



927006

LEGISLATIVE ACTION

Senate

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House

The Committee on Health Policy (Passidomo) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

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

465.027 Exceptions.—

(2) This chapter does ~~shall~~ not apply to a manufacturer, or
its agent, holding an active manufacturer or third-party
logistics provider permit ~~as a manufacturer~~ under chapter 499,



11 to the extent the manufacturer, or its agent, is ~~and~~ engaged
12 ~~solely~~ in the manufacture or distribution of dialysate, drugs,
13 or devices necessary to perform home renal dialysis on patients
14 with chronic kidney failure, if the dialysate, drugs, or devices
15 are:

16 (a) Approved or cleared by the United States Food and Drug
17 Administration; and

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

20 1. A patient with chronic kidney failure, or the patient's
21 designee, for the patient's self-administration of the dialysis
22 therapy; or

23 2. A health care practitioner or an institution for
24 administration or delivery of the dialysis therapy to a patient
25 with chronic kidney failure.

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

27 ===== T I T L E A M E N D M E N T =====

28 And the title is amended as follows:

29 Delete everything before the enacting clause
30 and insert:

31 A bill to be entitled

32 An act relating to distributing pharmaceutical drugs
33 and devices; amending s. 465.027, F.S.; revising an
34 exception to pharmacy regulations for certain
35 manufacturers and distributors of dialysis drugs or
36 supplies; providing an effective date.