

By Senator Brodeur

9-01070-22

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1                   A bill to be entitled  
2           An act relating to regulation of compounded drug  
3           products; providing legislative intent; requiring the  
4           Surgeon General, on behalf of the Department of  
5           Health, to sign and become a party to the United  
6           States Food and Drug Administration's Memorandum of  
7           Understanding Addressing Certain Distributions of  
8           Compounded Human Drug Products; requiring the Surgeon  
9           General to notify the Division of Law Revision within  
10          a specified timeframe after signing the memorandum;  
11          creating s. 465.036, F.S.; requiring certain pharmacy  
12          permittees to annually report information to the  
13          National Association of Boards of Pharmacy's  
14          information sharing network as required by the  
15          memorandum; requiring the department to ensure such  
16          permittees comply with the reporting requirements;  
17          providing effective dates.

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19 Be It Enacted by the Legislature of the State of Florida:

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21           Section 1. (1) It is the intent of the Legislature to  
22 enhance communication and maximize federal and state resources  
23 for the oversight of compounded drug products produced and  
24 shipped by pharmacies in this state, and to enact an information  
25 sharing agreement with the United States Food and Drug  
26 Administration for the purpose of monitoring compounded drug  
27 products produced in this state which are shipped outside of  
28 this state.

29           (2) Upon release of the United States Food and Drug

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30 Administration's Memorandum of Understanding Addressing Certain  
31 Distributions of Compounded Human Drug Products, as provided for  
32 in section 503A(b) (3) (B) (i) of the Federal Food, Drug, and  
33 Cosmetic Act, 21 U.S.C. s. 353a, the Surgeon General, on behalf  
34 of the Department of Health, shall sign and become a party to  
35 the memorandum. The Surgeon General must notify the Division of  
36 Law Revision within 5 days after signing the memorandum.

37 Section 2. Effective upon the date the Surgeon General  
38 signs the United States Food and Drug Administration's  
39 Memorandum of Understanding Addressing Certain Distributions of  
40 Compounded Human Drug Products, section 465.036, Florida  
41 Statutes, is created to read:

42 465.036 Annual reporting on shipments of compounded drug  
43 products.—By April 1 of each year, permittees that ship  
44 compounded drug products to another state shall report  
45 information to the National Association of Boards of Pharmacy's  
46 information sharing network as required by the Memorandum of  
47 Understanding Addressing Certain Distributions of Compounded  
48 Human Drug Products between the department and the United States  
49 Food and Drug Administration. The department shall ensure that  
50 permittees comply with this section.

51 Section 3. Except as otherwise expressly provided in this  
52 act, this act shall take effect upon becoming a law.