2022 Regular Session

HOUSE BILL NO. 497

BY REPRESENTATIVES TURNER, ROBBY CARTER, AND COX

HEALTH: Exempts certain facilities that provide home dialysis drugs or devices from the provisions of the La. Pharmacy Practice Act

AN ACT

To amend and reenact R.S. 37:1250, relative to regulation of pharmacists and pharmacies by the Louisiana Board of Pharmacy; to provide relative to facilities which engage solely in the distribution of drugs or other products necessary for home kidney dialysis for patients with end stage renal disease; to exempt such facilities from the provisions of the Louisiana Pharmacy Practice Act; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1250 is hereby amended and reenacted to read as follows:

§1250. Exceptions

A. Nothing in this Chapter shall be construed to prevent or restrict the practice of nursing by a licensed registered nurse or an advanced practice registered nurse in accordance with R.S. 37:911 et seq., R.S. 37:1031 through 1034, or any other laws, rules, or regulations governing the practice of nursing in the state of Louisiana.

B. Nothing in this Chapter shall apply to a facility which engages solely in the distribution of dialysate, drugs, or devices necessary to perform home kidney dialysis to patients with end stage renal disease if all of the following criteria are met:

(1) The dialysate, drugs, or devices are approved or cleared by the United States Food and Drug Administration as required by federal law.

(2) The dialysate, drugs, or devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with the board as a distributor of legend drugs or legend devices.

(3) The dialysate, drugs, or devices are held and delivered in their original, sealed packaging from the manufacturing facility.

(4) The dialysate, drugs, or devices are delivered only by the manufacturer or the manufacturer's agent and only upon receipt of a physician's order.

(5) The manufacturer or manufacturer's agent delivers the dialysate, drugs, or devices directly to any of the following parties:

(a) A patient with end stage renal disease, or his designee, for self-administration of the dialysis therapy by the patient.

(b) A healthcare provider or institution for administration or delivery of the dialysis therapy to a patient with end stage renal disease.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 497 Engrossed 2022 Regular Session Turner

Abstract: Exempts from the provisions of the La. Pharmacy Practice Act facilities that provide home dialysis drugs or devices and meet certain specifications.

Proposed law stipulates that nothing in the La. Pharmacy Practice Act (present law, R.S. 37:1161 et seq.), shall apply to a facility which engages solely in the distribution of dialysate, drugs, or devices necessary to perform home kidney dialysis to patients with end stage renal disease if all of the following criteria are met:

(1) The dialysate, drugs, or devices are approved or cleared by the U.S. Food and Drug Administration as required by federal law.

(2) The dialysate, drugs, or devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with the La. Board of Pharmacy as a distributor of legend drugs or legend devices.

(3) The dialysate, drugs, or devices are held and delivered in their original, sealed packaging from the manufacturing facility.

(4) The dialysate, drugs, or devices are delivered only by the manufacturer or the manufacturer's agent and only upon receipt of a physician's order.

(5) The manufacturer or manufacturer's agent delivers the dialysate, drugs, or devices directly to any of the following parties:

(a) A patient with end stage renal disease, or his designee, for self-administration of the dialysis therapy by the patient.

(b) A healthcare provider or institution for administration or delivery of the dialysis therapy to a patient with end stage renal disease.

(Amends R.S. 37:1250)