

## CHAPTER 2018-50

### House Bill No. 513

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

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

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

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

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

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

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

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

Approved by the Governor March 21, 2018.

Filed in Office Secretary of State March 21, 2018.