CS FOR HOUSE BILL NO. 96(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-THIRD LEGISLATURE - FIRST SESSION

BY THE HOUSE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered: 4/14/23
Referred: Labor and Commerce

Sponsor(s): REPRESENTATIVE PRAX

A BILL

FOR AN ACT ENTITLED

"An Act relating to licensing and registration requirements for certain wholesale drug distributors; and providing for an effective date."

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

*** Section 1.** AS 08.80.157(h) is amended to read:

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

(3) the furnishing of false or fraudulent material in an application made in connection with drug or device manufacturing or distribution;

(4) suspension or revocation by federal, state, or local government of a

license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

(6) dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy **unless**

(A) the drug or device is a dialysate, drug composed solely of fluids, electrolytes, and sugars, or device that is

(i) necessary to perform home dialysis;

(ii) approved by the United States Food and Drug Administration, as required by federal law; and

(iii) delivered in its original, sealed, and labeled packaging only upon the receipt of a physician's order; and

(B) the wholesale drug distributor

(i) delivers the dialysate drug or device directly to a patient with end-stage renal disease, or to the patient's designee, for the patient's self-administration of dialysis therapy;

(ii) uses a bar code scanning and verification system confirming that the dialysate drug or device selected to fill the patient-specific order matches the information on the patient-specific label; and

(iii) has additional secondary accuracy and delivery checks in place; and

(C) a licensed pharmacist serves as a consultant to the wholesale drug distributor to

(i) conduct a retrospective audit of 10 percent of the dialysate drug and device orders provided directly to patients processed by the wholesale drug distributor every month; and

(ii) perform assessments at least twice monthly to ensure quality of product storage, handling, and distribution by the

wholesale drug distributor;

(8) violation of this chapter or a regulation adopted under this chapter.

*** Sec. 2.** This Act takes effect May 7, 2023.