THE SENATE
THIRTY-SECOND LEGISLATURE, 2023
STATE OF HAWAII

S.B. NO. 473 S.D. 1 H.D. 2

A BILL FOR AN ACT

RELATING TO THE PRACTICE OF PHARMACY.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 461, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§461- Distribution of dialysate drugs and devices.** (a) The license, registration, and permit requirements of this chapter shall not apply to a manufacturer, wholesale distributor, manufacturer engaged in direct distribution to qualified persons, or third-party logistics provider, to the extent the manufacturer, wholesale distributor, manufacturer engaged in direct distribution to qualified persons, or third-party logistics provider is engaged in the distribution of dialysate drugs or devices necessary to perform home dialysis on patients with end-stage renal disease; provided that the following criteria shall be met:

(1) The dialysate drugs or devices are approved 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 a manufacturer's agent that is properly licensed with the board as a manufacturer, wholesale distributor, or manufacturer engaged in direct distribution to qualified persons;

(3) The dialysate drugs or devices are held and delivered in the original, sealed, and labeled 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 an order by a physician, a physician assistant, or an advanced practice registered nurse with prescriptive authority; and

(5) The manufacturer or the manufacturer's agent delivers the dialysate drugs or devices directly to:

(A) A patient with end stage renal disease, or the patient's designee, for the patient's self-administration of dialysis therapy; or

(B) A health care provider or an institution for administration or delivery of dialysis therapy to a patient with end stage renal disease.

(b) For the purposes of this section:

"Manufacturer" has the same meaning as in section 328-112.

"Third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services on behalf of a manufacturer, wholesale distributor, or dispenser of a product.

"Wholesale distributor" has the same meaning as in section 328-112."

SECTION 2. New statutory material is underscored.

SECTION 3. This Act shall take effect on June 30, 3000.

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Report Title:
Practice of Pharmacy; Dialysate Drugs or Devices; Manufacturers; Wholesalers; Third-Party Logistics Providers; Exemption

Description:
Exempts manufacturers, wholesale distributors, manufacturer engaged in direct distribution to qualified persons, and third-party logistics providers of home dialysate drugs or devices from the license, registration, and permit requirements for pharmacies, under certain conditions. Effective 6/30/3000. (HD2)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.