

## AMENDMENTS TO SENATE BILL NO. 3 (As amended by A05835)

Sponsor: REPRESENTATIVE WATSON

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1 Amend Bill, page 1, line 13 (A05835), by inserting after

2 "for"

3 academic clinical research centers and for

4 Amend Bill, page 2, by inserting between lines 48 and 49

5 (A05835)

6 Chapter 20. Academic Clinical Research Centers

7 Section 2001. Definitions.

8 Section 2002. Registration as both grower/processor and

9 dispensary collaborating with an academic clinical

10 research center.

11 Section 2003. Research study.

12 Amend Bill, page 16, line 34 (A05835), by inserting after

13 "organization"

14 , including a clinical registrant under Chapter 20,

15 Amend Bill, page 18, line 38 (A05835), by inserting after

16 "organization"

17 , including a clinical registrant under Chapter 20,

18 Amend Bill, page 25, line 42 (A05835), by inserting after

19 "organization"

20 , including registration under Chapter 20,

21 Amend Bill, page 26, line 2 (A05835), by inserting after

22 "organization"

23 , including registration under Chapter 20,

24 Amend Bill, page 27, line 25 (A05835), by inserting after

25 "value."

26 However, money in the fund may not be expended on activity

1 under Chapter 20.

2 Amend Bill, page 27, line 46 (A05835), by inserting after "7"

3 and Chapter 20

4 Amend Bill, page 33, by inserting between lines 30 and 31

5 (A05835)

6 (31) Regulations necessary to implement Chapter 20.

7 Amend Bill, page 33, line 31 (A05835), by striking out "(31)"

8 and inserting

9 (32)

10 Amend Bill, page 34, line 49 (A05835), by inserting after

11 "organization"

12 , including an employee or principal of a clinical registrant

13 under Chapter 20,

14 Amend Bill, page 35, line 51 (A05835), by inserting after

15 "organization"

16 , including an employee or principal of a clinical registrant

17 under Chapter 20,

18 Amend Bill, page 36, line 10 (A05835), by inserting after

19 "organization"

20 , including an employee or principal of a clinical registrant

21 under Chapter 20,

22 Amend Bill, page 38, line 39 (A05835), by inserting after

23 "conditions."

24 The program shall not include a clinical registrant or

25 academic clinical research center under Chapter 20.

26 Amend Bill, page 42, by inserting between lines 12 and 13

27 (A05835)

28 CHAPTER 20

29 ACADEMIC CLINICAL RESEARCH CENTERS

30 Section 2001. Definitions.

31 The following words and phrases when used in this chapter

32 shall have the meanings given to them in this section unless the

33 context clearly indicates otherwise:

34 "Academic clinical research center." An accredited medical

35 school within this Commonwealth that operates or partners with

36 an acute care hospital licensed within this Commonwealth.

37 "Clinical registrant." An entity registered as both a

grower/processor and a dispensary which has a contractual relationship with an academic clinical research center as set forth under section 2002.

Section 2002. Registration as both grower/processor and dispensary collaborating with an academic clinical research center.

Notwithstanding the limitations in sections 706 and 707, the department may register up to eight entities which are registered as both a grower/processor and a dispensary that have a contractual relationship with an academic clinical research center under which the academic clinical research center or its affiliate provides advice to the entities registered as both a grower/processor and a dispensary regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances. Each entity may provide medical marijuana at not more than six separate locations. The total number of locations authorized to dispense medical marijuana under this section shall not exceed 48. The following apply with respect to this category of clinical registrant:

(1) A clinical registrant must be registered as both a grower/processor and a dispensary.

(2) A clinical registrant must pay the fees and meet all other requirements under this act for registration, except as provided in section 708(g)(1)(iv) and (2)(v), as a grower/processor and a dispensary.

(3) The clinical registrant must have a minimum of \$15,000,000 in capital. The department shall verify the capital requirement.

(4) The clinical registrant must comply with all other requirements of this act regarding growing, processing and dispensing medical marijuana.

Section 2003. Research study.

Notwithstanding any provision of this act to the contrary, the department may, upon application, approve the dispensing of medical marijuana by a clinical registrant to the academic clinical research center for the purpose of conducting a research study. The department shall develop the application and standards for approval of such dispensing by the clinical registrant. The following apply to the research study:

(1) The clinical registrant shall disclose the following information to the department in its application:

(i) The reason for the research project, including the reason for the trial.

(ii) The strain of medical marijuana to be used and the strength of the medical marijuana to be used in the research study.

(iii) The anticipated duration of the study.

(iv) Evidence of approval of the trial by accredited institutional review board, including any other required regulatory approvals.

(v) Other information required by the department,

1 except that the department may not require disclosure of  
2 any information that would infringe upon the academic  
3 clinical research center's exclusive right to  
4 intellectual property or legal obligations for patient  
5 confidentiality.

6 (2) The academic clinical research center shall provide  
7 its findings to the department within 365 days of the  
8 conclusion of the research study or within 365 days of  
9 publication of the results of the research study in a peer-  
10 reviewed medical journal, whichever is later.

11 (3) The department shall allow the exchange of medical  
12 marijuana seed between clinical registrants for the conduct  
13 of research.

14 Amend Bill, page 42, lines 30 through 42 (A05835), by  
15 striking out all of said lines and inserting

16 (a) Licensure.--None of the following shall be subject to  
17 arrest, prosecution or penalty in any manner, or denied any  
18 right or privilege, including civil penalty or disciplinary  
19 action by a Commonwealth licensing board or commission, solely  
20 for lawful use of medical marijuana or manufacture or sale or  
21 dispensing of medical marijuana, or for any other action taken  
22 in accordance with this act:

23 (1) A patient.

24 (2) A caregiver.

25 (3) A practitioner.

26 (4) A medical marijuana organization.

27 (5) A health care medical marijuana organization or  
28 university participating in a research study under Chapter  
29 19.

30 (6) A clinical registrant or academic clinical research  
31 center under Chapter 20.

32 (7) An employee, principal or financial backer of a  
33 medical marijuana organization.

34 (8) An employee of a health care medical marijuana  
35 organization or an employee of a university participating in  
36 a research study under Chapter 19.

37 (9) An employee of a clinical registrant or an employee  
38 of an academic clinical research center under Chapter 20.

39 (10) A pharmacist or certified registered nurse  
40 practitioner under section 707(9).

41 Amend Bill, page 44, lines 46 through 51; page 45, lines 1  
42 and 2 (A05835), by striking out all of said lines on said pages  
43 and inserting

44 (xvi) Chapter 20.

45 (xvii) Section 2101.

46 (xviii) Section 2102.

1 (xix) Section 2103.  
2 (xx) Section 2104.  
3 (xxi) Section 2105.  
4 (xxii) Section 2106.  
5 (xxiii) Section 2108.  
6 (xxiv) Section 2109.