

By Senator Crist

12-1612A-07

See HB

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

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

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

17 465.003 Definitions.--As used in this chapter, the
18 term:

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

1 drug shall not be considered dispensing. The administration
2 shall not be considered dispensing. For purposes of compounded
3 medicinal drugs only, the term "ultimate consumer or her or
4 his agent" shall specifically include a licensed prescriber
5 using such compounded medicinal drugs for in-office use
6 pursuant to s. 465.055.

7 Section 2. Section 465.055, Florida Statutes, is
8 created to read:

9 465.055 Compounding for in-office use.--

10 (1) Notwithstanding any other provision of law, a
11 pharmacist for a community pharmacy may compound a reasonable
12 amount of a medicinal drug and deliver such drug to a licensed
13 prescriber for such prescriber's administration or provision
14 of the compounded medicinal drug to a patient by the
15 prescriber or other health care practitioner working under the
16 supervision and authority of such prescriber, in the
17 prescriber's office or such other state-licensed health care
18 facility where the prescriber is authorized to prescribe and
19 administer drug therapies, including, but not limited to, a
20 hospital licensed under chapter 395, an ambulatory surgical
21 center licensed under part I of chapter 395, a hospice
22 licensed under part IV of chapter 400, or a pharmacy licensed
23 under this chapter.

24 (2) A pharmacist may dispense a compounded medicinal
25 drug for in-office use to a licensed prescriber authorized to
26 prescribe, administer, or treat a patient with such compounded
27 medicinal drug pursuant to subsection (1) if:

28 (a) The amount of the compounded medicinal drug
29 dispensed does not exceed the amount that either the
30 prescriber or the pharmacist reasonably anticipates, based
31 upon the exercise of his or her professional judgment, may be

1 used by the prescriber for in-office use prior to the
2 expiration date of all such compounded medicinal drug;

3 (b) The amount of the compounded medicinal drug
4 dispensed is reasonable based upon the prescriber's intended
5 use of such compounded drug given the nature of such
6 prescriber's intended practice and patient profiles;

7 (c) The amount of the compounded medicinal drug
8 dispensed by the pharmacist is capable of compounding in
9 compliance with the pharmaceutical standards for identity,
10 strength, quality, and purity of the compounded drug that are
11 consistent with the United States Pharmacopoeia guidelines and
12 accreditation practices; and

13 (d) The compounded medicinal drug provided by the
14 pharmacist is medically necessary according to the prescriber
15 at the time of its use.

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