



GOV. MSG. NO. 1202

EXECUTIVE CHAMBERS
KE KE'ENA O KE KIA'ĀINA

JOSH GREEN, M.D.
GOVERNOR
KE KIA'ĀINA

June 22, 2023

The Honorable Ronald D. Kouchi
President of the Senate,
and Members of the Senate
Thirty-Second State Legislature
State Capitol, Room 409
Honolulu, Hawai'i 96813

✓ The Honorable Scott K. Saiki
Speaker, and Members of the
House of Representatives
Thirty-Second State Legislature
State Capitol, Room 431
Honolulu, Hawai'i 96813

Dear President Kouchi, Speaker Saiki, and Members of the Legislature:

This is to inform you that on June 22, 2023, the following bill was signed into law:

SB473 SD1 HD2 CD1

RELATING TO THE PRACTICE OF PHARMACY.
ACT 101

Sincerely,

Josh Green, M.D.
Governor, State of Hawai'i

on JUN 22 2023

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:

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 manufacturer, wholesale
7 distributor, manufacturer engaged in direct distribution to
8 qualified persons, or third-party logistics provider, to the
9 extent the manufacturer, wholesale distributor, manufacturer
10 engaged in direct distribution to qualified persons, or third-
11 party logistics provider is engaged in the distribution of
12 dialysate drugs or devices necessary to perform home dialysis on
13 patients with end-stage renal disease; provided that the
14 following criteria shall be met:

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

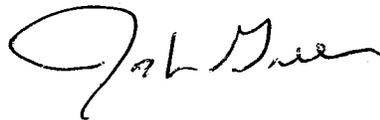


- 1 (2) The dialysate drugs or devices are lawfully held by a
2 manufacturer or a manufacturer's agent that is
3 properly licensed with the board as a manufacturer,
4 wholesale distributor, or manufacturer engaged in
5 direct distribution to qualified persons;
- 6 (3) The dialysate drugs or devices are held and delivered
7 in the original, sealed, and labeled packaging from
8 the manufacturing facility;
- 9 (4) The dialysate drugs or devices are delivered only by
10 the manufacturer or the manufacturer's agent and only
11 upon receipt of an order by a physician, a physician
12 assistant, or an advanced practice registered nurse
13 with prescriptive authority; and
- 14 (5) The manufacturer or the manufacturer's agent delivers
15 the dialysate drugs or devices directly to:
- 16 (A) A patient with end-stage renal disease, or the
17 patient's designee, for the patient's self-
18 administration of dialysis therapy; or
- 19 (B) A health care provider or an institution for
20 administration or delivery of dialysis therapy to
21 a patient with end-stage renal disease.



1 (b) For the purposes of this section:
2 "Manufacturer" has the same meaning as in section 328-112.
3 "Third-party logistics provider" means an entity that
4 provides or coordinates warehousing or other logistics services
5 on behalf of a manufacturer, wholesale distributor, or dispenser
6 of a product.
7 "Wholesale distributor" has the same meaning as in section
8 328-112."
9 SECTION 2. New statutory material is underscored.
10 SECTION 3. This Act shall take effect upon its approval.

APPROVED this 22nd day of June, 2023



GOVERNOR OF THE STATE OF HAWAII

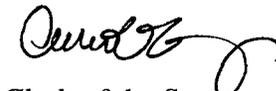


THE SENATE OF THE STATE OF HAWAI'I

Date: May 2, 2023
Honolulu, Hawai'i 96813

We hereby certify that the foregoing Bill this day passed Final Reading in the Senate of the Thirty-Second Legislature of the State of Hawai'i, Regular Session of 2023.


President of the Senate


Clerk of the Senate

SB No. 473, SD 1, HD 2, CD 1

THE HOUSE OF REPRESENTATIVES OF THE STATE OF HAWAII

Date: May 2, 2023
Honolulu, Hawaii

We hereby certify that the above-referenced Bill on this day passed Final Reading in the House of Representatives of the Thirty-Second Legislature of the State of Hawaii, Regular Session of 2023.



Scott K. Saiki
Speaker
House of Representatives



Brian L. Takeshita
Chief Clerk
House of Representatives