

By Senator Passidomo

28-01376-18

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1                                   A bill to be entitled  
 2           An act relating to home renal dialysis; amending s.  
 3           465.027, F.S.; revising conditions under which  
 4           manufacturers, or agents thereof, who distribute home  
 5           dialysis supplies are exempt from the requirements of  
 6           the Florida Pharmacy Act; providing an effective date.

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 permit ~~as a manufacturer~~ under chapter 499 who is and  
 16           engaged ~~solely~~ in the ~~manufacture or~~ distribution of dialysate,  
 17           drugs, or devices necessary to perform home renal dialysis on  
 18           patients with chronic kidney failure, if the dialysate, drugs,  
 19           or devices are:

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

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

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

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

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Section 2. This act shall take effect July 1, 2018.