

By Senator Martin

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1 A bill to be entitled
2 An act relating to treatment of chronic and terminal
3 illnesses; creating s. 499.0296, F.S.; defining terms;
4 providing that chronically and terminally ill patients
5 have the right, with assistance and guidance from
6 their health care providers, to determine their
7 individual courses of treatment; authorizing
8 compounding pharmacies to obtain certain active
9 pharmaceutical ingredients to provide the prescribed
10 course of treatment in such cases, provided the active
11 pharmaceutical ingredients meet specified conditions;
12 providing applicability; providing construction;
13 providing an effective date.

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

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17 Section 1. Section 499.0296, Florida Statutes, is created
18 to read:

19 499.0296 Safe compounding to treat chronic or terminal
20 illnesses.-

21 (1) As used in this section, the term:

22 (a) "Chronically ill patient" means a patient whose
23 physician has diagnosed the patient with a long-term disease or
24 condition that, if left untreated, may cause major irreversible
25 morbidity and who might benefit from individualized or
26 specialized medication that is not commercially available.

27 (b) "Compounding pharmacy" means a pharmacy licensed under
28 chapter 465 which is classified as a 503A pharmacy by the United
29 States Food and Drug Administration to compound drugs according

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30 to prescriptions specific to particular patients.

31 (c) "Monograph" means the quality standards for
32 prescription drugs and dietary supplements which articulate the
33 quality expectations for a drug or dietary supplement, including
34 its identity, strength, purity, and performance.

35 (d) "Terminally ill patient" means a patient whose
36 physician has diagnosed the patient with a progressive disease
37 or medical or surgical condition that causes significant
38 functional impairment, is not considered by a treating physician
39 to be reversible without the administration of life-sustaining
40 procedures, and, taking into account the patient's medical
41 circumstances, will result in the patient's death within 1 year
42 after diagnosis if the condition runs its normal course.

43 (2) Chronically ill patients and terminally ill patients
44 have the right to determine, with the assistance and guidance of
45 their health care providers, individual courses of treatment
46 through the use of individualized or specialized prescription
47 drugs obtained from a compounding pharmacy.

48 (3) Compounding pharmacies licensed under chapter 465 may
49 obtain active pharmaceutical ingredients that do not have a
50 United States Pharmacopeia, National Formulary, or Food
51 Chemicals Codex monograph for use in compounding to provide
52 chronically ill patients and terminally ill patients with the
53 prescribed individual course of treatment, provided the active
54 pharmaceutical ingredient is:

55 (a) Purchased from an active pharmaceutical ingredient
56 manufacturer, repackager, relabeler, or wholesaler registered
57 with the United States Food and Drug Administration; and

58 (b) Shipped into this state in compliance with state law

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59 and arrives with a certificate of analysis detailing quality
60 specifications, including any medications, dietary supplements,
61 biologics, proteins, peptides, and amino acids that are already
62 in use by compounding pharmacies in this state.

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64 This subsection does not apply if the active pharmaceutical
65 ingredient is withdrawn or removed from the market for safety
66 and efficacy reasons by the United States Food and Drug
67 Administration or is placed on its Interim 503A Category 2 or 3
68 Bulk Drug Substances List. Compounding pharmacies may use
69 substances placed on the Interim 503A Category 2 or 3 Bulk Drug
70 Substances List only if the substance meets the requirements of
71 this section.

72 (4) This section does not allow any treatment or use of
73 medication that is intended to cause the death of the patient.

74 Section 2. This act shall take effect July 1, 2025.