

By Senator Bradley

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1 A bill to be entitled
2 An act relating to compounded drugs; creating s.
3 499.038, F.S.; defining the term "compounded
4 medication"; prohibiting any person or entity from
5 engaging in the sale, transfer, or distribution of
6 compounded medications for weight loss unless they
7 provide specified documentation to the Department of
8 Business and Professional Regulation; providing
9 administrative penalties; authorizing the department
10 to adopt rules and conduct inspections as necessary to
11 implement specified provisions; providing an effective
12 date.

13
14 WHEREAS, the Legislature finds that the safety and
15 integrity of compounded medications are paramount for the health
16 and well-being of the residents of this state, and

17 WHEREAS, the Legislature recognizes that while the United
18 States Food and Drug Administration (FDA) sets internationally
19 recognized standards for drug approval and regulatory oversight,
20 there have been increasing attempts by bad actors to circumvent
21 these regulations, undermining public trust and patient safety,
22 and

23 WHEREAS, the Legislature further finds that foreign
24 entities, including those from countries such as China, have
25 exploited regulatory gaps to introduce inferior or contaminated
26 active pharmaceutical ingredients into the supply chain for
27 medications intended for compounding, and

28 WHEREAS, recent cases, including those involving
29 medications for weight loss, have demonstrated that high demand

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can lead to the proliferation of the use of illicit,
substandard, and potentially harmful active pharmaceutical
ingredients that jeopardize patient health and safety, and

WHEREAS, while the FDA bears responsibility for enforcing
federal laws to protect citizens from misbranded and adulterated
pharmaceutical ingredients, its enforcement has proven
insufficient to curtail the influx of these substances into this
state, and despite FDA action to curb imports of active
pharmaceutical ingredients for weight loss medications from
entities that are not compliant with current good manufacturing
practices, patients in our state remain at risk of receiving
compounded medications containing such active pharmaceutical
ingredients, and

WHEREAS, the Legislature therefore finds it necessary for
the state to take action to protect its residents by ensuring
that all active pharmaceutical ingredients used in compounding
are sourced from reputable, registered, and inspected
establishments, and that only pharmaceutical-grade, safe, and
unadulterated ingredients are used in medications for weight
loss, NOW, THEREFORE,

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

Section 1. Section 499.038, Florida Statutes, is created to
read:

499.038 Regulation of medications containing certain active
pharmaceutical ingredients.-

(1) DEFINITION.—As used in this section, the term
"compounded medication" means a customized drug prepared by a

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59 licensed pharmacist or licensed physician by combining, mixing,
60 or altering the ingredients of one or more drugs or products,
61 which drug is commonly prescribed if a commercially available
62 medication does not meet a patient's specific health need.

63 (2) PROHIBITION.—A person or an entity may not engage in
64 the sale, transfer, or distribution of a compounded medication
65 for weight loss unless the person or entity provides
66 documentation to the department certifying all of the following:

67 (a) If a licensed pharmacist or licensed physician
68 compounds the medication pursuant to 21 U.S.C. s.
69 353a(b)(1)(A)(i)(II), that the active pharmaceutical ingredient
70 used is:

71 1. Identical to that used in the manufacture of a drug
72 approved by the United States Food and Drug Administration
73 (FDA); and

74 2. Manufactured according to the manufacturing process for
75 that ingredient as specified on the label of a drug approved by
76 the FDA.

77 (b) That the active pharmaceutical ingredient is a
78 pharmaceutical-grade product.

79 (c) That the active pharmaceutical ingredient is
80 accompanied by a valid certificate of analysis that provides
81 informational material as to the safety and effectiveness of the
82 drugs compounded using the active pharmaceutical ingredient,
83 including the identity and content of the active pharmaceutical
84 ingredient and the identity of each impurity by chemical name
85 and amount present. A certificate of analysis is not valid
86 unless it is accompanied by testing data from the original
87 manufacturing establishment demonstrating that the information

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on the certificate of analysis is accurate.

(d) That the active pharmaceutical ingredient was manufactured in a facility that:

1. Is registered with the FDA pursuant to 21 U.S.C. s. 360; and

2. Has been inspected by the FDA as a human drug establishment within the preceding 2 years, and such inspection:

a. Included monitoring compliance with current good manufacturing practices for the relevant active pharmaceutical ingredient; and

b. Resulted in a "Voluntary Action Indicated" or "No Action Indicated" classification under the FDA's inspection classification system.

(e) That the person or entity conducted quality control testing of the active pharmaceutical ingredient before its use in a compounded drug to confirm:

1. The identity and content of the active pharmaceutical ingredient; and

2. That any impurity present in the active pharmaceutical ingredient has been identified, characterized, quantified, and justified given the product or the product's intended use.

(3) ENFORCEMENT AND PENALTIES.—A person or an entity that violates this section is subject to the following penalties:

(a) A fine of \$1,000 per dose of the illegally compounded drug sold, dispensed, transferred, or distributed by the person or entity; and

(b) Revocation of the person's or entity's license or permit by the Board of Pharmacy or the department, as applicable.

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117 (4) RULEMAKING.—The department may adopt rules and conduct
118 inspections as necessary to implement this section.

119 Section 2. This act shall take effect upon becoming a law.