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LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/20/2020	.	
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The Committee on Appropriations (Hutson) recommended the following:

**Senate Amendment (with title amendment)**

Delete lines 169 - 236

and insert:

(3) DISPENSING OF DRUGS OR COMPOUNDED DRUGS OR PRODUCTS.-

(a) A pharmacist at a nonembryonic stem cell bank that is also permitted as a pharmacy under chapter 465 may dispense any of the following to a stem cell bank within the state, for office use:

1. Human nonembryonic stem cells;



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11           2. A compounded drug containing human nonembryonic stem  
12 cells; or

13           3. A compounded product containing human nonembryonic stem  
14 cells.

15           (b) Human nonembryonic stem cells, compounded drugs  
16 containing human nonembryonic stem cells, or products containing  
17 human nonembryonic stem cells may not be sold or dispensed by  
18 any person or establishment other than the nonembryonic stem  
19 cell bank or pharmacist at the nonembryonic stem cell bank that  
20 manufactured the human nonembryonic stem cells or the compounded  
21 drug or product containing human nonembryonic stem cells, except  
22 that:

23           1. A health care practitioner who requests the dispensing  
24 of the human nonembryonic stem cells, compounded drug, or  
25 compounded product from the manufacturing nonembryonic stem cell  
26 bank may sell or dispense such items to his or her patient if  
27 the health care practitioner is authorized within the scope of  
28 his or her license to prescribe and administer human  
29 nonembryonic stem cells; or

30           2. A pharmacist, pharmacy, or establishment that requests  
31 the dispensing of the human nonembryonic stem cells, compounded  
32 drug, or compounded product from the manufacturing nonembryonic  
33 stem cell bank may sell or dispense such items to a health care  
34 practitioner who is authorized within the scope of his or her  
35 license to prescribe and administer human nonembryonic stem  
36 cells to patients.

37           (4) HEALTH CARE PRACTITIONER RESPONSIBILITIES.—

38           (a) A physician licensed under chapter 458 or chapter 459,  
39 an advanced practice registered nurse licensed under chapter



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40 464, or a physician assistant licensed under chapter 458 or  
41 chapter 459 may not practice in a nonembryonic stem cell bank  
42 that is not licensed with the agency as required by the rules  
43 adopted pursuant to s. 400.9925. The license of a health care  
44 practitioner who violates this paragraph is subject to  
45 disciplinary action by the appropriate regulatory board.

46 (b) In the performance of any procedure collecting,  
47 storing, using, or purporting to use nonembryonic stem cells or  
48 products containing nonembryonic stem cells, a health care  
49 practitioner must adhere to the applicable current good  
50 manufacturing practices for the collection, removal,  
51 manufacturing, processing, compounding, and implantation of stem  
52 cells or products containing stem cells pursuant to the federal  
53 act and 21 C.F.R., parts 1270-1271.

54 (5) RULEMAKING.—The agency shall adopt rules necessary to  
55 administer the licensure and regulation of nonembryonic stem  
56 cell banks, including, but not limited to, rules regarding all  
57 of the following, which must be consistent with the best  
58 practices specified in the federal act and 21 C.F.R., parts  
59 1270-1271:

60 (a) Advertising.

61 (b) Nonembryonic stem cell bank procedures and protocols  
62 for the collection, manufacturing, storing, dispensing, and use  
63 of nonembryonic stem cells, drugs containing nonembryonic stem  
64 cells, and products containing nonembryonic stem cells in  
65 accordance with the applicable current best practices.

66 (c) Adverse incident reporting.

67 (d) Informed consent.

68 (e) Recordkeeping, record retention, and availability of



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69 records for inspection.

70       Section 2. This act shall take effect July 1, 2020,  
71 contingent on SB 7066 or similar legislation taking effect on  
72 that same date, if such legislation is adopted in the same  
73 legislative session or an extension thereof and becomes a law.

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75 ===== T I T L E   A M E N D M E N T =====

76 And the title is amended as follows:

77       Delete lines 16 - 17

78 and insert:

79       the agency to adopt specified rules; providing a  
80       contingent effective date.