21a-408-58(c)(9), an underlined comma should be inserted after "including" and "limited to", and in both instances "Connecticut General Statutes" should be "of the Connecticut General Statutes" and moved to after "inclusive,", for proper form.

53. On page 68, in section 21a-408-59(a)(3), "has" should be inserted before "a minimum", for clarity.

54. On page 69, in section 21a-408-59(a)(4), subclauses (i) to (iv), inclusive, should be subparagraphs (A) to (D), inclusive, for proper form and in subsection (a)(4)(i), "must" should be "shall", in accordance with the committee's mandate regarding directives.

55. On page 73, in section 21a-408-62(a)(4), the closing bracket after "(4)" should be deleted, for proper form.

56. On page 74, in section 21a-408-62(c)(2), "of" should be inserted after "outside" and in subsection (d) of said section, "location" should be "locations", for proper form.

57. On pages 76 and 77, in sections 21a-408-64(a)(2) and (a)(5) to (8), inclusive, "A" or "An "should be inserted before the first word and such word should be made lower case, for proper form. For example, on page 76 in section 21a-408-64(a)(2), "Motion" should be "A motion", for proper form.

58. On page 78, in section 21a-408-65(b), in the next to last line, "dispensary or producer" should be "dispensary, producer, laboratory or research program", for consistency.

59. On page 79, in section 21a-408-65(d), "(a) through" should be "(a) to", for proper form.

60. On page 82, in section 21a-408-67(e), "state of Connecticut food, drug and cosmetic statutes and regulations" should be "Connecticut Food, Drug and Cosmetic Act and any regulations adopted thereunder", for clarity and consistency.

61. On page 82, in section 21a-408-68(a), "(1)" should be inserted after "(a)", subclauses "(i)" to "(iv)" should be subparagraphs "(A)" to "(D)", inclusive, "A" should be moved to after subparagraph (A), "a" should be inserted after subparagraphs (B) and (C) and "an" should be inserted after subparagraph (D) and "Notwithstanding the above" should be "(2) Notwithstanding the provisions of subdivision (1) of this subsection", for clarity and proper form.

62. On page 84, the catchline for section 21a-408-70 should be "**[Inspection of records; entry on premises] Marijuana marketing; advertising at a dispensary facility; producer advertising of prices**", to accurately reflect the contents of the new language in said section.

63. On page 85, in section 21a-408-72(b)(2) and (b)(3), "therein" should be "in such place", for clarity and in subsection (b)(2), a comma should be inserted before "including", for proper form.

Recommendation:

	Approval in whole
	with technical corrections
	with deletions
	with substitute pages
	Disapproval in whole or in part
X	**Rejection without prejudice**

Reviewed by: Richard Hanratty / Shannon McCarthy

Date: July 13, 2018

Sec. 21a-408m. Regulations re palliative use of marijuana. Fees. Additional debilitating conditions. (a) The Commissioner of Consumer Protection may adopt regulations, in accordance with chapter 54, to establish (1) a standard form for written certifications for the palliative use of marijuana issued by physicians and advanced practice registered nurses under subdivision (1) of subsection (a) of section 21a-408a, and (2) procedures for registrations under section 21a-408d. Such regulations, if any, shall be adopted after consultation with the Board of Physicians established in section 21a-408*l*.

(b) The Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to establish a reasonable fee to be collected from each qualifying patient to whom a written certification for the palliative use of marijuana is issued under subdivision (1) of subsection (a) of section 21a-408a, for the purpose of offsetting the direct and indirect costs of administering the provisions of sections 21a-408 to 21a-408n, inclusive. The commissioner shall collect such fee at the time the qualifying patient registers with the Department of Consumer Protection under subsection (a) of section 21a-408d. Such fee shall be in addition to any registration fee that may be charged under said subsection. The fees required to be collected by the commissioner from qualifying patients under this subsection shall be paid to the State Treasurer and credited to the General Fund.

(c) The Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to implement the provisions of sections 21a-408 to 21a-408g, inclusive, and section 21a-408*l*. At a minimum, such regulations shall:

(1) Govern the manner in which the department considers applications for the issuance and renewal of registration certificates for qualifying patients and primary caregivers, and establish any additional information to be contained in such registration certificates;

(2) Define the protocols for determining the amount of usable marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amounts for topical treatments;

(3) Establish criteria for adding medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the palliative use of marijuana;

(4) Establish a petition process under which members of the public may submit petitions, in such manner and in such form as prescribed in the regulations, regarding the addition of medical conditions, medical treatments or diseases to the list of debilitating medical conditions;

(5) Establish a process for public comment and public hearings before the board regarding the addition of medical conditions, medical treatments or diseases to the list of debilitating medical conditions, medical treatments or diseases;

(6) Add additional medical conditions, medical treatments or diseases to the list of debilitating medical conditions that qualify for the palliative use of marijuana as recommended by the board; and

(7) Develop a distribution system for marijuana for palliative use that provides for:

(A) Marijuana production facilities within this state that are housed on secured grounds and operated by licensed producers; and

(B) Distribution of marijuana for palliative use to qualifying patients or their primary caregivers by licensed dispensaries.

(d) The commissioner shall submit regulations pursuant to subsections (b) and (c) of this section to the standing legislative regulation review committee not later than July 1, 2013.

Sec. 21a-408r. Laboratory employees. Licensure. Regulations. Fees. (a) Except as provided in subsection (b) of this section, no person may act as a laboratory employee or represent that such person is a licensed laboratory employee unless such person has obtained a license from the Commissioner of Consumer Protection pursuant to this section.

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

(c) The Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to (1) provide for the licensure of laboratories and laboratory employees, (2) establish standards and procedures for the revocation, suspension, summary suspension and nonrenewal of laboratory and laboratory employee licenses, provided such standards and procedures are consistent with the provisions of subsection (c) of section 4-182, (3) establish a license and renewal fee for each licensed laboratory and licensed laboratory employee, provided the aggregate amount of such license and renewal fees shall not be less than the amount necessary to cover the direct and indirect cost of licensing and regulating laboratories and laboratory employees in accordance with the provisions of this chapter, and (4) establish other licensing, renewal and operational standards deemed necessary by the commissioner.

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

Sec. 21a-408t. Research programs. Licensure. Regulations. Fees. (a) The

Commissioner of Consumer Protection may approve a research program if such research program will (1) be administered or overseen by (A) a hospital or health care facility licensed by the Connecticut Department of Public Health pursuant to chapter 368v, (B) an institution of higher education, as defined in section 10a-55, (C) a licensed producer, or (D) a licensed dispensary, and (2) have institutional review board oversight and, if the research program involves the use of animals, have an institutional animal care and use committee.

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

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

(d) The Commissioner of Consumer Protection shall adopt regulations, in accordance with chapter 54, to (1) provide for the approval of research programs and licensure of research program employees, (2) establish standards and procedures for the termination or suspension of a research program, (3) establish standards and procedures for the revocation, suspension, summary suspension and nonrenewal of a research program employee license, provided such standards and procedures are consistent with the provisions of subsection (c) of section 4-182, (4) establish a (A) fee for research program review and approval, and (B) license and renewal fee for each research program employee, provided the aggregate amount of such fees shall not be less than the amount necessary to cover the direct and indirect cost of approving research programs and licensing and regulating research program employees pursuant to the provisions of this chapter, and (5) establish other licensing, renewal and operational standards deemed necessary by the commissioner.

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