

By Senator Crist

12-03738-08

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1 A bill to be entitled

2 An act relating to pharmaceutical compounding; creating s.  
3 465.1895, F.S.; providing definitions; providing  
4 pharmaceutical compounding for provision and  
5 administration of compounded drug to patient by  
6 practitioner in practitioner's office or in health care  
7 facility or other treatment setting; providing for  
8 pharmacist to dispense and deliver reasonable quantity of  
9 compounded drug, including certain controlled substances,  
10 to practitioner for office use; providing for distribution  
11 of compounded and prepackaged pharmaceutical preparations  
12 by a special parenteral or enteral extended scope pharmacy  
13 to a permitted institutional pharmacy or licensed  
14 dispensing practitioner; providing an effective date.

15  
16 Be It Enacted by the Legislature of the State of Florida:

17  
18 Section 1. Section 465.1895, Florida Statutes, is created  
19 to read:

20 465.1895 Pharmaceutical compounding.--

21 (1) DEFINITIONS.--As used in this section:

22 (a) "Office use" means the provision and administration of  
23 a compounded drug to a patient by a practitioner in the  
24 practitioner's office or by the practitioner in a health care  
25 facility or treatment setting, including a hospital, ambulatory  
26 surgical center, or pharmacy, in accordance with this chapter.

27 (b) "Reasonable quantity" means, with reference to drug  
28 compounding, an amount of a drug that:

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29       1. Does not exceed the amount a practitioner anticipates  
30 may be used in the practitioner's office before the expiration  
31 date of the compounded drug;

32       2. Is reasonable considering the intended use of the  
33 compounded drug and the nature of the practitioner's practice;  
34 and

35       3. Is not greater than the amount the pharmacy is capable  
36 of compounding in compliance with the pharmaceutical standards  
37 for identity, strength, quality, and purity of the compounded  
38 drug that are consistent with the United States Pharmacopoeia  
39 guidelines and accreditation practices.

40       (2) PHARMACY COMPOUNDING FOR OFFICE USE.--A pharmacist may  
41 dispense and deliver a reasonable quantity of a compounded drug  
42 to a practitioner for office use by a practitioner, including:

43       (a) Non-patient-specific controlled substances within  
44 Schedules III, IV, and V.

45       (b) Non-patient-specific controlled substances within  
46 Schedule II.

47  
48 The controlled substances in paragraphs (a) and (b) may be  
49 ordered by the practitioner using authorized forms.

50       (3) DISTRIBUTION OF COMPOUNDED AND PREPACKAGED PREPARATIONS  
51 TO CERTAIN PHARMACIES.--A special parenteral or enteral extended  
52 scope permitted pharmacy may distribute compounded and  
53 prepackaged pharmaceutical preparations to a permitted  
54 institutional pharmacy or to a licensed dispensing practitioner.

55       Section 2. This act shall take effect July 1, 2008.