

## 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

1 grower/processor and a dispensary which has a contractual  
2 relationship with an academic clinical research center as set  
3 forth under section 2002.  
4 Section 2002. Registration as both grower/processor and  
5 dispensary collaborating with an academic clinical  
6 research center.

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

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

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

26 (3) The clinical registrant must have a minimum of  
27 \$15,000,000 in capital. The department shall verify the  
28 capital requirement.

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

32 Section 2003. Research study.

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

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

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

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

47 (iii) The anticipated duration of the study.

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

51 (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.