

1 A bill to be entitled
 2 An act relating to compounded medicinal drugs; amending s.
 3 465.003, F.S.; revising a definition; creating s. 465.055,
 4 F.S.; authorizing certain pharmacists and pharmacies to
 5 compound medicinal drugs and deliver such drugs to certain
 6 prescribers for the in-office use of the prescriber;
 7 authorizing certain pharmacists to dispense compounded
 8 medicinal drugs to certain prescribers; providing minimum
 9 standards to govern the dispensing of such compounded
 10 medicinal drugs; providing an effective date.

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

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 14 Section 1. Subsection (6) of section 465.003, Florida
 15 Statutes, is amended to read:

16 465.003 Definitions.--As used in this chapter, the term:
 17 (6) "Dispense" means the transfer of possession of one or
 18 more doses of a medicinal drug by a pharmacist to the ultimate
 19 consumer or her or his agent. As an element of dispensing, the
 20 pharmacist shall, prior to the actual physical transfer,
 21 interpret and assess the prescription order for potential
 22 adverse reactions, interactions, and dosage regimen she or he
 23 deems appropriate in the exercise of her or his professional
 24 judgment, and the pharmacist shall certify that the medicinal
 25 drug called for by the prescription is ready for transfer. The
 26 pharmacist shall also provide counseling on proper drug usage,
 27 either orally or in writing, if in the exercise of her or his
 28 professional judgment counseling is necessary. The actual sales

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29 transaction and delivery of such drug shall not be considered
30 dispensing. The administration shall not be considered
31 dispensing. For purposes of compounded medicinal drugs only, the
32 term "ultimate consumer or her or his agent" shall specifically
33 include an authorized prescriber, or his or her agent, using
34 such compounded medicinal drugs for in-office use pursuant to s.
35 465.055.

36 Section 2. Section 465.055, Florida Statutes, is created
37 to read:

38 465.055 Compounding for in-office use.--

39 (1) Notwithstanding any other provision of law, a Florida-
40 licensed pharmacist or a Florida-licensed pharmacy may compound
41 a reasonable amount of a medicinal drug and deliver such drug to
42 an authorized prescriber for such prescriber's administration or
43 provision of the compounded medicinal drug to a patient by the
44 prescriber or his or her agent, in the prescriber's primary
45 practice office or any other state-licensed health care facility
46 where the prescriber or his or her agent is authorized by law to
47 prescribe or otherwise treat a patient with any prescription
48 drug therapy.

49 (2) A Florida-licensed pharmacist may dispense a
50 compounded medicinal drug for in-office use to a prescriber
51 authorized by law to prescribe, administer, or otherwise treat a
52 patient with such compounded medicinal drug.

53 (3) The amount of a compounded medicinal drug dispensed
54 under this section shall not exceed the amount that either the
55 prescriber or the pharmacist reasonably anticipates, based upon
56 the exercise of each of such prescriber's or pharmacist's

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57 independent professional judgment, may be used by the prescriber
58 for in-office use prior to the expiration date of all such
59 compounded medicinal drug.

60 (4) The substantive quantity of a compounded medicinal
61 drug dispensed under this section shall be reasonably
62 calculated, based upon the pharmacist's understanding of the
63 prescriber's intended use of such compounded drug given the
64 nature of such prescriber's professional practice and the nature
65 of the patient profiles served by such practice.

66 (5) The amount of a compounded medicinal drug dispensed
67 under this section by the pharmacist shall be in compliance with
68 the pharmaceutical standards for identity, strength, quality,
69 and purity of the compounded drug that are consistent with the
70 United States Pharmacopoeia guidelines and accreditation
71 practices.

72 (6) A compounded medicinal drug provided by a pharmacist
73 under this section shall be, under the independent professional
74 judgment of the prescriber, medically necessary for a particular
75 patient at the time of its delivery by the prescriber to the
76 patient.

77 (7) A compounded medicinal drug, once dispensed under this
78 section by the pharmacist, to the medical practitioner for in-
79 office use, shall not be further subdivided for the purpose of
80 retail distribution beyond what is otherwise deemed usual and
81 customary.

82 Section 3. This act shall take effect July 1, 2007.