THE SENATE
THIRTY-SECOND LEGISLATURE, 2023
STATE OF HAWAII

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

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 upon its approval.

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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, manufacturers 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. (CD1)

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