Alberta Darling

Wisconsin State Senator

Co-Chair, Joint Committee on Finance

Testimony before the Senate Committee on Health and Human Services
Senate Bill 38
Thursday, March 14

Thank you Chair Testin and committee members for holding a public hearing on Senate Bill 38. This important piece of legislation removes an unnecessary regulation that requires in home dialysis distribution centers to obtain a pharmacist license.

Chronic Kidney Disease (CKD) is an affliction that damages the kidneys and prevents them from performing their job. Nearly 30 million Americans have CKD and millions of others are at risk. End-stage renal disease is an advanced stage of CKD. For someone with end-stage renal disease, dialysis or a kidney transplant are the only options for survival. Dialysis is a lifesaving treatment that removes waste, salt, and extra water from a patient's blood. For patients with end-stage renal disease, they can opt for dialysis treatments in a hospital or in-home dialysis.

In-home dialysis grants patients greater flexibility and comfort while undergoing dialysis. Manufacturers produce the packages and equipment for in-home dialysis. These pre-packaged shipments are then sent to distributors who in turn, send them to patients upon receipt of a prescription. Under current law, these distribution centers are required to obtain a pharmacist license because they send the drugs directly to patients. However, in practice, this additional license is an unnecessary burden, as the shipments from the manufacturers are unaltered and unopened before reaching patients.

Senate Bill 38 removes this unnecessary regulation on the distribution centers, while still protecting patient safety. Distribution centers are only exempt from obtaining a pharmacist licensure if the drugs are delivered to patients in their original, sealed packaging from the manufacturing facility, if the dispensing occurs only upon receipt of a prescription from a licensed physician, and if the delivery is only made to a patient with end-stage renal disease or their beneficiary. These stipulations ensure that the exemption from licensure only applies in cases where distributors are simply shipping pre-packaged dialysis solutions to patients.

By removing this regulation, Senate Bill 38 streamlines the process for in-home dialysis patients to receive their medication. This bill cuts red tape and removes a barrier between patients and their healthcare.

Thank you for taking the time to hear Senate Bill 38. I hope to count on your support for this important reform.

MIKE ROHRKASTE

STATE REPRESENTATIVE • 55TH ASSEMBLY DISTRICT

Testimony on Senate Bill 38
March 14, 2019

Mr. Chair and committee members, thank you for the opportunity to provide written testimony on behalf of Senate Bill 38, which exempts dispensers, distributors, and sellers of products necessary for home kidney peritoneal dialysis from the current requirement to be licensed as pharmacies.

People with end-stage kidney disease who conduct peritoneal dialysis at home receive shipments of the necessary supplies each month. The supplies include the dialysate – a solution of sugar water or icodextrin, a kind of starch – and plastic tubing. The dialysate is regulated as a drug by the Food and Drug Administration, and the FDA also regulates and inspects the manufacturing facilities that produce it. The manufacturers send the finished product to the distribution centers.

Distribution centers do not do any mixing or compounding. They do not even open the packaging. They simply receive the finished products from the manufacturer and distribute them. Nevertheless, current law requires them to be licensed as pharmacies, with all the associated regulations and responsibilities. This requirement serves no purpose and only increases the cost to patients.

SB 38 eliminates this requirement for dialysate distribution centers that deliver the products in their original, sealed packaging from the manufacturer, dispense the products pursuant to a prescription from a licensed physician, and deliver only to patients with end-stage renal disease.

Senate Amendment 1 is a technical amendment that clarifies the scope of the bill.

Thank you for your consideration, and please let my office know if we can provide any additional information.

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STATE REPRESENTATIVE
DEBRA KOLSTE

44TH DISTRICT

WISCONSIN STATE ASSEMBLY

Senate Bill 38: Dispensing, distributing, or selling dialysate, drugs, or devices necessary for providing home peritoneal kidney dialysis
Senate Committee on Health and Human Services
March 14, 2019

Thank you, Chairman Testin, Vice-Chair Kooyenga, and fellow committee members, for holding a public hearing on SB 38.

It is becoming more common for individuals with end-stage renal disease (the last stage of kidney disease) to receive the supplies and training to perform dialysis on their own, at home. This process is known as peritoneal dialysis and offers the patient greater flexibility and independence.

Under current law, distribution centers that deliver the dialysate and devices necessary for home dialysis are required to be registered as fully licensed pharmacies. They are required to comply with the regulations of a retail pharmacy despite providing substantially fewer and different services.

Senate Bill 38 would exempt these distribution centers from the requirement to obtain a pharmacist license as long as: the dialysate solution is in its original, sealed packaging; the manufacturer delivers directly to a patient with end-stage renal disease; and the dispensing occurs only after the receipt of a prescription issued by a licensed pharmacist.

Distribution centers receive the dialysate after it has been produced and packaged at a manufacturing facility. These manufacturers are already subject to inspection and oversight by the U.S. Food and Drug Administration. Once at the distribution center, the dialysate is not altered or opened prior to being delivered to the patient.

This bill is a technical fix that will remove an unnecessary layer of regulation and cost to the supply chain. I thank you for your consideration of SB 38 and respectfully ask for your support of this legislation.

Debra Kolste

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Baxter Healthcare Testimony to the Senate Committee on Health and Human Services
In Support of SB 38 Distribution of Dialysate
March 14, 2019

Thank you Chairman Testin and the members of the Senate Committee on Health and Human Services for inviting me here today. My name is Elizabeth Stoll and I am the Director of State Government Affairs at Baxter Healthcare.

Baxter is a global healthcare company that provides a broad portfolio of essential renal and hospital products, including:

- home, acute and in-center dialysis;
- sterile IV solutions and infusion systems;
- parenteral nutrition;
- biosurgery products and anesthetics.

Today I am here to talk about a treatment for End Stage Renal Disease or ESRD. This is when a person's kidneys stop working and they just use a new way to filter their blood of deadly toxins.

PD was widely used in the 70s and 80s but due to changes in reimbursement policy by Medicare most patients began to use in center hemodialysis. The rates of PD plummeted.

Today only about 10% of the ESRD population uses PD even though there is evidence of:

- better outcomes for future transplant patients,
- less cost to the healthcare system
- more opportunity for working and attending school
- less hospitalizations

CMS just recently announced an initiative to sustainably grow the use of PD within Medicare.

For reference, in Wisconsin there are 450 patients that use PD which is only 4.9% of the ESRD population in the state.

Our focus today is on how dialysis patients receive their PD products in their 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 boxes at Baxter's Marion, NC 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.

- 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 Baxter Healthcare's Remote Prescription Order Processing Pharmacy in Deerfield, IL to a licensed pharmacist.

- The Illinois pharmacy obtains the physician prescription order via fax, electronic or verbal means and is entered as a standing order for the patient into Baxter Healthcare's 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 one of our distribution centers. For Wisconsin patients that is our centers in Champlain, MN or Waukegan, IL.

- 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.

What the current law requires:

- Current Wisconsin law requires the Champlain, MN and Waukegan, IL distribution centers to be registered as a full licensed pharmacy since they deliver their products directly to a patient's home.

- This means they must comply with all regulations of a full retail pharmacy like CVS with closed/locked doors, a sink, filing cabinet, refrigerator, among many other requirements.

- The law also requires a licensed pharmacist (above and beyond the one in the Illinois pharmacy that has processed the order) to apply a second pharmacy label next to the first label before the boxes can leave the warehouse.

What does SB38 do:

- This bill would amend the pharmacy practice act remove the additional requirement of a second licensed pharmacist to review the order and to place the second label on each box prior to delivery.
- I would like to point out that the National Association of the Boards of Pharmacy (NABP) support this process and include it in their model pharmacy board act.

Why are we asking for the change in statute?

- In Wisconsin, we believe the law to require a pharmacist to review and place a second label onto the boxes prior to leaving the warehouse is onerous and unnecessary.

- There are 27 states that currently operate under the model with zero instances of harm to any patient.

Thank you for your time and attention. I welcome any questions you might have.

Elizabeth Stoll
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