



114166

LEGISLATIVE ACTION

Senate

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House

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Floor: 1/AD/3R

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03/05/2020 04:05 PM

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Senator Hutson moved the following:

**Senate Amendment (with title amendment)**

Between lines 354 and 355

insert:

Section 2. Paragraph (d) of subsection (1) of section  
499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(1)

(d) A permit for a prescription drug manufacturer,  
prescription drug repackager, prescription drug wholesale  
distributor, limited prescription drug veterinary wholesale



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12 distributor, or retail pharmacy drug wholesale distributor may  
13 not be issued to the address of a health care entity or to a  
14 pharmacy licensed under chapter 465, except as provided in this  
15 paragraph. The department may issue a prescription drug  
16 manufacturer permit to a nonembryonic stem cell bank that is  
17 licensed by the Agency for Health Care Administration pursuant  
18 to s. 400.991 and part II of chapter 408. The department may  
19 issue a prescription drug manufacturer permit to an applicant at  
20 the same address as a licensed nuclear pharmacy, which is a  
21 health care entity, even if the nuclear pharmacy holds a special  
22 sterile compounding permit under chapter 465, for the purpose of  
23 manufacturing prescription drugs used in positron emission  
24 tomography or other radiopharmaceuticals, as listed in a rule  
25 adopted by the department pursuant to this paragraph. The  
26 purpose of this exemption is to assure availability of state-of-  
27 the-art pharmaceuticals that would pose a significant danger to  
28 the public health if manufactured at a separate establishment  
29 address from the nuclear pharmacy from which the prescription  
30 drugs are dispensed. The department may also issue a retail  
31 pharmacy drug wholesale distributor permit to the address of a  
32 community pharmacy licensed under chapter 465, even if the  
33 community pharmacy holds a special sterile compounding permit  
34 under chapter 465, as long as the community pharmacy does not  
35 meet the definition of a closed pharmacy in s. 499.003.

36  
37 ===== T I T L E A M E N D M E N T =====

38 And the title is amended as follows:

39 Delete line 23

40 and insert:



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41 Regulation, to adopt specified rules; amending s.  
42 499.012, F.S.; authorizing the Department of Business  
43 and Professional Regulation to issue a prescription  
44 drug manufacturer permit to a certain nonembryonic  
45 stem cell bank; providing an