

1                                   A bill to be entitled  
 2           An act relating to compounding pharmacies; creating s.  
 3           465.191, F.S.; providing definitions; authorizing  
 4           certain patients to determine, with assistance and  
 5           guidance of their health care providers, individual  
 6           courses of treatment; authorizing compounding  
 7           pharmacies to access certain ingredients for  
 8           compounding under certain circumstances; providing an  
 9           exception; providing construction; providing an  
 10          effective date.

11  
 12 Be It Enacted by the Legislature of the State of Florida:

13  
 14           **Section 1. Section 465.191, Florida Statutes, is created**  
 15 **to read:**

16           465.191 Compounding pharmacies.—

17           (1) For the purposes of this section, the term:

18           (a) "Chronically ill patient" means a patient who has been  
 19 diagnosed by his or her physician as having a long-term disease  
 20 or condition that, if left untreated, may cause major  
 21 irreversible morbidity and who may benefit from individualized  
 22 or specialized medication that is not commercially available.

23           (b) "Compounding pharmacy" means a pharmacy licensed under  
 24 this chapter that is designated as a 503A compounding pharmacy  
 25 by the United States Food and Drug Administration.

26 (c) "Monographs" means quality standards for prescription  
27 medicines and dietary supplements that provide the quality  
28 expectations for a medicine or dietary supplement, including its  
29 identity, strength, purity, and performance.

30 (d) "Terminally ill patient" means a patient who has been  
31 diagnosed by his or her physician with a disease that, taking  
32 into account the patient's medical circumstances, will cause the  
33 patient's death in a reasonably foreseeable time.

34 (2) Chronically ill patients and terminally ill patients  
35 may determine, with the assistance and guidance of their health  
36 care providers, individual courses of treatment through the use  
37 of medications and treatments obtained from compounding  
38 pharmacies.

39 (3) Compounding pharmacies licensed in this state may  
40 access active pharmaceutical ingredients for use in compounding  
41 that do not have a United States Pharmacopeia, National  
42 Formulary, or Food Chemicals Codex Monograph, if the active  
43 pharmaceutical ingredient is:

44 (a) Purchased from a United States Food and Drug  
45 Administration-registered active pharmaceutical ingredient  
46 manufacturer, repackager, relabeler, or wholesaler.

47 (b) Shipped into this state in compliance with general law  
48 with a certificate of analysis detailing quality specifications,  
49 including any medications, dietary supplements, biologics,  
50 proteins, peptides, and amino acids that are already in use by

51 compounding pharmacies in this state, in order to provide  
52 chronically ill patients and terminally ill patients with a  
53 prescribed individual course of treatment.

54 (4) Subsection (3) does not apply if the active  
55 pharmaceutical ingredient is withdrawn or removed from the  
56 market for safety and efficacy reasons by the federal Food and  
57 Drug Administration or is placed on the interim 503a category II  
58 or category III Bulk Drug Substances list. Compounding  
59 pharmacies may use substances placed on the interim 503a  
60 category II or category III Bulk Drug Substances list only if  
61 the substance meets the requirements of this section.

62 (5) This section does not allow any treatment or use of  
63 medication that is intended to cause the death of the patient.

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