



ALASKA HOUSE BILL 96

“AN ACT RELATING TO LICENSING AND REGISTRATION REQUIREMENTS FOR CERTAIN
WHOLESALE DRUG DISTRIBUTORS; AND PROVIDING FOR AN EFFECTIVE DATE.”

TREATMENT OF END STATE RENAL DISEASE (ESRD) IN ALASKA (2020)

- ESRD Alaska Patients TOTAL: 1086
- Incenter Hemodialysis Patients: 532
- **Home Dialysis Patients: 154**
- Renal Transplants: 399

HOW DIALYSIS PATIENTS RECEIVE THEIR DIALYSIS PRODUCTS AT HOME

- For ESRD patients who elect to receive their dialysis in the home vs in a center 3 days a week they must receive monthly home shipments of supplies to perform the dialysis.
- The shipments include dialysis solutions made up of sugar water or icodextrin, a water-soluble starch and plastic tubing sets.
- The solutions are manufactured and packaged into color-coded at a manufacturing facility under the jurisdiction, inspection, and supervision of the FDA
- Once manufactured at the facility, dialysis solutions are not mixed or compounded prior to delivery to the home patient, nor are the boxes opened.
- Each delivery weighs between 500 and 1,000 pounds. Because of the bulk and weight, home delivery is an essential service for the home PD patient.

HOW DIALYSIS PATIENTS RECEIVE THEIR DIALYSIS PRODUCTS AT HOME (CON'T)

- Once each ESRD patient's physician has determined that the patient may self-administer PD therapy and they are trained appropriately, the physician determines the patient's monthly supply needs, prepares an order and transmits it directly to a Remote Prescription Order Processing Pharmacy in another state to a licensed pharmacist.
- This pharmacy obtains the physician prescription order via fax, electronic or verbal means and is entered as a standing order for the patient into a central computer system which has built-in compliance checks.
- From this prescription order, the pharmacy generates the monthly shipment order, which will be sent to a near by distribution center.
- Specially trained distribution employees organize each patient's monthly supplies into deliveries. The supplies are verified for accuracy. All supplies from the patient's orders are labeled with order information such as the names of the patient and physician, 24 hour emergency phone number, etc.
- After several compliance checks the orders are delivered directly to the patient's home.



WHY DO WE NEED THE LAW CHANGED?

- The Alaska Pharmacy Board requires a pharmacy that only distributes dialysis supplies and solutions to the home of dialysis patients, to comply with the same arduous requirements as retail pharmacies that handle controlled substances, compounds, and dispense medications with varying safety profiles.
- These Pharmacies that deliver dialysis supplies and solutions only offer a limited product portfolio and follow all Quality and FDA requirements
- The law also requires a licensed pharmacist (above and beyond the Alaska licensed out of state central pharmacy that has processed the order) to physically view the boxes before they can leave the warehouse, which is onerous and unnecessary.

WHAT DOES THE BILL DO?

This bill will:

- Amend the pharmacy practice act to allow manufacturers of home dialysis drugs, supplies and devices to be exempted from being licensed as a pharmacy if they maintain control of all products from manufacturing to the patient.
- This would still require the location to maintain any additional licenses, such as an Alaska wholesaler license.
- This means the Alaska Board of Pharmacy still has jurisdiction over the location and its operations.

WHY IS THIS CHANGE OK FOR ALASKANS?

- In Alaska, we believe the requirement to require a pharmacist to review and place a second label onto the boxes prior to leaving the warehouse is onerous and unnecessary.
- This bill will mirror what the National Board of Pharmacy's Model Act outlines for these pharmacies and distribution centers.
- There are 24 states that currently operate under the model and an additional 8 states provide for some form of special licensure for the distribution of these products with zero instances of harm to any patient.

CURRENTLY, THIS IS THE STANDARD OF PRACTICE IN 32 STATES?

Currently, 24 states allow manufacturers of dialysis supplies and solutions, if registered as a wholesale drug distributor, to deliver directly to home dialysis patients. These states are:

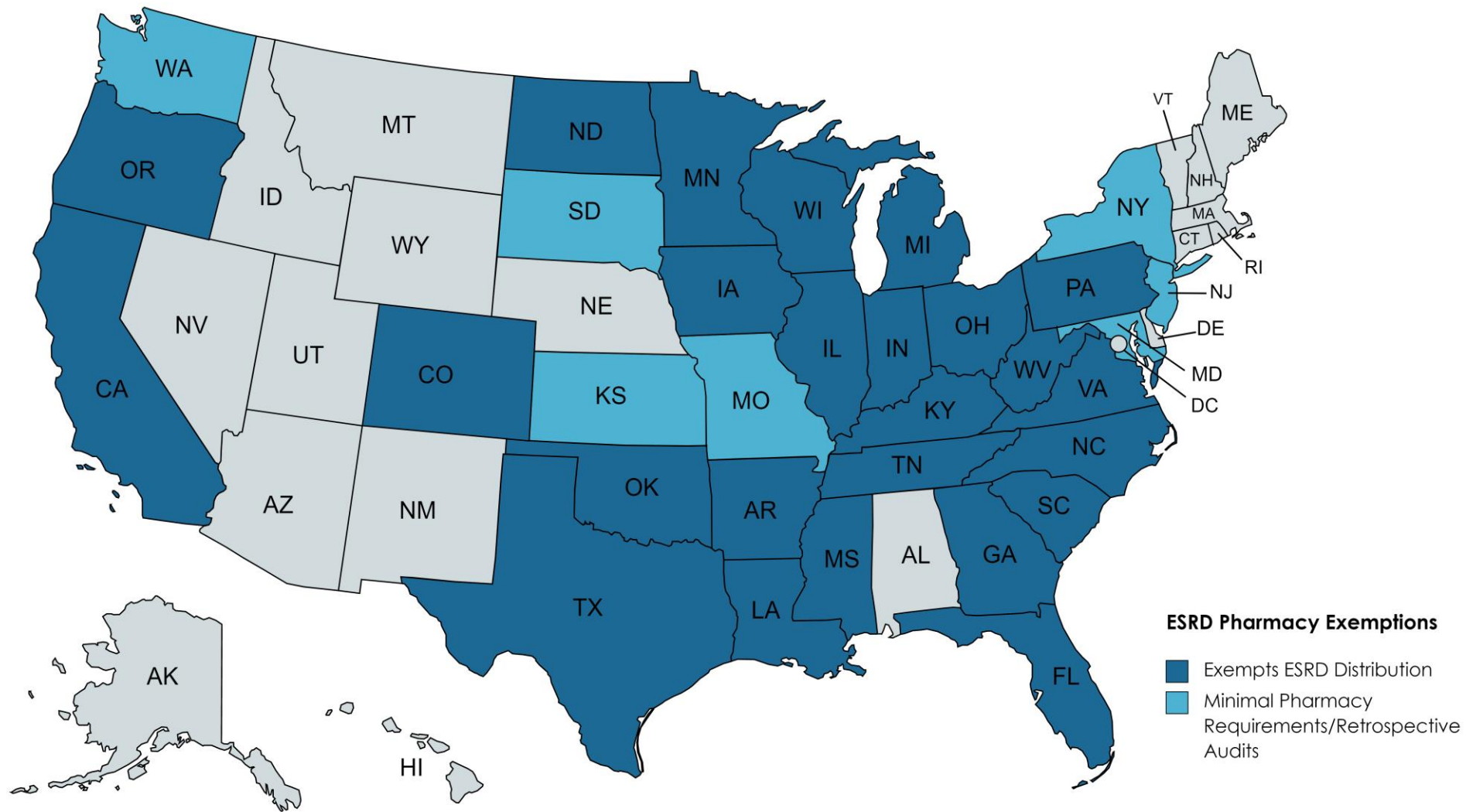
Arkansas, California, Colorado, Florida, Georgia, Iowa, Illinois, Indiana, Louisiana, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Virginia, Wisconsin, and West Virginia.

An additional 8 states provide for some form of special licensure for the distribution of these products:

Washington, Oregon, Kansas, Missouri, New York, New Jersey, Maryland, and Kentucky.

There are 2 additional states that have bills pending this session to do this as well:

Hawaii and Nevada





THINGS TO CONSIDER

- This bill would **NOT** include diabetes supplies or any other type of device, DME or pharmaceutical product.
- No compounding or manipulation of products would occur.
- Product arrives and leaves in manufactured, sealed packaging upon delivery by manufacturer.
- Solutions are under the manufacturers control from the site of the FDA-regulated and licensed manufacturing plant to the patient's home.
- This proposed change would be restricted to only pharmacies with a central pharmacy to process prescriptions, conduct medicine reviews, etc., along with the warehouse that is licensed in Alaska with the Board of Pharmacy. And applies only to dialysate, drugs, or devices delivered directly to a patient or their designee with end-stage renal disease or acute kidney injury.

THANK YOU

The background features three overlapping circles: a large light pink circle on the right, a dark blue circle at the top and bottom, and a white circle on the left. The pink circle contains several thin white concentric lines.