

HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

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

SPONSOR(S): Healthcare Regulation Subcommittee, Bell and others

TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 516

FINAL HOUSE FLOOR ACTION: 118 Y's 0 N's **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

CS/HB 201 passed the House on February 15, 2024, and subsequently passed the Senate on March 5, 2024.

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.

In the event a pharmacist receives a request for an insulin prescription refill, but is unable to readily obtain refill authorization from a prescriber, current law allows the pharmacist to dispense a one-time emergency refill of one vial of insulin. However, current law does not authorize pharmacists to dispense insulin-related supplies or equipment as part of an emergency prescription refill, and one vial may be insufficient for some patients' emergency needs.

CS/HB 201 expands the authority to dispense an emergency refill of insulin by eliminating both the one-vial limit and the one-time limit. The bill allows the pharmacist to dispense enough insulin until the patient can secure a current prescription order from their primary care physician. The bill allows a pharmacist to dispense emergency refills of insulin up to three nonconsecutive times per calendar year, per patient.

The bill also authorizes a pharmacist to dispense an emergency refill of insulin-related supplies or equipment, if the pharmacist is unable to readily obtain refill authorization from a prescriber. The bill allows a pharmacist to dispense emergency refills of insulin-related supplies or equipment up to three nonconsecutive times per calendar year, per patient.

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

The bill was approved by the Governor on April 11, 2024, ch. 2024-79, L.O.F., and will become effective on July 1, 2024.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

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 levels. 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 Jul. 2017) <https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-1-diabetes/> (last visited Mar. 5, 2024).

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 Mar. 5, 2024); 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 Mar. 5, 2024).

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. Cleveland Clinic, *Insulin*, (last reviewed Jan. 1, 2024) <https://my.clevelandclinic.org/health/body/22601-insulin> (last visited Mar. 18, 2024).

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.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. However, few people with type 1 diabetes take pramlintide. 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. 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 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

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, and some people do not find out they have the disease until they have diabetes-related health problems.¹³

⁶ *Id.*

⁷ *Supra*, FN 3.

⁸ *Supra*, FN 1.

⁹ *Id.*

¹⁰ *Supra*, FN 3.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

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 sleep apnea, depression, some types of cancer, and dementia.¹⁶

Treatment of Diabetes

Diabetics must take insulin to reduce their blood glucose levels. As the chart below demonstrates, the market categorizes various types of insulins by their differences in onset, peak, duration and route of delivery.¹⁷

Type	Onset	Peak	Duration	Route of Delivery
Rapid Acting Insulin Analogs	5-10 mins.	1-2 hrs.	4 hrs.	Injection, Pump or Inhaler
Long Acting Insulin Analogs	60-90 mins.	Flat (max effect in 5 hrs.)	12-24 hrs.	Injection
Fast Acting Synthetic Human Insulin	30-45 mins.	2-4 hrs.	5-8 hrs.	Injection or Pump
Intermediate Acting Synthetic Human Insulin	2 hrs.	4-12 hrs.	14-24 hrs.	Injection

Insulin analogs mimic the body's natural pattern of insulin release, act on cells like ordinary human insulin, and allow the body to absorb them with greater predictability than other insulins. Prescribers may order rapid acting insulin analogs¹⁸ or long acting insulin analogs.¹⁹ Rapid acting insulin analogs give diabetic patients much desired flexibility to administer insulin near mealtimes, and long acting insulin analogs help diabetic patients maintain healthy blood glucose levels throughout the night.²⁰ Analog insulins require a prescription in the United States.²¹

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 Mar. 5, 2024).

¹⁶ *Supra*, FN 3.

¹⁷ Diabetes Teaching Center, *Types of Insulin*, University of California, San Francisco, <https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/> (last visited Mar. 19, 2024); Diabetes Teaching Center, *Insulin Analogs*, University of California, San Francisco, <https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/insulin-analogs/> (last visited Mar. 19, 2024); Diabetes Teaching Center, *Human Insulin*, University of California, San Francisco, <https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/human-insulin/> (last visited Mar. 19, 2024); Cleveland Clinic, *Insulin*, (last reviewed Jan. 1, 2024) <https://my.clevelandclinic.org/health/body/22601-insulin> (last visited Mar. 19, 2024); Heather Grey and Kelly Wood, *Insulin Chart: What You Need to Know About Insulin Types and Timing*, Healthline, (last updated May 10, 2022) <https://www.healthline.com/health/type-2-diabetes/insulin-chart> (last visited Mar. 19, 2024).

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ Raje Chouhan, Shilpi Goswami, and Anil Kumar Bajpai, *Nanostructures for Oral Medicine, Ch. 15: Recent advancements in oral delivery of insulin: from challenges to solutions, 7.1 Insulin Analogs*, <https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/insulin-analog> (last visited Mar. 19, 2024).

²¹ Children with Diabetes, *Prescription Laws and Access to Insulin Resources*, <https://childrenwithdiabetes.com/insulin/prescription-laws-and-resources/> (last visited Mar. 18, 2024); See Juliette Cubanski, Tricia Neuman, and Meredith Freed, *Explaining Prescription*

Prior to the introduction of insulin analogs, synthetic human insulins commonly treated diabetes.²² Synthetic human insulins tend to be less expensive because they rely on older medical practices and may be available over-the-counter.²³

Insulin can be taken in several ways; common options include a syringe, insulin pen, insulin pump, or 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.²⁴

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.²⁵

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).²⁶

Drug Provisions in the Inflation Reduction Act, KFF (Jan. 24, 2023) <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/> (last visited Mar. 18, 2024).

²² Ignazio Vechhio, Cristina Tornali, Nicola Luigi Bragazzi, and Mariano Martini, *The Discovery of Insulin: An Important Milestone in the History of Medicine*, National Library of Medicine, (Oct. 23, 2018) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6205949/> (last visited Mar. 19, 2024).

²³ Kate Ruder and Kacy Church, *What to Know Before You Use OTC Insulin*, Everyday Health, (Apr. 23, 2019) <https://www.everydayhealth.com/diabetes/otc-insulin-what-know-before-you-buy/> (last visited Mar. 19, 2024); Kayla Sullivan, *Indiana no longer the only state to require prescriptions for all insulin*, CBS4 News Indy (Dec. 31, 2020) <https://cbs4indy.com/news/indiana-no-longer-the-only-state-to-require-prescriptions-for-all-insulin/> (last visited Mar. 18, 2024); Sarah Jane Tribble, *You Can Buy Insulin Without A Prescription, But Should You?* KFF Health News, (Dec. 14, 2015) <https://kffhealthnews.org/news/you-can-buy-insulin-without-a-prescription-but-should-you/> (last visited Mar. 18, 2024); Over-the-counter drugs maybe used without a prescriber's authorization if they have an acceptable safety margin, low potential for misuse or abuse, and are adequately labeled so that consumers can self-diagnose the condition, self-select the medication, and self-manage the condition. Hannah Sheikh, *FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress*, Congressional Research Service (Dec. 10, 2021) <https://crsreports.congress.gov/product/pdf/R/R46985> (last visited Mar. 18, 2024).

²⁴ Centers for Disease and Control and Prevention, *4 Ways to Take Insulin* (last reviewed Apr. 18, 2023) <https://www.cdc.gov/diabetes/basics/type-1-4-ways-to-take-insulin.html> (last visited Mar. 5, 2024).

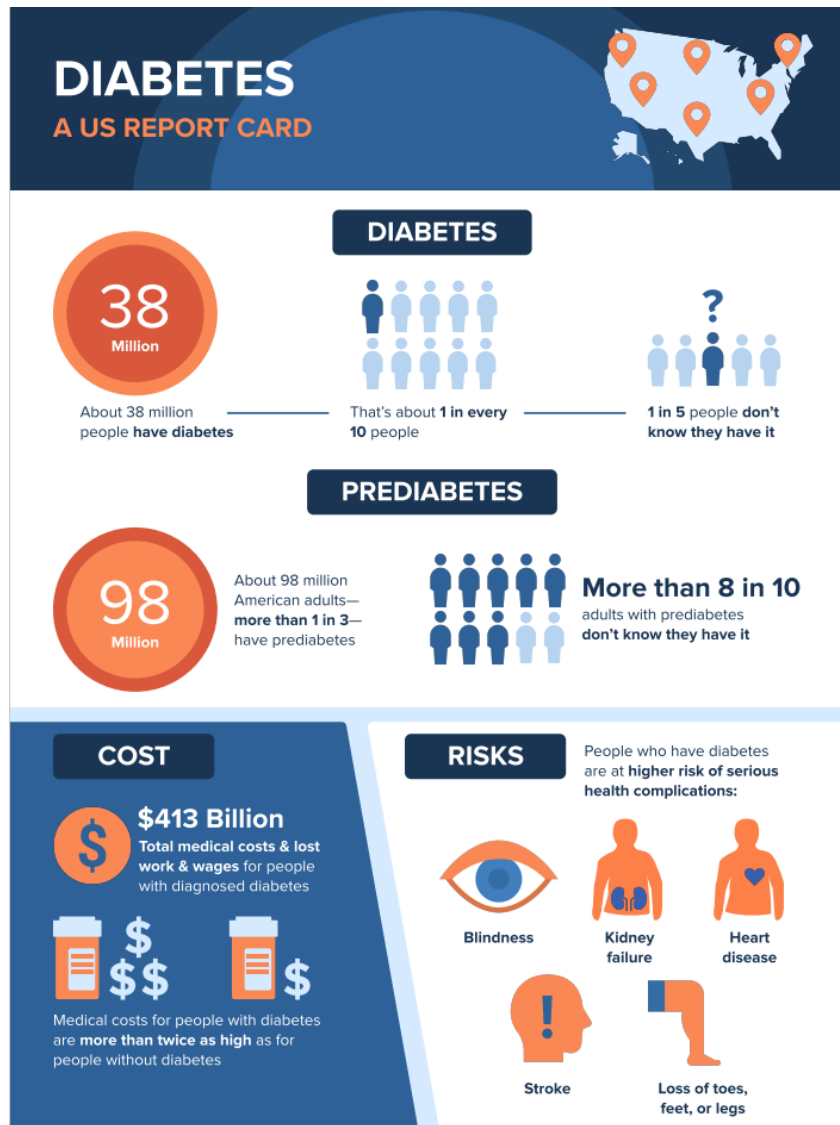
²⁵ *Id.*

²⁶ *Id.*

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 levels steady between meals and overnight. Inhaler device dosages are not as precise as other insulin administration devices.²⁷

Impact of Diabetes

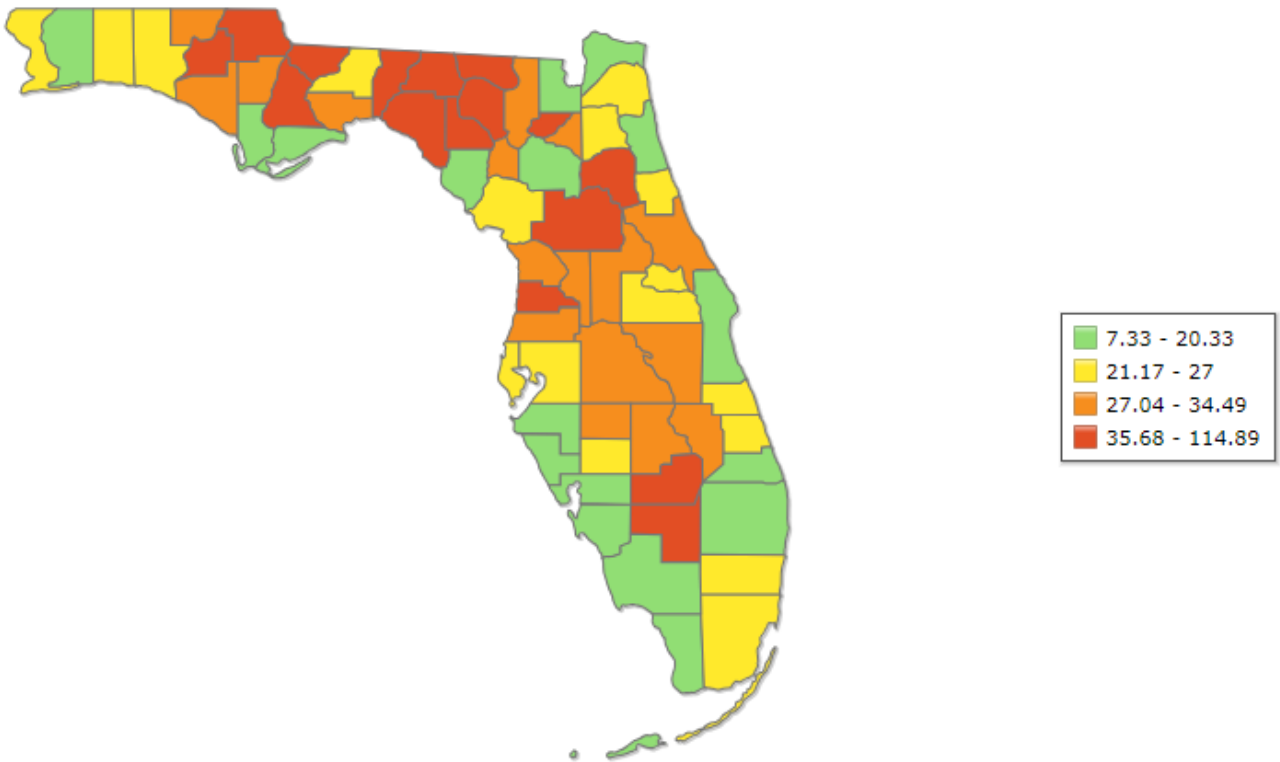
Diabetes is the eighth leading cause of death in the United States.²⁸ Below is a snapshot of diabetes prevalence and health care costs in the U.S.²⁹



²⁷ *Id.*
²⁸ 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 Mar. 5, 2024).
²⁹ 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 Mar. 5, 2024).

In Florida, diabetes is the seventh leading cause of death, claiming 7,550 lives in 2022.³⁰ 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 rate for each age group is multiplied by its representative proportion in the standard population before being summed together.³¹ In 2022, the age-adjusted deaths from diabetes rate per 100,000 population in Florida was 22.8.³²

Florida Age-adjusted Deaths from Diabetes, Rate Per 100,000 Population, 2022³³



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.³⁴

³⁰ 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.LeadingCausesOfDeathProfile> (last visited Mar. 5 2024).

³¹ Florida Department of Health, *Age-Adjusted Rate*, FLHEALTH Charts, Florida Department of Health, <https://www.flhealthcharts.gov/Charts/documents/AARDescription.pdf> (last visited Mar. 5, 2024).

³² 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 Mar. 5, 2024).

³³ *Id.*

³⁴ 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 Mar. 5, 2024).

Pharmacists

Practice of Pharmacy

The Board of Pharmacy (Board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacy under ch. 465, F.S.³⁵ In Florida, the practice of the pharmacy profession includes:³⁶

- 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;³⁷
- Administering vaccines to adults;³⁸
- Administering epinephrine injections;³⁹ and
- Administering antipsychotic medications by injection.⁴⁰

A pharmacist may only dispense a medicinal, or prescription, drug pursuant to a prescription or order issued by an authorized practitioner.⁴¹ Generally, a pharmacist cannot prescribe or order prescription drugs. 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.⁴²

However, pharmacists may order and dispense drugs without a prescription if the drugs are included in a formulary developed by a committee composed of members of the Boards of Medicine, Osteopathic Medicine, and Pharmacy.⁴³ Current law requires these three boards to adopt by rule a formulary of medicinal drugs and dispensing procedures established by the committee. The formulary may include:⁴⁴

- 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;
- 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.

³⁵ Ss. 465.004 and 465.005, F.S.

³⁶ S. 465.003(22), F.S.

³⁷ A Class III institutional pharmacy are those pharmacies affiliated with a hospital. See s. 465.019(2)(d), F.S.

³⁸ See s. 465.189, F.S.

³⁹ *Id.*

⁴⁰ S. 465.1893, F.S.

⁴¹ S. 465.003(15), F.S.

⁴² S. 465.003(22), F.S.

⁴³ Rule 64B16-27.220, F.A.C.

⁴⁴ S. 465.186(1), F.S.

Since the formulary does not include insulin,⁴⁵ pharmacists may not order insulin for patients under current law, and may not dispense it absent a prescription from an authorized practitioner.⁴⁶

Emergency Insulin Refills

While pharmacists cannot order insulin, current law addresses pharmacist authority for emergency refills of insulin without a prescription.

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.⁴⁷ 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 (1,000 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 (1,000 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.⁴⁸

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.

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:⁴⁹

- 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.

⁴⁵ R. 64B-16-27.220, F.A.C. The formulary lists certain oral analgesics, urinary analgesics, otic analgesics, anti-nausea preparations, antihistamines and decongestants, topical antifungal/antibacterials, keratolytics, vitamins with fluoride, medicinal drug shampoos containing Lindane, ophthalmics, histamine H2 antagonists, acne products, and topical antivirals.

⁴⁶ Since March 23, 2020, the United States Food & Drug Administration (FDA) regulates insulin as a biological product under the Public Health Service Act rather than a traditional pharmaceutical drug under the Food, Drug & Cosmetic Act. This regulatory change is meant to properly classify insulin as a matter of science and to encourage the development of biosimilar and interchangeable insulins. American Diabetes Association, *Insulin is Now a Biologic – What Does That Mean?* (Mar. 23, 2020) <https://diabetes.org/blog/insulin-now-biologic-what-does-mean> (last visited Mar. 18, 2024); U.S. Food & Drug Administration, *FDA Works to Ensure Smooth Regulatory Transition of Insulin and Other Biological Products: Transition is Expected to Increase Patient Access and Potentially Lower Prices on Insulin*, (Feb. 20, 2020) <https://www.fda.gov/news-events/press-announcements/fda-works-ensure-smooth-regulatory-transition-insulin-and-other-biological-products> (last visited Mar. 18, 2024); U.S. Food & Drug Administration, *100 Years of Insulin* (Jun. 8, 2022) <https://www.fda.gov/about-fda/fda-history-exhibits/100-years-insulin> (last visited Mar. 18, 2024);

⁴⁷ S. 465.0275(1), F.S.

⁴⁸ 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 visited Mar. 5, 2024); *Days' Supply Calculation*, Illinois State Board of Education <https://www.isbe.net/CTEDocuments/HST-690049.pdf> (last visited Mar. 5, 2024).

⁴⁹ S. 465.0275(2), F.S.

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 one vial limit on an emergency prescription refill of insulin. Instead, the bill authorizes pharmacists to supply a patient with enough insulin until the patient can secure a current prescription order from their primary care physician.

The bill also expands the number of times a pharmacist may dispense an emergency refill of insulin to treat diabetes, from once 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.

The bill provides 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.