

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 201 Emergency Refills of Insulin and Insulin-related Supplies or Equipment

SPONSOR(S): Healthcare Regulation Subcommittee, Bell

TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	18 Y, 0 N, As CS	DesRochers	McElroy
2) Health & Human Services Committee	14 Y, 0 N	DesRochers	Calamas

SUMMARY ANALYSIS

There are 38 million people in the United States diagnosed with diabetes, including more than 2 million people in Florida. Diabetes occurs when blood glucose, also called blood sugar, is too high due to an individual's inability to effectively produce or process insulin. Over time, high blood glucose leads to problems such as: heart disease, stroke, kidney disease, eye problems, dental disease, nerve damage, foot problems, depression, sleep apnea, and sexual and bladder problems.

Diabetics must take insulin to reduce their blood glucose levels. Different types of insulin start to work at different speeds, and the effects of each last a different length of time. Insulin can be taken in several ways; common options include a syringe, insulin pen, insulin pump and insulin inhaler.

A pharmacist may only dispense controlled substances, including insulin, upon a written, oral, or electronic prescription. Current law contains limited exceptions to this requirement for emergency prescription refills which include authority for a pharmacist to dispense a one-time refill of one vial of insulin to treat diabetes, if the pharmacist is unable to readily obtain refill authorization from a prescriber. Current law however, does not authorize pharmacists to dispense insulin-related supplies or equipment as part of an emergency prescription refill.

CS/HB 201 expands current law on emergency prescription refills to authorize a pharmacist to dispense an emergency refill of insulin and insulin-related supplies or equipment to treat diabetes up to three nonconsecutive times per calendar year, if the pharmacist is unable to readily obtain refill authorization from a prescriber.

The bill has no fiscal impact on state or local government.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Diabetes

Diabetes occurs when blood glucose, also called blood sugar, is too high.¹ Blood glucose is the body's main source of energy and comes mainly from one's diet.² Over time, high blood glucose leads to problems such as:³

- Heart disease
- Stroke
- Kidney disease
- Eye problems
- Dental disease
- Nerve damage
- Foot problems
- Depression
- Sleep apnea
- Sexual and bladder problems

There are two primary types of diabetes: type 1 and type 2.

Type 1 Diabetes

In most people with type 1 diabetes, the body's immune system, which normally fights infection, attacks and destroys the cells in the pancreas that make insulin.⁴ As a result, the pancreas stops making insulin. Without insulin, glucose cannot get into the cells and blood glucose rises above normal. People with type 1 diabetes need to take insulin every day to stay alive. Type 1 diabetes typically occurs in children and young adults, although it can appear at any age. Having a parent or sibling with the disease may increase the chance of developing type 1 diabetes.⁵

Symptoms of type 1 diabetes are serious and usually happen quickly, over a few days to weeks, and can include:

- Increased thirst and urination
- Increased hunger
- Blurred vision
- Fatigue
- Unexplained weight loss

¹ U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, *Type 1 Diabetes*, (last reviewed July 2017) <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-1-diabetes/> (last visited Nov. 17, 2023).

² *Id.*

³ Mayo Clinic, Patient Care & Health Information, Disease & Conditions, *Diabetic Ketoacidosis*, (Oct. 6, 2022) <https://www.mayoclinic.org/diseases-conditions/diabetic-ketoacidosis/symptoms-causes/syc-20371551> (last visited Nov. 17, 2023); U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, *Type 2 Diabetes*, (last reviewed May 2017) <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-2-diabetes> (last visited Nov. 17, 2023).

⁴ Insulin, a hormone made by the pancreas, helps the glucose in the blood get into the cells to be used for energy. Another hormone, glucagon, works with insulin to control blood glucose levels.

⁵ *Id.*

Sometimes the first symptoms of type 1 diabetes are signs of a life-threatening condition called diabetic ketoacidosis (DKA).⁶ The condition develops when the body cannot produce enough insulin. Without enough insulin, the body begins to break down fat as fuel. This causes a buildup of acids in the bloodstream called ketones; if left untreated, the buildup can lead to DKA. Symptoms of DKA include:⁷

- Breath that smells fruity
- Dry or flushed skin
- Nausea or vomiting
- Stomach pain
- Trouble breathing
- Trouble paying attention or feeling confused

Type 1 diabetics must take insulin because the body no longer makes it on its own. Different types of insulin start to work at different speeds, and the effects of each last a different length of time. Insulin can be taken in several ways; common options include a needle and syringe, insulin pen, or insulin pump.⁸

Some people who have difficulty reaching their blood glucose targets with insulin alone also might need to take another type of diabetes medicine that works with insulin, such as pramlintide. Pramlintide, given by injection, helps keep blood glucose levels from going too high after eating. Few people with type 1 diabetes take pramlintide, however. Another diabetes medicine, metformin, may help decrease the amount of insulin necessary.⁹

Type 2 Diabetes

Type 2 diabetes, the most common type of diabetes, occurs when blood glucose is too high. In type 2 diabetes, the body does not make enough insulin or does not use insulin well enough. Too much glucose then stays in the blood, and not enough reaches the cells.¹⁰

Type 2 diabetes can develop at any age, even during childhood. However, type 2 diabetes occurs most often in middle-aged and older people. A person is more likely to develop type 2 diabetes if he or she is aged 45 or older, has a family history of diabetes, or is overweight or has obesity. Diabetes is more common in people who are African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander.¹¹

Physical inactivity and certain health problems such as high blood pressure affects a person's chances of developing type 2 diabetes. A person is also more likely to develop type 2 diabetes if they have prediabetes or had gestational diabetes when they were pregnant. Symptoms of type 2 diabetes include:¹²

- Increased thirst and urination
- Increased hunger
- Feeling tired
- Blurred vision
- Numbness or tingling in the feet or hands
- Sores that do not heal
- Unexplained weight loss

⁶ *Id.*

⁷ *Supra*, FN 3.

⁸ *Supra*, FN 1.

⁹ *Id.*

¹⁰ *Supra*, FN 3.

¹¹ *Id.*

¹² *Id.*

Symptoms of type 2 diabetes often develop slowly, usually over the course of several years, and can be so mild as to not be noticed. Many people have no symptoms. Some people do not find out they have the disease until they have diabetes-related health problems.¹³

Type 2 diabetes is caused by several factors, including:¹⁴

- Overweight and obesity
- Not being physically active
- Insulin resistance
- Genes

Many people with type 2 diabetes also have nonalcoholic fatty liver disease, a disease in which fat appears inside the liver that can, over time, affect liver function and cause liver injury.¹⁵ Diabetes is also linked to other health problems such as sleep apnea, depression, some types of cancer, and dementia.¹⁶

Treatment of Diabetes

Diabetics must take insulin to reduce their blood glucose levels. Different types of insulin start to work at different speeds, and the effects of each last a different length of time. Insulin can be taken in several ways; common options include a syringe, insulin pen, insulin pump and insulin inhaler.

Syringe

A syringe delivers insulin through a needle. The patient's physician determines the amount of insulin required per dose, and the patient acquires a syringe with sufficient dosage capacity.¹⁷

Insulin Pen

An insulin pen also delivers insulin through a needle. Insulin pens offer greater portability and are more user-friendly than syringes. Needles in these pens are small, thin, and more comfortable. Some insulin pens use cartridges inserted into the pen while others are pre-filled. The insulin dose is dialed on the pen, and the insulin is injected through the needle.¹⁸

Insulin Pump

An insulin pump delivers insulin through a thin plastic tube placed semi-permanently into the fatty layer under the patient's skin – usually in the stomach area or back of the upper arm. Insulin pumps eliminate unpredictable effects of intermediate or long-acting insulin, and deliver short or rapid acting insulin taken at or before mealtimes to control blood sugar levels. Training is necessary to use the insulin pump, and there are risks of side-effects (e.g., weight gain, infection, and DKA).¹⁹

Insulin Inhaler

An oral insulin inhaler delivers ultra-rapid acting insulin at the beginning of meals. The inhaler device is small and is as effective as injectable rapid-acting insulins. Inhaler devices still must be used in conjunction with injections or a pump for intermediate- or long-acting insulin taken to keep blood sugar

¹³ *Id.*

¹⁴ *Id.*

¹⁵ Johns Hopkins Medicine, Health, Conditions and Diseases, *Nonalcoholic Fatty Liver Disease*, available at <https://hopkinsmedicine.org/health/conditions-and-diseases/nonalcoholic-fatty-liver-disease> (last visited Nov. 17, 2023).

¹⁶ *Supra*, FN 3.

¹⁷ Centers for Disease and Control and Prevention, *4 Ways to Take Insulin* (last reviewed April 18, 2023) <https://www.cdc.gov/diabetes/basics/type-1-4-ways-to-take-insulin.html> (last visited Dec. 5, 2023).

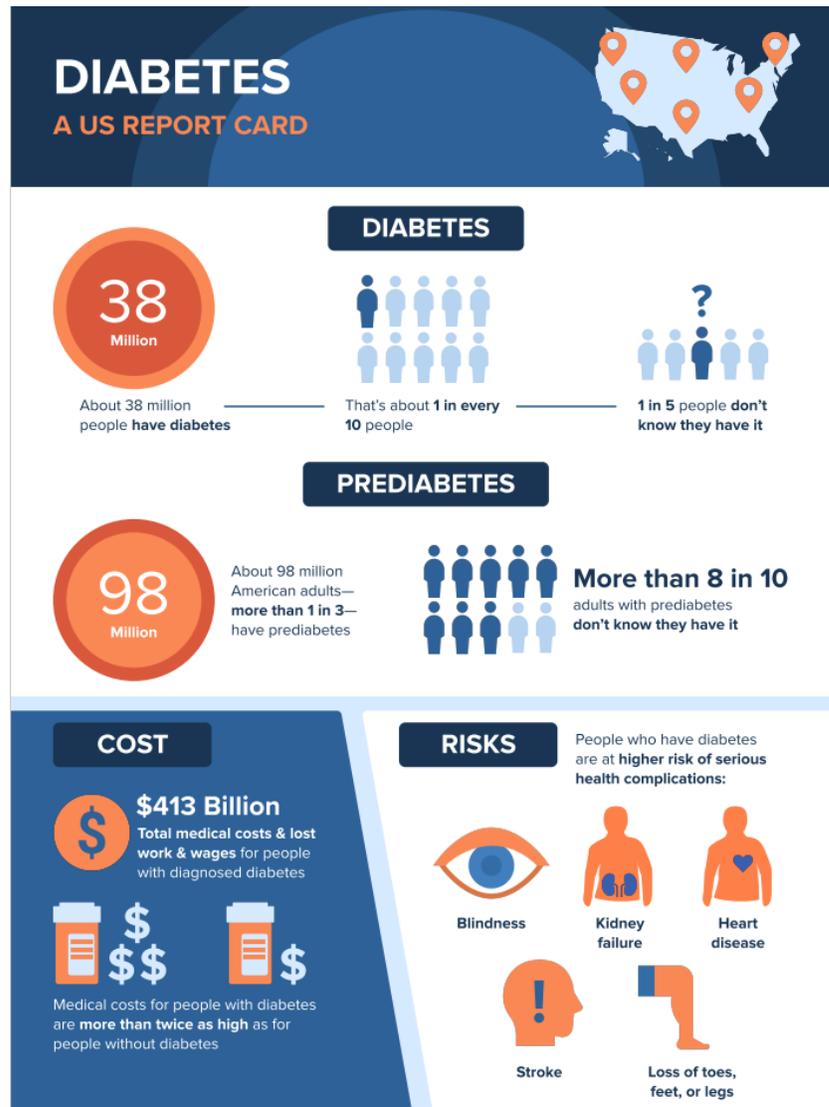
¹⁸ *Id.*

¹⁹ *Id.*

levels steady between meals and overnight. Inhaler device dosages are not as precise as other insulin administration devices.²⁰

Impact of Diabetes

Diabetes is the eighth leading cause of death in the United States.²¹ Below is a snapshot of diabetes prevalence and health care costs in the U.S.²²

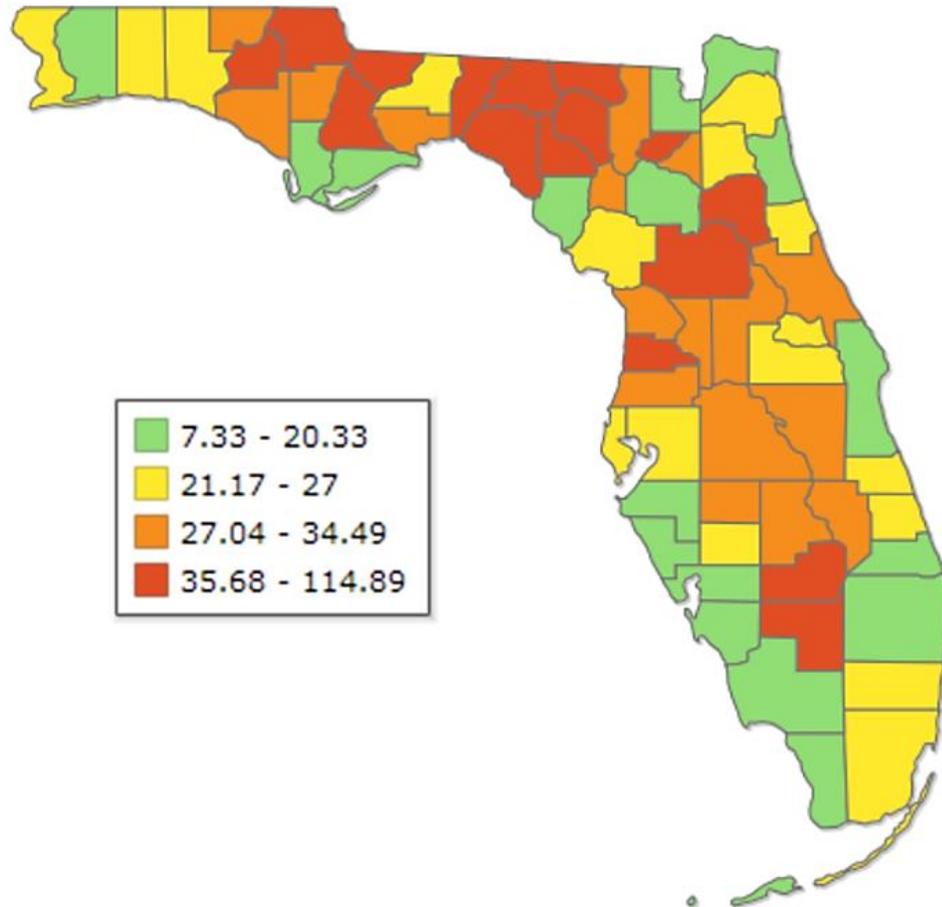


In Florida, diabetes is the seventh leading cause of death, claiming 7,550 lives in 2022.²³ The Florida Department of Health calculates an age-adjusted rate to measure deaths per 100,000. An age-adjusted rate is a weighted average where the crude each for each age group is multiplied by its representative

²⁰ *Id.*
²¹ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *What is Diabetes*, (last reviewed Sept. 5, 2023), <https://www.cdc.gov/diabetes/basics/diabetes.html> (last visited Nov. 27, 2023).
²² Centers for Disease Control and Prevention, *A Snapshot: Diabetes in the United States*, available at <https://www.cdc.gov/diabetes/library/socialmedia/infographics/diabetes.html> (last visited Nov. 27, 2023).
²³ Florida Department of Health, *Leading Causes of Death Profile*, Bureau of Community Health Assessment, Division of Public Health Statistics and Performance Management, Florida Department of Health, <https://www.flhealthcharts.gov/ChartsReports/rdPage.aspx?rdReport=ChartsProfiles.LeadngCausesOfDeathProfile> (last visited Jan. 13, 2024).

proportion in the standard population before being summed together.²⁴ In 2022, the age-adjusted deaths from diabetes rate per 100,000 population in Florida was 22.8.²⁵

Florida Age-adjusted Deaths from Diabetes, Rate Per 100,000 Population, 2022²⁶



The American Diabetes Association estimates that 2,071,045 Floridians, or 11.6% of the adult population, have diagnosed diabetes. People with diabetes have medical expenses about 2.3 times higher than those without diabetes, and diagnosed diabetes costs approximately \$25 billion in Florida each year.²⁷

Pharmacists

Pharmacist Licensure

²⁴ Florida Department of Health, *Age-Adjusted Rate*, FLHEALTH Charts, Florida Department of Health, <https://www.flhealthcharts.gov/Charts/documents/AARDescription.pdf> (last visited Nov. 27, 2023).

²⁵ Florida Department of Health, *Deaths from Diabetes*, FLHEALTH Charts, Florida Department of Health, <https://www.flhealthcharts.gov/ChartsDashboards/rdPage.aspx?rdReport=Death.DataViewer&cid=0090> (last visited Jan. 13, 2024).

²⁶ *Id.*

²⁷ American Diabetes Association, *The Burden of Diabetes in Florida*, (last reviewed Mar. 2023), https://diabetes.org/sites/default/files/2023-09/ADV_2023_State_Fact_sheets_all_rev_Florida.pdf (last visited Nov. 27, 2023).

Pharmacy is the third largest health profession behind nursing and medicine.²⁸ The Board of Pharmacy (Board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacy under ch. 465, F.S.²⁹ To be licensed as a pharmacist in Florida, a person must:³⁰

- 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;³¹
- Have completed a board-approved internship; and
- Successfully complete the board-approved examination.

Pharmacist Scope of Practice

In Florida, the practice of the pharmacy profession includes:³²

- Compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of a 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;
- Preparing prepackaged drug products in facilities holding Class III institutional facility permits;³³
- Administering vaccines to adults;³⁴
- Administering epinephrine injections;³⁵ and
- Administering antipsychotic medications by injection.³⁶

A pharmacist may only dispense controlled substances, including insulin, upon a written, oral, or electronic prescription.³⁷

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.³⁸

Pharmacists may order and dispense drugs that are included in a formulary developed by a committee composed of members of the Boards of Medicine, Osteopathic Medicine, and Pharmacy. The formulary may only include:³⁹

- Medicinal drugs 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 United States Food and Drug Administration;

²⁸ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited Nov. 27, 2023).

²⁹ ss. 465.004 and 465.005, F.S.

³⁰ s. 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.

³¹ If the applicant has graduated from a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, 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

³² s. 465.003(22), F.S.

³³ A Class III institutional pharmacy are those pharmacies affiliated with a hospital. See s. 465.019(2)(d), F.S.

³⁴ See s. 465.189, F.S.

³⁵ *Id.*

³⁶ s. 465.1893, F.S.

³⁷ s. 893.04, FS

³⁸ s. 465.003(22), F.S.

³⁹ s. 465.186, F.S.

- Medicinal drugs recommended by the United States Food and Drug Administration Advisory Panel for transfer to over-the-counter status pending approval by the United States Food and Drug Administration;
- Medicinal drugs containing an antihistamine or decongestant as a single active ingredient or in combination;
- Medicinal drugs containing fluoride in any strength;
- Medicinal drugs containing lindane in any strength;
- Over-the-counter proprietary drugs under federal law that have been approved for reimbursement by the Florida Medicaid Program; and
- Topical anti-infectives, excluding eye and ear topical anti-infectives.

A pharmacist may order, within his or her professional judgment and subject to the stated conditions:⁴⁰

- 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;
- Certain urinary analgesics;
- Certain otic analgesics;
- Anti-nausea preparations;
- Certain antihistamines and decongestants;
- Certain topical antifungal/antibacterials.
- Certain topical anti-inflammatory products;
- Certain otic antifungal/antibacterial preparations;
- Certain keratolytics;
- 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;
- Certain ophthalmic solutions;
- Certain histamine H2 antagonists;
- Certain acne products;
- Topical Antiviral for herpes simplex infections of the lips; and
- Penciclovir.

Emergency Insulin Refills

If a pharmacist is unable to readily obtain refill authorization from a prescriber, the pharmacy practice act authorizes a pharmacist to dispense a one-time refill of one vial of insulin to treat diabetes.⁴¹ The practice act does not include emergency refills for insulin-related supplies or equipment.

The standard concentration for most insulin is 100 units per every 1mL. Insulin vials are usually 10mL (1000 units). As insulin intake varies per patient, the total daily insulin calculation is a patient's body weight (in pounds) divided by 4. For example, if a patient weighs 160 pounds, that patient requires 40 units of insulin per day. Therefore, one vial of insulin (1000 units divided by 40 units per day) supplies that individual patient with 25 days of insulin. Patients of greater weight will use up a single vial more quickly.⁴²

For diabetic patients without current prescription orders, an emergency vial of insulin is life-saving. However, depending on the patient's rate of use, a single vial may not offer enough time to secure a current prescription order from their primary care physician.

⁴⁰ Rule 64B16-27.220, F.A.C.

⁴¹ S. 465.0275(1), F.S.

⁴² Diabetes Teaching Center, *Calculating Insulin Dose*, University of California, San Francisco, <https://dtc.ucsf.edu/types-of-diabetes/type1/treatment-of-type-1-diabetes/medications-and-therapies/type-1-insulin-therapy/calculating-insulin-dose/> (last accessed Jan. 14, 2024); *Days' Supply Calculation*, Illinois State Board of Education <https://www.isbe.net/CTEDocuments/HST-690049.pdf> (last accessed Jan. 14, 2024).

In the case of a natural disaster or other declared emergency, different standards apply for emergency refills. When the Governor declares a state of emergency under ch. 252, F.S., a pharmacist may dispense an emergency refill up to a 30-day supply in the areas affected by the order if:⁴³

- The prescription is not for a medicinal drug listed in Schedule II of ch. 893;
- 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.

The 30-day supply of insulin authorized under the emergency authority in ch. 252, F.S., is a greater amount of insulin than the one vial authorized for emergency refills under the pharmacy practice act. However, just as in the practice act, ch. 252, F.S., does not authorize emergency refills for insulin-related supplies or equipment.

Effect of the Bill

CS/HB 201 expands current law on emergency insulin refills in the pharmacy practice act.

The bill eliminates the current one vial limit on an emergency prescription refill of insulin. This means pharmacists can supply a patient with enough insulin until the patient can secure a current prescription order from their primary care physician – regardless of extenuating circumstances.

The bill also expands the number of times a pharmacist may dispense an emergency refill of insulin to treat diabetes, from one time a year to up to three nonconsecutive times per calendar year. The precondition that the pharmacist be unable to readily obtain refill authorization from a prescriber remains in the bill.

The bill adds authority for a pharmacist to dispense an emergency refill of insulin-related supplies or equipment to treat diabetes, if the pharmacist is unable to readily obtain refill authorization from a prescriber. This allows diabetes patients to effectively use their emergency refills of insulin. The bill allows this refill up to three nonconsecutive times per calendar year, just as for the insulin itself.

The bill also makes conforming changes to the Florida Comprehensive Drug Abuse Prevention and Control Act.

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

B. SECTION DIRECTORY:

Section 1: Amending s. 465.0275, F.S., relating to emergency prescription refill.

Section 2: Amending s. 893.04, F.S., relating to pharmacist and practitioner.

Section 3: Providing an effective date of July 1, 2024.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Pharmacy has sufficient rulemaking authority to implement the bill in current law.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On December 6, 2023, the Health Regulation Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The amendment:

- Authorizes a pharmacist to dispense an emergency refill of insulin and insulin-related supplies or equipment to treat diabetes, if the pharmacist is unable to readily obtain refill authorization from a prescriber; and
- Limits a pharmacist's authority to dispense an emergency refill of insulin to a maximum of 3 nonconsecutive times per calendar year.

The analysis is drafted to the amended bill as passed by the Healthcare Regulation Subcommittee.