A M E N D M E N T

OFFERED IN THE SENATE

TO: SB 94

Page 1, line 2, following "**manufacturers;**":

Insert "**relating to licensing and registration requirements for certain wholesale drug distributors;**"

Page 4, following line 11:

Insert a new bill section to read:

"*** Sec. 4.** 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, and to ensure product expiration dates are later than three months after the date of assessment;

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

Renumber the following bill sections accordingly.

Page 9, line 20:

Delete "sec. 18"

Insert "sec. 19"

Page 9, line 21:

Delete "sec. 18"

Insert "sec. 19"

Page 9, line 31:

Delete "Section 20"

Insert "Sections 4 and 21"

Page 10, line 1:

Delete "sec. 21"

Insert "sec. 22"