

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:

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
 51 PREPARATIONS TO CERTAIN PHARMACIES.--A special parenteral or
 52 enteral extended scope permitted pharmacy may distribute
 53 compounded and prepackaged pharmaceutical preparations to a
 54 permitted institutional pharmacy or to a licensed dispensing
 55 practitioner.

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