

ACT 101

S.B. NO. 473

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.¹

SECTION 3. This Act shall take effect upon its approval.

(Approved June 22, 2023.)

Note

- 1. Edited pursuant to HRS §23G-16.5.