HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	HB 513	**FINAL HOUSE FLOOR ACTION:**	
SUBJECT/SHORT TITLE	Distributing Pharmaceutical Drugs and Devices	114 **Y's**	0 **N's**
SPONSOR(S):	Rommel	**GOVERNOR'S ACTION:**	Approved
COMPANION BILLS:	CS/SB 1252		

SUMMARY ANALYSIS

HB 513 passed the House on January 31, 2018, and subsequently passed the Senate on March 7, 2018.

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. These entities do not take title to or have responsibility to direct the sale or disposition of the prescription drug. The Florida Drug and Cosmetic Act requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics, including third-party logistics providers. They must obtain a third-party logistics provider permit from DBPR to operate in Florida.

The Board of Pharmacy recognizes six types of pharmacy permits, including Special Pharmacy – End Stage Renal Dialysis (ESRD). 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. 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.

Section 465.027(2), F.S., provides an exemption from pharmacy permitting requirements, including ESRD permits, for a manufacturer, or its agent, licensed by DBPR, who is engaged *solely* in manufacturing or distributing dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure.

HB 513 expands the exemption from permitting requirements in s. 465.027(2), F.S., to include third-party logistics providers who are engaged in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure. It also removes the requirement that a manufacturer or its agent be engaged solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure to qualify for the 465.027(2), F.S., exemption.

The bill does not have a fiscal impact on state or local governments.

The bill was approved by the Governor on March 21, 2018, ch. 2018-50, L.O.F., and will become effective on July 1, 2018.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

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.

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] These are the same basic treatment; however, 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]

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[1] National Kidney Foundation, *About Chronic Kidney Disease*, available at https://www.kidney.org/kidneydisease/aboutckd (last visited March 7, 2018).
[2] National Kidney Foundation, *Dialysis*, https://www.kidney.org/atoz/content/dialysisinfo (last visited March 7, 2018).
[3] *Id.*
[4] National Kidney Foundation, *Hemodialysis*, https://www.kidney.org/atoz/content/hemodialysis (last visited March 7, 2018).
[5] National Kidney Foundation, *Peritoneal Dialysis: What You Need to Know*, https://www.kidney.org/atoz/content/peritoneal (last visited March 7, 2018).
[6] *Supra*, note 4.
[7] *Supra*, note 5.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*

Regulation of Pharmacies and Pharmacists

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy, within the Department of Health, licenses and regulates the practice of pharmacy. The term "pharmacy" includes a community pharmacy,[12] an institutional pharmacy,[13] a nuclear pharmacy,[14] a special pharmacy,[15] and an internet pharmacy.[16] The board regulates the operation of pharmacies and disciplines pharmacies for failure to comply with state and federal regulations.[17]

Special Pharmacy – End Stage Renal Dialysis Permit

The Board of Pharmacy recognizes six types of pharmacy permits, including Special Pharmacy – End Stage Renal Dialysis (ESRD).[18] 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.[19] To obtain an ESRD permit, an applicant must:[20]

- 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 manufacturer or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure from pharmacy permitting 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, to a health care practitioner, or an institution.

[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. S.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. S. 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. S. 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. S. 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. S. 465.003(11)(a)5., F.S.
[17] *See* ss. 465.022 and 465.023, F.S.
[18] Rule 64B16-28.100(5)(d), F.A.C.
[19] Rule 64B16-28.850(1), F.A.C.
[20] Rule 64b16-28.100(1) and (5), F.A.C.

Currently, the Board of Pharmacy has seven pharmacies permitted as a Special Pharmacy – ESRD.[21]

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.[22] 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.[23]

Manufacturer Permits

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 drug in Florida.[24] If someone manufactures prescription drugs outside of Florida, but distributes their prescription drugs in Florida, a nonresident prescription drug manufacturer permit is required, unless that person is permitted as a third party logistics provider.[25] Virtual permits are available for those individuals who manufacture prescription drugs but do not make or take physical possession of any prescription drugs.[26] An over-the-counter drug manufacturer permit is required for anyone manufacturing or repackaging over-the-counter drugs[27] and a cosmetic manufacturer permit is required for anyone manufacturing or repackaging cosmetics in Florida.[28]

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: [29]

- 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

[21] Email from Paul Runk, Director, Office of Legislative Planning, Florida Department of Health, RE: HB 513 Question, (Jan. 16, 2018) (on file with Health Quality Subcommittee staff).
[22] S. 27, ch. 2010-161, Laws of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.
[23] 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. S. 499.01(1), F.S.
[24] S. 499.01(2)(a), F.S.
[25] S. 499.01(2)(c), F.S.
[26] S. 499.01(2)(a)1., F.S. and S. 499.01(2)(c), F.S.
[27] S. 499.01(2)(n), F.S.
[28] S. 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.
[29] S. 499.01(2)(o), F.S.

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 of 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.[30]

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.[31] 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.[32]

Currently, DBPR has 177 active permitted third-party logistics providers.[33] None of the 177 third-party logistics providers permitted by DBPR also hold an ESRD permit from the Board of Pharmacy.[34]

Effect of Proposed Changes

HB 513 expands the eligibility for the exemption from pharmacy permitting requirements in s. 465.027(2), F.S., to include third-party logistics providers who distribute dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure. Third-party logistics providers will no longer be required to obtain an ESRD permit from the Board of Pharmacy, but will still have to obtain a third-party logistics permit from DBPR.

The bill also removes the requirement that a manufacturer be engaged *solely* in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure in order to qualify for the pharmacy permit exemption.

The bill provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None. Because none of third-party logistics providers permitted by DBPR also hold an ESRD permit from the Board of Pharmacy, there will be no loss of permitting revenues from third-party logistics providers that will no longer be required to hold an ESRD permit.

2. Expenditures:

   None. Because none of third-party logistics providers permitted by DBPR also hold an ESRD permit from the Board of Pharmacy, there will be no reduction in workload for the Board of Pharmacy related fewer ESRD permits.

[30] S. 499.01(2)(q), F.S.
[31] Id. 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.
[32] Rule 64B16-28.100(5)(d)4., F.A.C.
[33] Email from Colton L. Madill, Deputy Legislative Affairs Director, Office of Legislative Affairs, Department of Business and Professional Regulation, RE: Agency Bill Analysis Request, (Jan. 16, 2018) (on file with Health & Human Services Committee staff).
[34] *Supra*, note 21.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.