

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: CS/SB 516

INTRODUCER: Health Policy Committee and Senator Rodriguez

SUBJECT: Emergency Refills of Insulin and Insulin-related Supplies or Equipment

DATE: January 31, 2024

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Fav/CS
2.	_____	_____	AHS	_____
3.	_____	_____	RC	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 516 amends ss. 465.0275 and 893.04, F.S., relating to emergency prescription refills. The bill eliminates the current one-vial limit on emergency insulin refills and expands current law on emergency insulin refills to include related supplies and equipment.

The bill authorizes pharmacists who have received a prescription refill request from a patient but are unable to obtain an authorization from a prescriber, to dispense to the patient an emergency refill of insulin and insulin-related supplies or equipment to treat diabetes, not to exceed three nonconsecutive times per calendar year, as opposed to a “one-time emergency refill of one vial of insulin” as provided under current law.

The bill provides an effective date of July 1, 2024.

II. Present Situation:

Pharmacist Licensure

Pharmacy is the third largest health profession behind nursing and medicine.¹ The Board of Pharmacy (BOP), in conjunction with the Department of Health (DOH), regulates the practice of pharmacists pursuant to ch. 465, F.S.² To be licensed as a pharmacist, a person must:³

- Complete an application and remit an examination fee;
- Be at least 18 years of age;
- Hold a degree from an accredited and approved school or college of pharmacy;⁴
- Have completed a BOP approved internship; and
- Successfully complete the BOP approved examination.

A pharmacist must complete at least 30 hours of BOP-approved continuing education during each biennial renewal period.⁵ Pharmacists who are certified to administer vaccines or epinephrine auto-injections must complete a three-hour continuing education course on the safe and effective administration of vaccines and epinephrine auto-injections as a part of the biennial licensure renewal.⁶ Pharmacists who administer long-acting antipsychotic medications must complete an approved eight-hour continuing education course as a part of the continuing education for biennial licensure renewal.⁷

Pharmacist Scope of Practice

In Florida, the practice of the profession of pharmacy includes:⁸

- Compounding, dispensing, and consulting concerning the contents, therapeutic values, and uses of any medicinal drug;
- Consulting concerning therapeutic values and interactions of patent or proprietary preparations;
- Monitoring a patient's drug therapy and assisting the patient in the management of his or her drug therapy, including the review of the patient's drug therapy and communication with the patient's prescribing health care provider or other persons specifically authorized by the patient, regarding the drug therapy;
- Transmitting information from prescribers to their patients;

¹ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited Jan. 30, 2024).

² Sections 465.004 and 465.005, F.S.

³ Section 465.007, F.S. The DOH may also issue a license by endorsement to a pharmacist who is licensed in another state upon meeting the applicable requirements set forth in law and rule. *See* s. 465.0075, F.S.

⁴ If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the U.S., the applicant must demonstrate proficiency in English, pass the board-approved Foreign Pharmacy Graduate Equivalency Examination, and complete a minimum of 500 hours in a supervised work activity program within Florida under the supervision of a DOH licensed pharmacist.

⁵ Section 465.009, F.S.

⁶ Section 465.009(6), F.S.

⁷ Section 465.1893, F.S.

⁸ Section 465.003(13), F.S.

- Administering vaccines to adults and influenza vaccines to persons seven years of age or older;⁹
- Administering epinephrine autoinjections;¹⁰ and
- Administering antipsychotic medications by injection.¹¹

A pharmacist may not alter a prescriber's directions, diagnose or treat any disease, initiate any drug therapy, or practice medicine or osteopathic medicine, unless permitted by law.¹²

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Board of Medicine, the Board of Osteopathic Medicine, and the BOP.¹³ The formulary may only include:¹⁴

- Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the U.S. Food and Drug Administration (FDA);
- Any medicinal drug recommended by the FDA Advisory Panel for transfer to over-the-counter status pending approval by the FDA;
- Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination;
- Any medicinal drug containing fluoride in any strength;
- Any medicinal drug containing lindane in any strength;
- Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program; and
- Any topical anti-infectives excluding eye and ear topical anti-infectives.

A pharmacist may order the following, within his or her professional judgment and subject to the following conditions:

- Certain oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription is limited to a six day supply for one treatment of:
 - Magnesium salicylate/phenyltoloxamine citrate;
 - Acetylsalicylic acid (Zero order release, long acting tablets);
 - Choline salicylate and magnesium salicylate;
 - Naproxen sodium;
 - Naproxen;
 - Ibuprofen;
 - Phenazopyridine, for urinary pain; and
 - Antipyrine 5.4%, benzocaine 1.4%, glycerin, for ear pain if clinical signs or symptoms of tympanic membrane perforation are not present;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;

⁹ See s. 465.189, F.S.

¹⁰ *Id.*

¹¹ Section 465.1893, F.S.

¹² Section 465.003(13), F.S.

¹³ Section 465.186, F.S.

¹⁴ *Id.*

- Certain topical antifungal/antibacterials;
- Topical anti-inflammatory preparations containing hydrocortisone not exceeding 2.5%;
- Certain otic antifungal/antibacterial;
- Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under 2 years of age, and those with diabetes or impaired circulation;
- Vitamins with fluoride, excluding vitamins with folic acid in excess of 0.9 mg.;
- Medicinal drug shampoos containing Lindane for the treatment of head lice;
- Ophthalmic. Naphazoline 0.1% ophthalmic solution;
- Certain histamine H2 antagonists;
- Acne products; and
- Topical Antiviral for herpes simplex infections of the lips.¹⁵

Emergency Prescription Refills

Section 465.0275(1), F.S., authorizes a pharmacist to dispense, if the pharmacist is unable to readily obtain refill authorization from a prescriber, a one-time emergency refill of up to a 72-hour supply of a prescribed medication or a one-time emergency refill of one vial of insulin to treat diabetes. Current law however does not authorize pharmacists to dispense insulin-related supplies or equipment as part of an emergency prescription refill.

A pharmacist may also dispense an emergency refill of up to a 30-day supply if the Governor declares a state of emergency in areas affected by the order if:¹⁶

- The prescription is not for a medicinal drug listed in Schedule II of ch. 893, F.S.;
- The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;
- In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort;
- The dispensing pharmacist creates a written order containing all the prescription required by law and signs that order; and
- The dispensing pharmacist notifies the prescriber of the emergency refill within a reasonable time after such dispensing.

Diabetes

Diabetes is a chronic health condition that affects how the human body converts food into energy.

The human digestive system breaks down carbohydrates consumed as food into glucose¹⁷ and releases it into the bloodstream, which increases the blood's glucose level. Such an increase in blood glucose should signal the pancreas to release the hormone insulin, which acts as a catalyst to allow the body's cells to metabolize the glucose and convert it to energy, or to convert the glucose into forms suitable for short-term or long-term storage.

¹⁵ Fla. Admin. Code R. 64B16-27.220 (2023).

¹⁶ Section 465.0275(2), F.S.

¹⁷ Glucose is the simplest type of carbohydrate (chemical formula C₆H₁₂O₆), and all carbohydrates consumed as food must be broken down into glucose before the body can metabolize them.

With diabetes, depending on the type of diabetes, the pancreas either does not make any insulin or does not make enough insulin, or the body cannot use insulin as well as it should. When there is not enough insulin or if cells stop responding to insulin, blood glucose levels elevate and stay elevated for extended periods. Over time, such elevated blood glucose levels can cause serious health problems, such as heart disease, vision loss, kidney disease, vascular disease, and other maladies. Such outcomes are often known as long-term complications of diabetes.

Approximately 2,164,009 people in Florida have diabetes, according to the American Diabetes Association.

Types of Diabetes

There are three main types of diabetes: Type 1, Type 2, and gestational diabetes.

Type 1 Diabetes

Type 1 diabetes is thought to be caused by an autoimmune reaction in which the body's immune system attacks and destroys the cells in the pancreas that normally produce insulin. Approximately 5 to 10 percent of the people with diabetes have Type 1. Symptoms of Type 1 often develop quickly. It is usually diagnosed in children, teens, and young adults. Someone with Type 1 diabetes must take insulin, usually through subcutaneous injection, on a regular basis to survive, usually one or more times per day. Currently, Type 1 diabetes can be neither prevented nor cured.¹⁸

Type 2 Diabetes

With Type 2 diabetes, the body does not use insulin well and cannot keep blood glucose at normal levels. About 90 to 95 percent of people with diabetes have Type 2. It develops over many years and is usually diagnosed in overweight, middle-aged adults, although it can sometimes manifest in adolescents and young adults. Type 2 diabetes can often be prevented or delayed, or even eliminated altogether, with healthy lifestyle changes, such as losing weight, eating healthy food, and exercising regularly.¹⁹ Type 2 diabetes is usually treated with oral medications but can require insulin injections in some cases.

Gestational Diabetes

Gestational diabetes develops in pregnant women who have never had diabetes. In pregnant women with gestational diabetes, the baby could be at higher risk for health problems. Gestational diabetes usually goes away after the baby is born. However, it correlates to a higher risk for Type 2 diabetes later in life. A baby delivered by a woman with gestational diabetes is more likely to become obese as a child or teen and to develop Type 2 diabetes later in life.²⁰

¹⁸ Centers for Disease Control and Prevention, *What Is Diabetes?*, available at: <https://www.cdc.gov/diabetes/basics/diabetes.html> (last visited Jan. 30, 2024).

¹⁹ *Id.*

²⁰ *Id.*

Managing Diabetes

In order for Type 1 or Type 2 diabetics to avoid long-term complications, or for a pregnant woman with gestational diabetes to mitigate the effects of that condition, blood glucose levels must be managed to stay as close to normal ranges as possible.

A widely accepted “normal” level of blood glucose is 100 milligrams of glucose per deciliter (mg/dL) of whole blood, although normal levels may vary. A normal fasting blood glucose level for someone without diabetes is 70 to 99 mg/dL.²¹

Testing blood glucose levels is key to managing diabetes. Years of elevated blood glucose levels can lead to diabetes’ costly and disabling long-term complications, while levels that are too low (hypoglycemia) can be dangerous in an immediate sense and can lead to disorientation, unusual confusion, unconsciousness, grand mal seizure, brain damage, or death.

Medications and Supplies

Insulin

All Type 1 diabetics and some Type 2 diabetics require insulin to be artificially introduced into the diabetic’s body. Different types of insulin work at different speeds, and each lasts for different lengths of time. A patient may need to use more than one type of insulin such as long-acting and short-acting. Insulin may be administered in a number of ways. Common options include a needle and syringe, insulin pen, or insulin pump.²² Inhalers and insulin jet injectors are less common ways to take insulin. Artificial pancreas systems are now approved by the U.S. Food and Drug Administration (FDA).²³

Medication Delivery Devices

Needle and Syringe

Insulin injections using a needle and syringe are a common way to receive insulin. Some people with diabetes who take insulin need two to four injections a day to keep their blood glucose in their target range. Others can take a single dose.²⁴

Pen

An insulin pen looks like an oversized writing pen but has a needle for its point. Some insulin pens come filled with insulin and are disposable. Others have room for an insulin cartridge that is inserted and replaced after use. Many people find insulin pens easier to use, but pens might be more expensive than needles and syringes. Different pen types have features that can help with injections. Some reusable pens have a memory function, which can recall dose amounts and

²¹ Cleveland Clinic, *Blood Glucose (Sugar) Test*, available at: <https://my.clevelandclinic.org/health/diagnostics/12363-blood-glucose-test> (last visited Jan. 30, 2024).

²² U.S. Department of Health and Human Services, National Institute of Diabetes and digestive and Kidney Diseases, *Type 1 Diabetes*, available at <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-1-diabetes#medicines> (last visited Jan. 30, 2024).

²³ U.S. Department of Health and Human Services, National Institute of Diabetes and digestive and Kidney Diseases, *Insulin, Medicines, & Other Diabetes Treatments*, available at <https://www.niddk.nih.gov/health-information/diabetes/overview/insulin-medicines-treatments#waystotakeinsulin> (last visited Jan. 30, 2024).

²⁴ *Id.*

timing. Other “connected” insulin pens can be programmed to calculate insulin doses and provide downloadable data reports, which can help health care practitioners adjust insulin doses.²⁵

Pump

An insulin pump is a small machine that gives a steady dose of insulin throughout the day, usually worn outside the body on a belt or in a pocket or pouch. The pump has a mechanism to pierce the patient’s skin with a tiny plastic tube and stay attached on the surface of the skin continuously, usually via an adhesive. The plastic tube will stay inserted for several days while attached to the insulin pump. The machine pumps insulin through the tube into the body 24 hours a day and can be programmed to give the patient more or less insulin as needed. The patient can also give himself or herself doses of insulin through the pump at mealtimes.

Oral and Injectables

Numerous types of oral medications are available for regulating the blood glucose of patients with Type 2 diabetes. In recent years, other types of medications for Type 2 diabetes have been brought to market which are administered by injection. Combining two or three kinds of diabetes medicines can lower blood glucose levels for Type 2 diabetics better than taking just one medicine.²⁶

III. Effect of Proposed Changes:

CS/SB 516 amends ss. 465.0275 and 893.04, F.S., relating to emergency prescription refills. The bill eliminates the current one-vial limit on emergency insulin refills and expands current law on emergency insulin refills to include related supplies and equipment.

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The bill provides an effective date of July 1, 2024.

²⁵ *Id.*

²⁶ *Id.*

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill may provide diabetics, during times of emergency or when their prescribers are unavailable to authorize a refill, with a way to obtain emergency refills of insulin and insulin-related supplies and equipment to treat their diabetes without having to resort to emergency room visits.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 465.0275 and 893.04.

IX. Additional Information:

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

CS by Health Policy on January 30, 2024:

The committee substitute removes the underlying bill’s reference to “a standard unit of dispensing or a 30-day supply” for emergency refills, up to three times per calendar year, and replaces that language with an emergency refill up to three nonconsecutive times per calendar year.

- B. **Amendments:**

None.