

1                                   A bill to be entitled  
 2           An act relating to distributions of compounded human  
 3           drug products; creating s. 465.41, F.S.; providing  
 4           legislative intent; requiring the State Surgeon  
 5           General to sign and become a party to a specified  
 6           memorandum of understanding on behalf of the  
 7           Department of Health; providing reporting requirements  
 8           for certain persons who ship compounded human drug  
 9           products interstate; providing an effective date.

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

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 13           Section 1. Section 465.41, Florida Statutes, is created to  
 14           read:

15           465.41 Distribution of compounded human drug products.-

16           (1) It is the intent of the Legislature to enhance  
 17           communication and maximize federal and state resources for  
 18           oversight of compounded drugs produced by traditional pharmacies  
 19           and to enact an information sharing agreement with the federal  
 20           Food and Drug Administration as a tool to monitor such drug  
 21           products.

22           (2) Upon release of the standard Memorandum of  
 23           Understanding Addressing Certain Distributions of Compounded  
 24           Human Drug Products, as provided for in s. 503A(b)(3)(i) of the  
 25           Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 353a, the

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26 State Surgeon General shall sign and become a party to the  
27 memorandum on behalf of the department.

28 (3) On an annual basis, and within 90 days after the  
29 beginning of the calendar year, all licensed persons who ship  
30 compounded human drug products interstate shall report to the  
31 National Association of Boards of Pharmacy Information-Sharing  
32 Network the information required by the Memorandum of  
33 Understanding Addressing Certain Distributions of Compounded  
34 Human Drug Products between the department and the United States  
35 Food and Drug Administration as provided by the federal Food and  
36 Drug Administration.

37 Section 2. This act shall take effect July 1, 2022.