



# MIKE ROHRKASTE

STATE REPRESENTATIVE • 55<sup>TH</sup> ASSEMBLY DISTRICT

## **Testimony on Assembly Bill 42 April 17, 2019**

Mr. Chair and committee members, thank you for the opportunity to testify on behalf of Assembly Bill 42, 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.

AB 42 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.

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

Thank you for your consideration.

**Alberta Darling**  
**Wisconsin State Senator**  
Co-Chair, Joint Committee on Finance

Testimony before the Assembly Committee on Health  
Assembly Bill 42  
Wednesday, April 17, 2019

Thank you Chair Sanfelippo and committee members for holding a public hearing on Assembly Bill 42. This important piece of legislation removes an unnecessary regulation that requires in home dialysis distribution centers to obtain a pharmacist license.

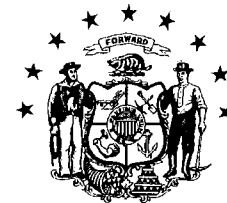
Chronic Kidney Disease (CKD) is an affliction that damages the kidneys and prevents them from performing their job. Nearly 30 million Americans have CKD and millions of others are at risk. End-stage renal disease is an advanced stage of CKD. For someone with end-stage renal disease, dialysis or a kidney 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.

Assembly Bill 42 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, Assembly Bill 42 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 Assembly Bill 42. I hope to count on your support for this important reform.



**Assembly Bill 42: Dispensing, distributing, or selling dialysate, drugs, or devices necessary for providing home peritoneal kidney dialysis**  
**Assembly Committee on Health**  
**April 17, 2019**

Thank you, Chairman Sanfelippo, Vice-Chair Kurtz, and fellow committee members, for holding a public hearing on AB 42.

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.

Assembly Bill 42 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 AB 42 and respectfully ask for your support of this legislation.

A handwritten signature in cursive script that reads "Debra Kolste".

Deb Kolste  
44<sup>th</sup> Assembly District

Baxter Healthcare Testimony to the Assembly Committee on Health  
In Support of AB42 Distribution of Dialysate  
April 17, 2019



Thank you Chairman Sanfelippo and the members of the Assembly Committee on Health. My name is Vince Hanks and I am the Field Pharmacy Supervisor for Baxter Healthcare, focusing on pharmacy compliance.

**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 Dextrose or icodextrin, which are both derivatives of the sugar glucose.
- 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 Champlin, 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 AB42 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. Now Bill Crates will discuss the partnership with Baxter and Cardinal on the distribution of dialysate to patients in Wisconsin.

Baxter Healthcare Testimony to the Assembly Committee on Health  
In Support of AB42 Distribution of Dialysate  
April 17, 2019



Thank you Chairman Sanfelippo and the members of the Assembly Committee on Health. 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 must use a new way to filter their blood of deadly toxins. This is dialysis.

Dialysis occurs two ways: through the blood called hemodialysis or through the peritoneum called peritoneal dialysis.

Peritoneal Dialysis (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 usage 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

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

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

My colleague Vince Hanks will further explain how the process of dialysate distribution works today and then Bill Crates from Cardinal Health will expand on the partnership between Baxter and Cardinal for this distribution.

At the end, we will be available for questions.



**Bill Crates, Vice President, Quality and Regulatory Affairs, Cardinal Health**  
**Assembly Bill 42 Proponent Testimony**  
**Health Committee**  
**Wednesday, April 17, 2019**

Chair Sanfelippo, Vice Chair Kurtz, and members of the Assembly Health Committee, my name is Bill Crates and I serve as Vice President, Quality and Regulatory Affairs at Cardinal Health. Thank you for the opportunity to testify before you today in support of Assembly Bill 42.

Cardinal Health is a Fortune 14 company that improves the cost-effectiveness of healthcare. As a leading provider of products and services supporting the healthcare industry, we strive each day to make healthcare more efficient, providers more effective, and patients as healthy as possible. Our employees are committed to providing cost-effective solutions that enhance supply chain efficiency from hospital to home. Cardinal Health employs more than 50,000 people worldwide, with more than 200 of those employees located here in Wisconsin. Every day Cardinal Health is committed to safely and securely supplying necessary pharmaceutical and medical products to more than 4,800 customers in Wisconsin. The security of the supply chain is of the utmost importance to Cardinal Health.

Cardinal Health is a leading distributor of medical devices in the United States. In this role, we deliver medical devices to hospitals, clinics, and direct to patients in their homes. Cardinal Health is proud to be the exclusive distributor for Baxter's peritoneal dialysis products for patients with end stage renal disease. This allows patients to have safe, convenient dialysis in their own homes rather than requiring they go to a clinic for their dialysis.

Following the manufacture of dialysis solutions and tubing at Baxter's Marion, NC facility, these products are sent to our Cardinal Health medical distribution centers (DCs). The role of our DCs is to receive from the manufacturer, warehouse, and send products to either the patient or dialysis center.

Currently, Wisconsin requires that our DCs have a pharmacist review the order and affix a second label to dialysate products shipped directly to a patient. These pharmacists do not interface with the patient. Instead, patients are receiving training from their physician on how to properly and safely administer their dialysis.

All orders for direct to home dialysate must be in tandem with a physician prescription. When we distribute dialysate directly to a patient, we send manufacturer-packaged boxes of dialysate and tubing. These boxes come from the manufacturer containing product information and instructions for use. Prior to shipment, the boxes are affixed with a label containing the prescription number and patient name. Our orders delivered in the 27 states that do not require pharmacist sign off have a product validation process that has 99.89% accuracy rate. Following this validation process or pharmacist check, the products are shrink wrapped and distributed to patients.

On behalf of Cardinal Health and myself, I urge you to vote in favor of Assembly Bill 42 which would remove the requirement that pharmacists review orders for direct to home dialysate distribution. This bill allows us to increase efficiency in the healthcare delivery system while still ensuring patient safety. Thank you.