The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1252
INTRODUCER:	Senator Passidomo
SUBJECT:	Home Renal Dialysis
DATE:	January 22, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	

I. Summary:

SB 1252 exempts any manufacturer holding a manufacturer permit, or its agent that holds a manufacturer or third party logistics permit, under the Florida Drugs and Cosmetics Act, from the requirements of the Florida Pharmacy Act if the manufacturer or its agent is engaged in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis under certain circumstances.

II. Present Situation:

Kidney Disease and Renal Dialysis

Chronic kidney disease is a condition in which a person gradually loses kidney function over time, and includes conditions that damage the kidneys and decrease their ability to process waste.[1] Renal dialysis is a common treatment for individuals with chronic kidney failure, and is used to:[2]

- Remove waste, salt, and extra water to prevent build up in the body;
- Maintain a safe level of certain chemicals in the blood, such as potassium, sodium, and bicarbonate; and
- Control blood pressure.

Renal dialysis can be performed in a hospital, in a dialysis unit that is not part of a hospital, or in a person's home.[3] Additionally, there are two types of dialysis, hemodialysis and peritoneal dialysis.

[1] National Kidney Foundation, *About Chronic Kidney Disease*, (February 15, 2017) https://www.kidney.org/kidneydisease/aboutckd (last visited Jan. 18, 2018).
[2] National Kidney Foundation, *Dialysis* https://www.kidney.org/atoz/content/dialysisinfo(last visited Jan. 18, 2018).
[3] Id.

In hemodialysis, an artificial kidney, called a hemodialyzer, is used to remove waste and extra chemicals and fluid from the blood.[4] Blood is pumped out of the body and into the hemodialyzer to be cleaned. The dialyzer, or filter, has two parts, separated by a thin membrane: one for blood and one for a washing fluid, called dialysate.[5] Blood cells and proteins remain in the blood because they are too large to pass through the membrane; however, smaller waste products, such as urea, creatinine, potassium and extra fluid pass through the membrane and are washed away.[6] The filtered blood is returned to the body when the process is complete.[7]

In peritoneal dialysis the inside lining of the abdominal cavity acts as a natural filter and wastes are taken out with dialysate, which is washed in and out of the abdominal cavity in cycles.[8] A catheter is surgically inserted into the abdominal cavity and is used to transfer the dialysate into and out of the abdominal cavity.[9] There are two kinds of peritoneal dialysis, continuous ambulatory peritoneal dialysis and automated peritoneal dialysis.[10] The former is manual and done while the person receiving treatment goes about normal daily activities, and the latter is a machine cycler that is usually done overnight, while the person is asleep.[11]

Regulation of Pharmacies and Pharmacists

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy, within the Department of Health (DOH), licenses and regulates the practice of pharmacy including community pharmacies,[12] institutional pharmacies,[13] nuclear pharmacies,[14] special pharmacies,[15] and internet pharmacies.[16] The board regulates the operation of pharmacies and disciplines pharmacies for failure to comply with state and federal regulations.[17] One aspect of the practice of pharmacy involves the dispensing of prescription drugs pursuant to a physician's prescription or order.[18]

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[4] National Kidney Foundation, *Hemodialysis*, https://www.kidney.org/atoz/content/hemodialysis (last visited Jan. 18, 2018).
[5] National Kidney Foundation, *Peritoneal Dialysis: What You Need to Know*, https://www.kidney.org/atoz/content/peritoneal (last visited Jan. 18, 2018).
[6] Supra note 4.
[7] Supra note 5.
[8] Id.
[9] Id.
[10] Id.
[11] Id.
[12] A community pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, or where prescriptions are filled or dispensed on an outpatient basis. Section 465.003(11)(a)1., F.S.
[13] An institutional pharmacy includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. Section 465.003(11)(a)2., F.S.
[14] A nuclear pharmacy includes every location were radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, but does not include hospitals or the nuclear medicine facilities of hospitals. Section 465.003(11)(a)3., F.S.
[15] A special pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, if not otherwise classified as a community pharmacy, institutional pharmacy, nuclear pharmacy, or internet pharmacy. Section 465.003(11)(a)4., F.S.
[16] An internet pharmacy includes locations not otherwise licensed or issued a permit pursuant to statute, within or outside of this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy. Section 465.003(11)(a)5., F.S.
[17] See ss. 465.022 and 465.023, F.S.
[18] See s. 465.003(6) and (14), F.S.

Special Pharmacy – End Stage Renal Dialysis Permit

The Board of Pharmacy recognizes six types of special pharmacy permits, including Special Pharmacy – End Stage Renal Dialysis (ESRD).[19] An ESRD permit is required for any person who provides dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.[20] To obtain an ESRD permit, an applicant must:[21]

- Complete an application and pay a $250 initial payment fee;
- Submit a legible set of fingerprint cards and $48 fee for each person having an ownership interest of at least 5 percent and any person who, directly or indirectly, manages, oversees, or controls the operation of the pharmacy, including officers and members of the board of directors, if the applicant is a corporation;
- Pass an on-site inspection;
- Provide written policies and procedures for preventing and controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships; and
- Designate a prescription department manager or consultant pharmacist of record.

Florida law provides an exemption to pharmacy permitting requirements, including ESRD permits, under limited circumstances. Specifically, s. 465.027(2), F.S., exempts a manufacturer, or its agent, holding an active permit as a manufacturer under ch. 499, F.S., who is engaged solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure from pharmacy permitting and regulatory requirements if the dialysate, drugs, or devices are:

- Approved by the federal Food and Drug Administration, and
- Delivered in the original, sealed packaging to the patient for self-administration after receipt of a physician's order to dispense, to a health care practitioner, or to an institution.[22]

Regulation of Drugs, Devices, and Cosmetics in Florida

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[23] Most of the regulations relate to the distribution of prescription drugs into and within Florida. The chapter also regulates manufacturing and distributing medical devices. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits. Florida has 18 distinct permits for these entities.[24]

[19] Rule 64B16-28.100(5)(d), F.A.C.
[20] Rule 64B16-28.850(1), F.A.C.
[21] Rule 64b16-28.100(1) and (5), F.A.C.
[22] This exemption was enacted in ch. 2016-230, Laws of Fla.
[23] Section 27, ch. 2010-161, Laws of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the DOH to the DBPR.
[24] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. Section 499.01(1), F.S.

Manufacturer Permits

The DBPR offers nine different manufacturer and repackager permits for prescription drugs, over-the-counter drugs, cosmetics, and medical devices.

Prescription drug manufacturer permits are required for anyone that manufactures a prescription drug and manufactures or distributes that prescription drugs in Florida.[25] If someone manufactures prescription drugs outside of Florida, but distributes their prescription drugs into Florida, a nonresident prescription drug manufacturer permit is required, unless that person is permitted as a third party logistics provider.[26] Virtual permits are available for those who manufacture prescription drugs but do not make or take physical possession of any prescription drugs.[27] An over-the-counter drug manufacturer permit is required for anyone manufacturing or repackaging over-the-counter drugs[28] and a cosmetic manufacturer permit is required for anyone manufacturing or repackaging cosmetics in Florida.[29]

A device manufacturer permit is required for anyone manufacturing, repackaging, or assembling medical devices for human use unless the person only manufactures, repackages, or assembles medical devices or components: [30]

- Pursuant to a practitioner's order for a specific patient; or,
- That are registered with the federal Food and Drug Administration and satisfy specified statutory requirements.

Regulation of Third-Party Logistics Providers

Third-party logistics providers act as an intermediary between the manufacturer or distributor of prescription drugs and the consumer by providing supply chain logistics services and transportation. A third party logistics provider contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf a manufacturer, wholesale distributor, or dispenser, but does not take title to or have responsibility to direct the sale or disposition of the prescription drug.[31]

Third-party logistic providers must obtain a DBPR permit before operating in Florida and out-of-state third-party logistics providers must also be licensed in the state or territory from where it distributes the prescription drug.[32] Third-party logistics providers that provide dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home must also obtain an ESRD permit from the Board of Pharmacy.[33]

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[25] Section 499.01(2)(a), F.S.
[26] Section 499.01(2)(c), F.S.
[27] Section 499.01(2)(a)1., F.S. and S. 499.01(2)(c), F.S.
[28] Section 499.01(2)(n), F.S.
[29] Section 499.01(2)(p), F.S. Someone that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a cosmetic manufacturer permit.
[30] Section 499.01(2)(o), F.S.
[31] Section 499.01(2)(q), F.S.
[32] If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required under federal law.
[33] Rule 64B16-28.100(5)(d)4., F.A.C.

III. Effect of Proposed Changes:

SB 1252 amends s. 465.027, F.S., to expand and clarify the exemption from the Florida Pharmacy Act for the distribution of certain drugs and devices directly to the patient by a manufacturer's third party logistics provider. The bill exempts a manufacturer's agent if the agent holds a third party logistics permit under ch. 499, F.S., related to the regulation of drugs, devices, and cosmetics, from the requirements of ch. 465, F.S., related to the regulation of pharmacies, if the manufacturer's agent is engaged in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

- Approved by the United States Food and Drug Administration; and
- Delivered in the original, sealed packaging after receipt of a physician's order to dispense to a patient or the patient's designee for the patient's self-administration or to a health care practitioner or institution for administration or delivery of dialysis therapy.

The effective date of the bill is July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Third party logistics permit holders made exempt under the bill may see a positive fiscal impact due to no longer being required to pay any permitting fees required by ch. 465, F.S.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

Lines 14-15 refer to a third party logistics permit. The correct name of the permit under ch. 499, F.S., is a third party logistics provider permit.

VII. Related Issues:

Striking the word "solely" on line 16 of the bill may allow a manufacturer or third party logistics permit holder to perform any action allowed under the Florida Pharmacy Act without obtaining the permit normally required for such action if the manufacturer or third party logistics permit holder is also engaged in the distribution of dialysate, drugs, or devices for renal dialysis as detailed in s. 465.027, F.S.

VIII. Statutes Affected:

This bill substantially amends section 465.027 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.