Assembly Bill No. 110–Committee
on Commerce and Labor

CHAPTER.....

AN ACT relating to pharmacy; authorizing a manufacturer or wholesaler to dispense a dialysate drug or deliver a device used to perform dialysis at a residence to certain persons and entities; providing a penalty; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law prohibits a manufacturer or wholesaler from dispensing dangerous drugs. (NRS 454.215, 639.100) **Sections 1-5** of this bill authorize a manufacturer or wholesaler to dispense certain dialysate drugs and deliver devices necessary to administer dialysis at a residence after satisfying certain requirements to a: (1) patient with irreversible renal disease, or his or her designee; (2) provider of health care; or (3) hospital or facility for the treatment of irreversible renal disease. **Section 1** requires a prescription provided to a manufacturer or a wholesaler for such purposes to comply with various requirements concerning format, contents and recordkeeping that apply to prescriptions generally. **Section 1** authorizes a manufacturer or wholesaler to use a third-party logistics provider to deliver the dialysate drug or device necessary to administer dialysis at home. **Section 6** of this bill requires a manufacturer or wholesaler that dispenses dialysate drugs pursuant to **section 1** to maintain certain records relating to dangerous drugs in the same manner as a pharmacy, hospital or practitioner that furnishes dangerous drugs and makes a violation of this requirement a misdemeanor. (NRS 454.286)

Section 7 of this bill authorizes a person to possess a dangerous dialysate drug dispensed to him or her by a manufacturer or wholesaler pursuant to **section 1**.

EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets ~~[omitted material]~~ is material to be omitted.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Chapter 639 of NRS is hereby amended by adding thereto a new section to read as follows:

1. Except as otherwise provided in subsection 4, a manufacturer or wholesaler may dispense a dialysate drug or deliver a device necessary to administer dialysis at a residence under the conditions prescribed by subsection 2 to:

(a) A patient with irreversible renal disease, or a designee of the patient, for the administration of dialysis at the residence of the patient;

(b) A provider of health care; or

(c) A hospital or facility for the treatment of irreversible renal disease.

2. A drug dispensed or a device delivered pursuant to subsection 1 must be:

(a) Approved by the United States Food and Drug Administration;

(b) Prescribed or ordered by a physician, physician assistant or advanced practice registered nurse; and

(c) Dispensed and delivered in the original, unopened packaging used by the manufacturer of the drug or device.

3. The provisions of NRS 454.223, 639.235 to 639.239, inclusive, and 639.2392 to 639.2397, inclusive, apply to a prescription provided to a manufacturer or wholesaler pursuant to this section to the same extent as if the prescription were provided to a pharmacist.

4. The provisions of this section do not authorize a manufacturer or wholesaler to dispense a dialysate drug that is a:

(a) Controlled substance to any person or entity; or

(b) Dangerous drug that is unsafe for self-administering directly to or unsupervised use directly by a patient or the designee of a patient.

5. A manufacturer or wholesaler may use a third-party logistics provider to deliver a dialysate drug or device necessary to administer dialysis at a residence pursuant to subsection 1.

6. As used in this section:

(a) "Dialysate drug" means a drug solely composed of fluids, electrolytes and sugars used for dialysis.

(b) "Dialysis" means the method by which a dissolved substance is removed from the body of a patient by diffusion, osmosis and convection from one fluid compartment to another fluid compartment across a semipermeable membrane.

(c) "Facility for the treatment of irreversible renal disease" has the meaning ascribed to it in NRS 449.0046.

(d) "Provider of health care" has the meaning ascribed to it in NRS 629.031.

(e) "Third-party logistics provider" means a person that transports, warehouses, packages, tracks or manages a drug or device.

Sec. 2. NRS 639.016 is hereby amended to read as follows:

639.016 "Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person other than the consumer or patient ~~[.]~~ ***, except where authorized by section 1 of this act.*** The term includes a person who derives,

produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Sec. 3. NRS 639.595 is hereby amended to read as follows:

639.595 1. A wholesaler may sell a prescription drug only if the sale is a bona fide transaction.

2. A wholesaler may purchase a prescription drug only from:

(a) A manufacturer;

(b) A pharmacy or practitioner if that pharmacy or practitioner maintains a valid license in the State in which the pharmacy or practitioner is domiciled; or

(c) Another wholesaler if:

(1) The wholesaler who sells the drug is licensed by the Board; and

(2) The sale is a bona fide transaction.

3. A wholesaler may receive a prescription drug from a pharmacy or practitioner only if the wholesaler does not pay the pharmacy or practitioner an amount, either in cash or credit, that is more than the price for which the wholesaler sells such prescription drugs to other pharmacies or practitioners at the time of return and:

(a) The prescription drug was originally shipped to the pharmacy or practitioner by the wholesaler; or

(b) The prescription drug could not be returned by the pharmacy or practitioner to the original wholesaler.

➥ If a wholesaler receives a prescription drug pursuant to this subsection and the wholesaler subsequently sells the prescription drug to another wholesaler, the prescription drug must be accompanied by a statement of prior sales as defined in NRS 639.535.

4. The Board shall not limit the quantity of prescription drugs a wholesaler may purchase, sell, distribute or otherwise provide to another wholesaler, distributor or manufacturer.

5. For the purposes of this section:

(a) A purchase shall be deemed a bona fide transaction if:

(1) The wholesaler purchased the drug:

(I) Directly from the manufacturer of the drug; or

(II) With a reasonable belief that the drug was originally purchased directly from the manufacturer of the drug;

(2) The circumstances of the purchase reasonably indicate that the drug was not purchased from a source prohibited by law;

(3) Unless the drug is purchased by the wholesaler from the manufacturer, before the wholesaler sells the drug to another wholesaler, the wholesaler who sells the drug conducts a reasonable visual examination of the drug to ensure that the drug is not:

(I) Counterfeit;

(II) Deemed to be adulterated or misbranded in accordance with the provisions of chapter 585 of NRS;

(III) Mislabeled;

(IV) Damaged or compromised by improper handling, storage or temperature control;

(V) From a foreign or unlawful source; or

(VI) Manufactured, packaged, labeled or shipped in violation of any state or federal law relating to prescription drugs;

(4) The drug is shipped directly from the wholesaler who sells the drug to the wholesaler who purchases the drug; and

(5) The documents of the shipping company concerning the shipping of the drug are attached to the invoice for the drug and are maintained in the records of the wholesaler.

(b) A sale shall be deemed a bona fide transaction if the wholesaler sells the prescription drug only to:

(1) A pharmacy or practitioner if that pharmacy or practitioner maintains a valid license in the state in which the pharmacy or practitioner is domiciled.

(2) Another wholesaler who maintains a valid license in the state in which he or she is domiciled if the wholesaler who sells the prescription drug has complied with NRS 639.575, 639.580 and 639.585.

(3) A patient with irreversible renal disease, the designee of such a patient, a provider of health care, a hospital or a facility for the treatment of irreversible renal disease, if the drug is a dialysate drug dispensed pursuant to section 1 of this act.

(c) The purchase or sale of a prescription drug includes, without limitation, the distribution, transfer, trading, bartering or any other provision of a prescription drug to another person by a wholesaler. A transfer of a prescription drug from a wholesale facility of a wholesaler to another wholesale facility of the wholesaler shall not be deemed a purchase or sale of a prescription drug pursuant to this section if the wholesaler is a corporation whose securities are publicly traded and regulated by the Securities Exchange Act of 1934.

Sec. 4. NRS 454.0098 is hereby amended to read as follows:

454.0098 "Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies dangerous drugs or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person other than the consumer or patient ~~[.]~~ ***, except where authorized by section 1 of this act.*** The term does not include:

1. A person who derives, produces or prepares medicines, chemicals or devices on sales orders for resale.

2. A nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Sec. 5. NRS 454.215 is hereby amended to read as follows:

454.215 A dangerous drug may be dispensed by:

1. A registered pharmacist upon the legal prescription from a practitioner or to a pharmacy in a correctional institution upon the written order of the prescribing practitioner in charge;

2. A pharmacy in a correctional institution, in case of emergency, upon a written order signed by the chief medical officer;

3. A practitioner, or a physician assistant licensed pursuant to chapter 630 or 633 of NRS if authorized by the Board;

4. A registered nurse, when the nurse is engaged in the performance of any public health program approved by the Board;

5. A medical intern in the course of his or her internship;

6. An advanced practice registered nurse who holds a certificate from the State Board of Pharmacy permitting him or her to dispense dangerous drugs;

7. A registered nurse employed at an institution of the Department of Corrections to an offender in that institution;

8. A registered pharmacist from an institutional pharmacy pursuant to regulations adopted by the Board; ~~[or]~~

9. ***A manufacturer or wholesaler dispensing a dialysate drug pursuant to section 1 of this act; or***

10. A registered nurse to a patient at a rural clinic that is designated as such pursuant to NRS 433.233 and that is operated by the Division of Public and Behavioral Health of the Department of Health and Human Services if the nurse is providing mental health services at the rural clinic,

➥ except that no person may dispense a dangerous drug in violation of a regulation adopted by the Board.

Sec. 6. NRS 454.286 is hereby amended to read as follows:

454.286 1. Every retail pharmacy, hospital or any practitioner who engages in the practice of dispensing or furnishing drugs to

patients ***and every manufacturer or wholesaler that dispenses dialysate drugs to patients pursuant to section 1 of this act*** shall maintain a complete and accurate record of all dangerous drugs purchased and those sold on prescription, dispensed, furnished or disposed of otherwise.

2. The records must be retained for a period of 2 years and must be open to inspection by members, inspectors or investigators of the Board or inspectors of the Food and Drug Administration.

3. Invoices showing all purchases of dangerous drugs constitute a complete record of all dangerous drugs received.

4. For the purpose of this section, the prescription files of a pharmacy constitute a record of the disposition of all dangerous drugs.

5. A person who violates any provision of this section is guilty of a misdemeanor.

Sec. 7. NRS 454.316 is hereby amended to read as follows:

454.316 1. Except as otherwise provided in this section, a person who possesses a dangerous drug, except that furnished to the person by a pharmacist pursuant to a legal prescription ***, by a manufacturer or wholesaler pursuant to section 1 of this act*** or by a practitioner, is guilty of a gross misdemeanor. A person who has been twice previously convicted of any offense:

(a) Described in this section; or

(b) Pursuant to any other law of the United States or this or any other state or district which if committed in this State would have been punishable as an offense under this section,

➥ is guilty of a category E felony and shall be punished as provided in NRS 193.130.

2. A prescription is not required for possession of a dangerous drug by a person authorized by NRS 454.213, any other person or class of persons approved by the Board pursuant to regulation, jobbers, wholesalers, manufacturers or laboratories authorized by laws of this State to handle, possess and deal in dangerous drugs if the drugs are in stock containers properly labeled and have been procured from a manufacturer, wholesaler or pharmacy, or by a rancher who possesses a dangerous drug in a reasonable amount for use solely in the treatment of livestock on his or her own premises.