

JAN 20 2023

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# A BILL FOR AN ACT

RELATING TO THE PRACTICE OF PHARMACY.

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

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

4           "§461-    Distribution of dialysate drugs and devices.    (a)

5   The license, registration, and permit requirements of this  
6   chapter shall not apply to a drug manufacturer, a wholesale  
7   prescription drug distributor, or a third-party logistics  
8   provider, to the extent the manufacturer, wholesale distributor,  
9   or third-party logistics provider is engaged in the distribution  
10   of dialysate drugs or devices necessary to perform home  
11   peritoneal dialysis on patients with end-stage renal disease;  
12   provided that the following criteria are met:

13           (1)   The dialysate drugs or devices are approved by the  
14                United States Food and Drug Administration, as  
15                required by federal law;

16           (2)   The dialysate drugs or devices are lawfully held by a  
17                manufacturer or a manufacturer's agent that is



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- 1           properly registered with the board as a manufacturer  
2           or wholesale distributor;
- 3       (3) The dialysate drugs or devices are held and delivered  
4           in their original, sealed, and labeled packaging from  
5           the manufacturing facility;
- 6       (4) The dialysate drugs or devices are delivered only by  
7           the manufacturer or the manufacturer's agent and only  
8           upon receipt of a physician's order; and
- 9       (5) The manufacturer or the manufacturer's agent delivers  
10           the dialysate drugs or devices directly to a:
- 11           (A) Patient with end stage renal disease, or the  
12                patient's designee, for the patient's self-  
13                administration of dialysis therapy; or
- 14           (B) Health care provider or institution for  
15                administration or delivery of the dialysis  
16                therapy to a patient with end stage renal  
17                disease.
- 18       (b) For the purposes of this section:
- 19           "Manufacturer" shall have the same meaning as in section  
20           328-112.



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

5       "Wholesale distributor" shall have the same meaning as in  
6 section 328-112."

7       SECTION 2. New statutory material is underscored.

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

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INTRODUCED BY: \_\_\_\_\_



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**Report Title:**

Pharmacy; Dialysis Drugs and Supplies; Manufacturers;  
Wholesalers; Third-Party Logistics Providers; Exemption

**Description:**

Exempts drug manufacturers, wholesale prescription drug distributors, and third-party logistics providers of home dialysis drugs, supplies, and devices from the license, registration, and permit requirements for pharmacies; provided that certain conditions are met.

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

