

By the Committee on Health Policy; and Senator Passidomo

588-02385-18

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1 A bill to be entitled
2 An act relating to distributing pharmaceutical drugs
3 and devices; amending s. 465.027, F.S.; revising an
4 exception to pharmacy regulations for certain
5 manufacturers and distributors of dialysis drugs or
6 supplies; providing an effective date.

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

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10 Section 1. Subsection (2) of section 465.027, Florida
11 Statutes, is amended to read:

12 465.027 Exceptions.—

13 (2) This chapter does ~~shall~~ not apply to a manufacturer, or
14 its agent, holding an active manufacturer or third-party
15 logistics provider permit ~~as a manufacturer~~ under chapter 499,
16 to the extent the manufacturer, or its agent, is and engaged
17 ~~solely~~ in the manufacture or distribution of dialysate, drugs,
18 or devices necessary to perform home renal dialysis on patients
19 with chronic kidney failure, if the dialysate, drugs, or devices
20 are:

21 (a) Approved or cleared by the United States Food and Drug
22 Administration; and

23 (b) Delivered in the original, sealed packaging after
24 receipt of a physician's order to dispense to:

25 1. A patient with chronic kidney failure, or the patient's
26 designee, for the patient's self-administration of the dialysis
27 therapy; or

28 2. A health care practitioner or an institution for
29 administration or delivery of the dialysis therapy to a patient

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30 with chronic kidney failure.

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