



Healthcare Regulation Subcommittee

Wednesday, December 6, 2023

2:00 PM

Reed Hall (102 HOB)

Meeting Packet

Paul Renner
Speaker

Michelle Salzman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Healthcare Regulation Subcommittee

Start Date and Time: Wednesday, December 06, 2023 02:00 pm
End Date and Time: Wednesday, December 06, 2023 05:00 pm
Location: Reed Hall (102 HOB)
Duration: 3.00 hrs

Consideration of the following bill(s):

HB 201 Emergency Refills of Insulin and Insulin-related Supplies or Equipment by Bell
HB 227 Intravenous Vitamin Treatment by Garcia

Consideration of the following proposed committee substitute(s):

PCS for HB 197 -- Relating to Health Care Practitioners and Massage Therapy

Briefing on the Florida Medicaid Study of Enrollees with Sickle Cell Disease by the Agency for Health Care Administration

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m. Tuesday, December 5, 2023.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Tuesday, December 5, 2023.

To submit an electronic appearance form, and for information about attending or testifying at a committee meeting, please see the "Visiting the House" tab at www.myfloridahouse.gov.

NOTICE FINALIZED on 11/29/2023 3:36PM by Arnold.Sabrina

AHCA



Florida Medicaid: Prevalence and Treatment of Sickle Cell Disease

House Health Care Regulation Subcommittee

December 6, 2023

Florida Medicaid Report to the Legislature: February 2023

- In 2022, the Florida Legislature directed the Agency for Health Care Administration (Agency), in consultation with the Florida Medical School Quality Network (FMSQN), to conduct a review and provide a report regarding Medicaid enrollees diagnosed with sickle cell disease.
- The report was completed and submitted on February 1, 2023. Subsequently, it was posted to the [Agency's publicly accessible website](#).
- The report documented the impact of sickle cell disease in Florida Medicaid.
- In 2023, the Florida Legislature directed the Agency in SB 1352 to review sickle cell disease medications, treatments, and services for Medicaid recipients and develop a written report every 2 years beginning November 1, 2024.



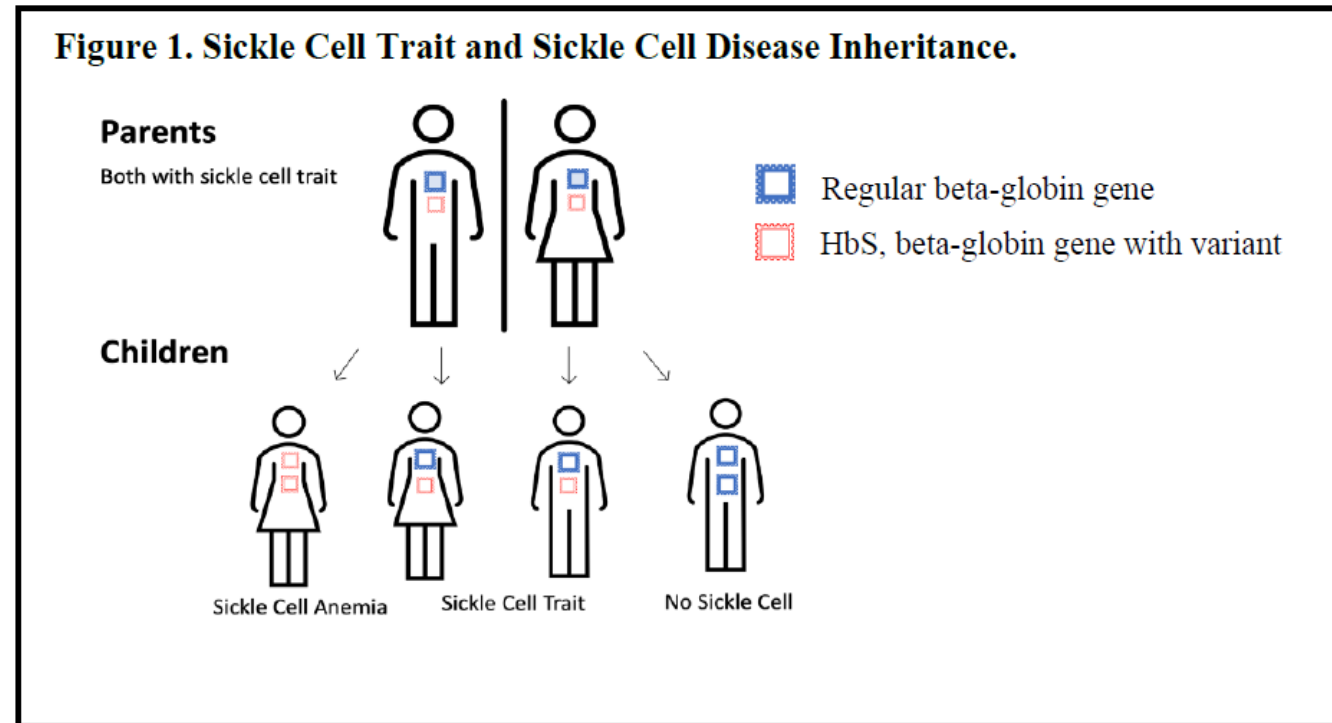
Florida Medicaid Report to the Legislature: February 2023

- In general, the report contains information on sickle cell disease including:
 - Background
 - Prevalence
 - Demographics and utilization
 - Geographic distribution
 - Treatment
- The report analyzed Medicaid program data from 2018-2021.
- The report cohort included individuals who:
 - were continuously enrolled in Medicaid for at least 12 of 12 months; and
 - had at least 2 health care encounters associated with sickle cell disease during the study period.
- This approach identified 9,206 Medicaid recipients for inclusion in the study.



What is Sickle Cell Disease?

- Sickle cell disease, sometimes called sickle cell anemia, is a blood disorder that affects hemoglobin, the protein that carries oxygen through the body.
- Sickle cell disease is an inherited disease – if both parents carry a gene for sickle cell, their children have a 25% chance of having sickle cell disease.



Sickle Cell Disease - Continued



Sickle cell disease (SCD) causes misshaped red blood cells to occlude blood vessels and chronically infarct multiple organs, including bones, brain, spleen, eyes, and kidneys.



Repeated crises suffocate downstream tissues, such as bones, spleen, brain, eyes, and kidneys, causing wracking bone pain attacks, unguarded bacterial infections, stroke, blindness, and kidney failure among many other organ failures.



Currently, the life expectancy of a person with sickle cell disease is approximately 20 years less than the general population at 54 years of age compared to 76 years for people without sickle cell disease.

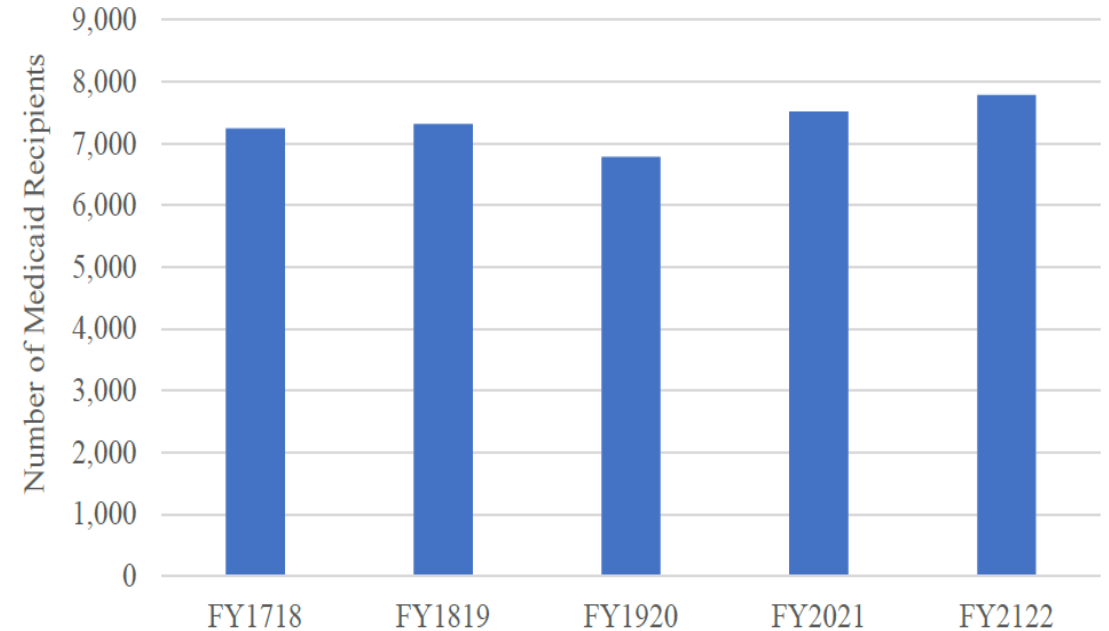


Florida Medicaid: Prevalence of Sickle Cell Disease

In Florida Medicaid:

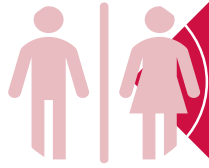
- The prevalence rate of sickle cell disease is twice as high as the national average and Florida Medicaid has one of the highest numbers of sickle cell disease patients in the U.S., indicating a disproportionate impact from a national perspective.
- Since 2017, Florida and New York have the highest Medicaid cases of sickle cell disease in the United States.
- The yearly average of recipients with sickle cell disease is **7,328**.

Figure 2. Sickle Cell Disease in Florida Medicaid. The number of unique Medicaid recipients with sickle cell disease are plotted with respect to fiscal year (FY).



Florida Medicaid: Demographics for Recipients with Sickle Cell Disease

- The Florida Medicaid sickle cell disease (SCD) population was predominately female, young and black:



Recipient Demographic Breakdown:
58% Female, 42% Male



Majority of SCD cases are in recipients
under 21, Median recipient age is 18 years



63% of Florida Medicaid recipients with SCD
identified as black



Florida Medicaid: Service Utilization and Experience of Recipients with Sickle Cell Disease

Of those in the study cohort, nearly all were evaluated by a Florida physician at least once in the 4-year study period.

Care and treatment is received in both inpatient and outpatient settings.

~85% recipients were evaluated or treated in an outpatient clinic setting at least once.

52% recipients were admitted to an inpatient hospital.

Majority of recipients experience crisis events with trips to the Emergency Room (ER).

61% of the recipients were evaluated and treated in an ER at least once.

39% did not seek ER care.

Children between ages 2-16 years, should have an annual screening for stroke risk through a Transcranial Doppler Ultrasound (TCD).

Of the 2,906 children, 1,068 (41%) had at least one Transcranial Doppler (TCD) during the four-year study.

77% of recipients had a pharmacy expenditure for a sickle cell disease-relevant medication, such as disease-modifying treatments, prophylactic antibiotics, opioids, or iron chelating agents.

23% had no pharmacy expenditures for sickle cell disease-relevant medication.



Florida Medicaid: Treatment of Sickle Cell Disease

Medication	Number of Eligible Patients	Percent of Eligible Population Taking Medication
Oral Penicillin	2,054	58%
Hydroxyurea (Generic, Droxia, Siklos)	7,613	22%
L-glutamine	6,840	2%
Voxelotor	5,629	0.1%
Crizanlizumab	4,956	0.08%

The most commonly prescribed medications among the cohort were:

- Oral penicillin, which is recommended for children under 5 to reduce infection risk and mitigate damage to the spleen; and
 - Hydroxyurea, to reduce pain episodes, stroke risk, and prevent organ damage.
-
- In the four-year study period, recipients' total pharmacy expenditures per year ranged from \$4,378.26 to \$6,232.30 and increased incrementally by year.

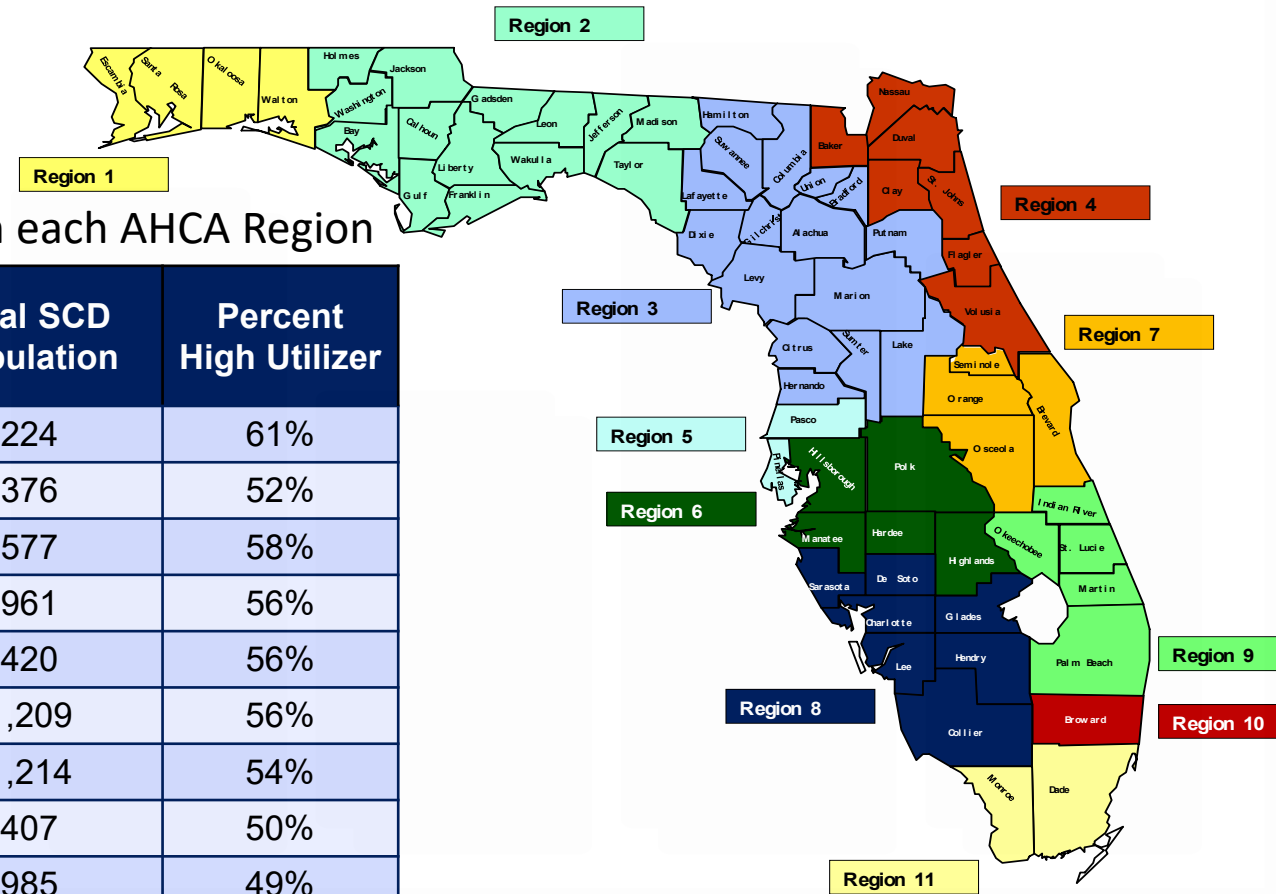


Florida Medicaid: Recipients with SCD who are High Utilizers

High utilizer was defined as two or more emergency room visits or two or more inpatient admissions in a 12-month period.

Percent of High Utilizers in each AHCA Region

AHCA Region	SCD High Utilizer Population	Total SCD Population	Percent High Utilizer
1	137	224	61%
2	196	376	52%
3	336	577	58%
4	541	961	56%
5	261	420	56%
6	678	1,209	56%
7	656	1,214	54%
8	202	407	50%
9	486	985	49%
10	739	1,352	55%
11	708	1,388	51%
Overall Number of High Utilizers in Florida 4,940			



Florida Medicaid: Clinical Treatment Programs for Sickle Cell Disease

Clinical treatment programs were identified by the FMSQN as available and contracted with managed care plans for the care of sickle cell recipients.

 = Recognized as a treatment center of excellence by The National Alliance of Sickle Cell Centers




- ### Hospital Systems
- AdventHealth System Orlando
 - Broward Health Sickle Cell Care
 - Memorial Health Care System
 - Orlando Health's Arnold Palmer Hospital



- ### Children's Hospitals
- Johns Hopkins All Children 
 - Nemours Children's Center for Cancer and Blood Disorders 
 - Nicklaus Children's Hospital
 - Wolfson Children's Hospital



- ### University Teaching Hospitals and Systems
- University of Florida Shands Hospital 
 - University of Miami Sylvester Comprehensive Cancer Center 
 - University of South Florida Comprehensive Sickle Cell Center



Emerging Treatments for Sickle Cell Disease



Gene Therapies

- Based on publicly available information, there are several new treatments for sickle cell disease currently going through the FDA approval process.
- This month, the Food and Drug Administration will decide on the regulatory approval of two gene therapies for sickle cell disease. Exa-cel and lovo-cel are potentially one-time treatment options for sickle cell patient.

How will Medicaid cover these newly FDA approved treatments?



Florida Medicaid: Coverage of Outpatient Prescription Drugs

The State requires outpatient drugs under the Prescribed Drug Services Rule (59G-4.250) to:

1

Be approved by the Food and Drug Administration (FDA)

2

Have a federal rebate



Food and Drug Administration (FDA) Approval

- For new drugs to be covered by State Medicaid Programs, they first must have FDA approval.
- To receive FDA approval the FDA evaluates:



Federal Drug Rebate

Second they need a federal rebate –

- The Medicaid Drug Rebate Program (MDRP) establishes rebate rates that are applied to all state Medicaid programs.
- In order for branded drugs to be covered by Medicaid, drug manufacturers must pay a rebate of at least 23.1%



Florida Medicaid: Process Once Federally Approved = Clinical Appropriateness

After FDA approval has been met, the Agency develops coverage criteria based on:

1. Determine clinical appropriateness
2. Is the drug preferred?
3. Payment Methodology

Key Considerations	
Indication(s) of the drug	Drug manufacturer prescribing information
Medical standards	Treatment algorithms
Number of Medicaid recipients impacted	Preferred drug alternatives



Florida Medicaid: Process Once Federally Approved = Is the Drug Preferred?

- Florida Medicaid has a single Preferred Drug List (PDL) that is established through a joint process with the Agency and the Medicaid Pharmacy and Therapeutics (P&T) Committee.
- Managed Care Organizations (MCOs) and Fee-For-Service (FFS) providers must follow the single PDL.
- Florida Medicaid utilizes the P&T Committee to review new drugs being considered for addition to the PDL.
- Drugs must be on the market and available for at least 90 days prior to review by the P&T Committee.

Drugs may be classified as:

Preferred	Non-Preferred
No clinical criteria	Requires additional steps for access compared to preferred
With clinical criteria (may be computer automated)	Requires prior authorization



Florida Medicaid: Supplemental Rebates

Florida Supplemental Rebates

- Florida Medicaid requires Branded products to have a total rebate.
- Florida Medicaid requires a total rebate (federal plus supplemental) that equals or exceeds 29% **for consideration** of addition to the PDL.
- Supplemental rebates are effective for one year if accepted.

- States can get CMS approval to enter into value-based agreements (VBA) for rebates.
- VBAs are utilized in health systems and generally involve linking payment to value or specific outcomes achieved.



Payment Options to Address Additional Costs for Reimbursement

There are three different payment options considered for payment of the newly approved drugs.

1. Risk Pool
2. Risk Adjustment
3. Kick Payment



Option 1: High Pharmacy Cost Risk Pool

AHCA could implement a high-risk pool for members with high drug costs during the year. This option would cover both new and existing drugs with high costs per treatment.

Pros	Cons
<ul style="list-style-type: none">• Directs more funding to capitated plans with higher total costs of drugs.• Monthly capitation rates can be paid on the usual schedule with risk pool payments occurring on a regular schedule after pharmacy costs are known.• Overall funding for pharmacy services in the capitation rates is consistent with recent observed costs and access to services.	<ul style="list-style-type: none">• The risk pool needs to be fully funded.• Does not mitigate capitated plan risk tied to uncertainty during the rate year.• Additional administrative burden associated with the risk pool:<ul style="list-style-type: none">○ Defining the cost threshold for recipient eligibility.○ Creating withholds on the capitation rates○ Calculating, paying, and reviewing appropriate funds to each plan based on their portion of the pool.



Option 2: Risk Adjustment

Monthly capitation rates include a component for new pharmacy drug costs which would vary in the payments made to plans based on relative risk scores developed by Milliman.

Pros	Cons
<ul style="list-style-type: none">• No additional administrative burden.• Overall funding for pharmacy services in the capitation rates is consistent with recent observed costs and access to services.• Payments will be directed to the specific capitated plans that incur new high pharmacy costs in the adjusted rate cells.	<ul style="list-style-type: none">• Milliman will need to develop an approach to include explicit adjustment for high pharmacy costs which may delay completion of risk weights.• Additional payments will not necessarily be directed to the specific plans whose recipients have higher pharmacy costs and will not distribute payments to specific plans with recipients using high pharmacy cost drugs in rate cells that are not risk adjusted.• Presents timing concerns due to not knowing if someone is using these drugs until data is submitted.• Does not mitigate capitated plan risk tied to uncertainty surrounding the number of total utilizers, or average cost per utilizer of the high-cost drugs in a rate year.



Option 3: Kick Payment

AHCA could implement a kick payment to be paid once a month for each MMA capitated plan recipient who utilizes the high-cost drugs during that month.

Pros	Cons
<ul style="list-style-type: none">• Mitigates capitated plan risk tied to uncertainty by paying plans a fixed amount per unique utilizer per month.• Payments are directed to the specific plans that cover individuals utilizing the new drugs.	<ul style="list-style-type: none">• Kick payment cannot be paid until after the claims have been reported.• Increased administrative complexity.• If the cost per utilizer changes significantly, the kick payment may be either too high or too low.• Multiple kick payments would be needed for multiple drugs.• Potential for increased cost and not budget neutral.



HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 197 Relating to Health Care Practitioners and Massage Therapy

SPONSOR(S): Healthcare Regulation Subcommittee

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Healthcare Regulation Subcommittee		Osborne	McElroy

SUMMARY ANALYSIS

The Board of Massage Therapy (Board), within the Department of Health (DOH), regulates massage practice, including massage therapists and massage establishments. Massage practice is the manipulation of the soft tissues of the human body with the hand, foot, knee, arm, or elbow, whether or not such manipulation is aided by hydrotherapy, including colonic irrigation or thermal therapy, or any electrical or mechanical device, or the application of a chemical or herbal preparation to the human body.

DOH is required to annually inspect massage establishments for compliance with statutory requirements. Under current law, DOH is required to issue an emergency suspension of the license of a massage establishment or massage therapist if specified criteria are met.

Human trafficking is a form of modern-day slavery involving the transporting, soliciting, recruiting, harboring, providing, enticing, maintaining, or obtaining another person for the purpose of exploiting that person. Illicit Massage Businesses (IMBs) are licensed or unlicensed massage establishments that purport to operate as legal businesses, but where sexual services are illegally bought and sold. IMBs are considered one of the primary venues for sex trafficking involving adults and comprised the largest group of citizen calls to the National Human Trafficking Hotline in 2019.

Florida has implemented several regulatory measures in statute in an effort to obstruct the operation of IMBs without interfering with legitimate massage establishments.

PCS for HB 197 significantly expands the circumstances under which DOH is required to issue emergency orders suspending the license of a massage therapist or of a massage establishment. The bill requires DOH to issue an emergency suspension of a massage therapist or establishment's license if any employee of a massage establishment is arrested for committing or attempting, soliciting, or conspiring to commit an offense listed in s. 465.074, F.S.

The bill expressly prohibits any sexual activity within a massage establishment. The bill prohibits advertisement by a massage therapist or establishment from being posted in any medium or website that advertises prostitution, escort, or other sexual services. The bill outlines further requirements for the operation of massage establishments and provides exemptions.

The bill expands the circumstances under which a massage establishment may be declared a public nuisance.

The bill will have a significant negative fiscal impact on DOH which is not currently addressed by an appropriation in the bill. The bill will have no fiscal impact on local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Massage Therapy

Massage practice is the manipulation of the soft tissues of the human body with the hand, foot, knee, arm, or elbow, whether or not such manipulation is aided by hydrotherapy, including colonic irrigation or thermal therapy, or any electrical or mechanical device, or the application of a chemical or herbal preparation to the human body.¹ Massage is therapeutic and a massage therapist must know anatomy and physiology and understand the relationship between the structure and function of the tissues being treated and the total function of the body.²

Chapter 480, F.S., entitled the “Massage Practice Act”, governs the practice of massage therapy in Florida. The Board of Massage Therapy (Board), within the Department of Health (DOH), regulates massage practice.³ The Board is responsible for establishing rules governing the licensure and practice of massage therapists and massage establishments. This includes approving massage therapy schools⁴, licensure exams⁵, establishing training requirements for massage therapy apprentices⁶, as well as setting minimum standards for and periodic inspections of massage establishments.⁷ DOH is responsible for providing investigative services to ensure compliance with regulations,⁸ while the Board has disciplinary authority over massage therapist and establishment licenses.⁹

Massage Therapist Licensure

A massage therapist is a person who administers massage for compensation.¹⁰ As of November 27, 2023, there are 36,178 actively licensed massage therapists in Florida.¹¹

To qualify for licensure as a massage therapist, an applicant must:¹²

- Be at least 18 years of age or have received a high school diploma or graduate equivalency diploma;
- Complete a course of study at a Board-approved massage school;
- Undergo background screening; and
- Pass an examination.¹³

A massage therapist is required to renew his or her license every two years and must complete 24 hours of continuing education for each renewal period.¹⁴

Massage Establishment Licensure

A massage establishment is the premises wherein a massage therapist practices massage therapy.¹⁵ A massage establishment must be licensed by the Board and adhere to rules set by the Board regarding

¹ S. 480.033(3), F.S.

² S. 480.032, F.S.

³ S. 480.035, F.S.

⁴ S. 480.033(3), F.S.

⁵ S. 480.041(1)(c), F.S.

⁶ S. 480.041(5), F.S.

⁷ Ss. 480.043(3) and (10), F.S.

⁸ S. 480.039, F.S.

⁹ S. 480.046, F.S.

¹⁰ S. 480.033(4), F.S.

¹¹ Department of Health, FLHealthSource.gov, Public Data Portal (search by Board/Council “Board of Massage Therapy”, then by Profession “massage therapist”, then by license status “practicing statuses only”), available at <https://mqa-internet.doh.state.fl.us/MQASearchServices/HealthCareProviders>, (last visited November 27, 2023).

¹² S. 480.041(1), F.S.

¹³ See rule 64B7-25.001, F.A.C. for Board approved examinations.

¹⁴ S. 480.0415, F.S., and rule 64B7-28.009, F.A.C.

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facilities, personnel, safety and sanitation requirements, financial responsibility, and insurance coverage.¹⁶ Massage establishments must be licensed in order to operate legally.¹⁷ There are approximately 8,966 massage establishments licensed in Florida.¹⁸

The Board requires the following be met for a license to be issued for a massage establishment:¹⁹

- Submit a completed application;²⁰
- Pass an inspection by DOH;²¹ and
- Submit proof of property damage and bodily injury liability insurance coverage.

The application includes background screening of the establishment owner and identification of the designated establishment manager (DEM).²² Under current law, a DEM must be a licensed massage therapist who holds a clear and active license without restriction. The DEM is responsible for the operation of a massage establishment, and must be designated the manager by the rules or practices at the establishment.²³

Massage establishment licenses may not be transferred from a licensee to another individual or entity.²⁴ Board approval is required for an establishment to move locations or change names.²⁵

Denial of Massage Establishment Licensure

A proposed massage establishment may be denied licensure for failing to meet the standards adopted by the Board, or if the owner or DEM has been convicted of or plead guilty or nolo contendere for a felony or misdemeanor relating to any of the following offenses:²⁶ prostitution,²⁷ kidnapping,²⁸ false imprisonment,²⁹ luring or enticing a child,³⁰ human trafficking or smuggling,³¹ sexual battery,³² female genital mutilation,³³ lewd or lascivious offenses in the presence of a minor, elderly, or disabled person,³⁴ or obscene or sexual acts involving a minor.³⁵

DOH may investigate the proposed massage establishment based on the application contents;³⁶ if DOH determines that the proposed establishment would fail to meet the standards adopted by the Board, DOH must deny the application for licensure and provide the denial in writing with a list of reasons for the denial. The establishment may correct the recorded deficiencies and reapply for licensure.³⁷

¹⁵ S. 480.033(7), F.S.

¹⁶ S. 480.043, F.S.

¹⁷ *Id.*

¹⁸ Department of Health, Agency Bill Analysis for House Bill 197 (2024), p. 2. On file with the Health care Regulation Subcommittee.

¹⁹ Rule 64B7-26.002, F.A.C.

²⁰ See also, Board of Massage Therapy, *Application for Massage Establishment License*. Available at <https://floridamassagetherapy.gov/applications/app-bus-original-mt.pdf> (last visited November 27, 2023).

²¹ The inspection must demonstrate that the proposed massage establishment is to be used for "massage" as defined in Section 480.033(3), F.S. and that the proposed massage establishment is in compliance with Chapters 456 and 480, F.S. and related rules. See rule 64B7-26.002, F.A.C.

²² *Supra*, note 20.

²³ S. 480.033(6), F.S.

²⁴ S. 480.043(9), F.S.

²⁵ *Id.*

²⁶ S. 480.043, F.S.

²⁷ Ch. 796, F.S.

²⁸ S. 787.01, FS.

²⁹ S. 787.02, F.S.

³⁰ S. 787.025, F.S.

³¹ Ss. 787.06 and 787.07, F.S.

³² S. 794.011, F.S.

³³ S. 794.08, F.S.

³⁴ Ss. 800.004 and 825.1025(2)(b), F.S.

³⁵ S. 827.071 and Ch. 847 F.S.

³⁶ S. 480.043(5), F.S.

³⁷ S. 480.043(6), F.S.

Human Trafficking

Human trafficking is a form of modern-day slavery involving the transporting, soliciting, recruiting, harboring, providing, enticing, maintaining, or obtaining another person for the purpose of exploiting that person.³⁸ Human trafficking can affect individuals of any age, gender, or nationality; however, some people are more vulnerable than others. Significant risk factors include recent migration or relocation, substance use, mental health concerns, and involvement in the child welfare system.³⁹

Victims of human trafficking are often subjected to force, fraud, or coercion for the purpose of sexual exploitation or forced labor.⁴⁰ It is estimated that at any given time in 2021, there were approximately 27.6 million people engaging in forced labor.⁴¹ In 2021, the National Human Trafficking Hotline⁴² identified 16,710 trafficking victims in the US, of which 1,253 were in Florida;⁴³ however, these figures do not reflect the true scope and scale of the issue which cannot be easily quantified due to the underground nature of the issue. An analysis of data collected by the Hotline showed that approximately 6% of reported victims in 2021 were associated with illicit massage, health, and beauty services.⁴⁴

Illicit Massage Businesses

Illicit Massage Businesses (IMBs) are licensed or unlicensed massage establishments that purport to operate as legal businesses, but where sexual services are illegally bought and sold.⁴⁵ IMBs are considered one of the top venues for sex trafficking involving adults and comprised the largest group of citizen calls to the National Human Trafficking Hotline in 2019.⁴⁶ In 2018, a study estimated that there were approximately 9,000 IMBs operating in the US;⁴⁷ it is expected that this number has risen in the years since.⁴⁸ The Collier County Sheriff's Office estimates that there are currently 40 IMBs operating in Collier County.⁴⁹

IMBs are successful in part due to their ability to operate in plain sight. They are often located in strip malls and present themselves publicly as legitimate massage establishments. Markers of an IMB include: opaque or covered windows, locked front doors with a buzzer to enter, listed prices significantly lower than the market value, serves exclusively or primarily male clientele, employees appearing to live on site, and advertising on commercial sex websites.⁵⁰

³⁸ S. 787.06, F.S.

³⁹ National Human Trafficking Hotline. *Human Trafficking: What Human Trafficking is, and isn't*. Available at <https://humantraffickinghotline.org/en/human-trafficking> (last visited November 27, 2023).

⁴⁰ *Id.*

⁴¹ International Labour Organization, *Global Estimates of Modern Slavery: Forced Labour and Forced Marriage* (Sep. 2022). Available at https://www.ilo.org/wcmsp5/groups/public/---ed_norm/---ipec/documents/publication/wcms_854733.pdf (last visited November 27, 2023).

⁴² The National Human Trafficking Hotline is a free service to connect victims and survivors of sex and labor trafficking with services and supports to find help and safety. The Hotline also receives tips about potential situations of sex and labor trafficking and facilitates reporting that information to the appropriate authorities. See also, National Human Trafficking Hotline, *About Us*. Available at <https://humantraffickinghotline.org/en/about-us> (last visited November 27, 2023).

⁴³ National Human Trafficking Hotline, *National Statistics (2021)*. Available at <https://humantraffickinghotline.org/en/statistics> (last visited November 27, 2023).

⁴⁴ Polaris, *Analysis of 2021 Data from the National Human Trafficking Hotline*. Available at <https://polarisproject.org/wp-content/uploads/2020/07/Polaris-Analysis-of-2021-Data-from-the-National-Human-Trafficking-Hotline.pdf> (last visited November 27, 2023).

⁴⁵ Chin, J. & Takahashi, L. (2022). *Sex for Sale: Illicit Massage Parlors*. 3rd Edition. Routledge. ISBN: 9781003228639

⁴⁶ de Vries, I. (2020). Crime, place, and networks in the age of the internet: The case of online-promoted illicit massage businesses. Northeastern University. Available at <https://repository.library.northeastern.edu/files/neu:m046sd37z/fulltext.pdf> (last visited November 27, 2023).

⁴⁷ Polaris, *Human Trafficking in Illicit Massage Businesses* (2018). Available at <https://massagetherapy.nv.gov/uploadedFiles/massagetherapy.nv.gov/content/Resources/FullReportHumanTraffickinginIllicitMassageBusinesses.pdf> (last visited November 27, 2023).

⁴⁸ Det. Sgt. Wade Williams, Collier County Sheriff's Office, *Illicit Massage Businesses Presentation*. On file with the Healthcare Regulation Subcommittee.

⁴⁹ *Id.*

⁵⁰ *Supra*, note 47.

The majority of people trafficked through IMBs are women of Chinese or South Korean origin who have recently arrived in the US. They are typically 35-55 years of age, have no more than a high school level education, and speak little to no English.⁵¹

Law Enforcement Response to IMBs

Traditional police techniques for controlling crime have proven to be largely ineffective in reducing the presence of IMBs and their impact on victims of human trafficking. Traditional tactics such as sting operations, undercover work, and reactive investigations are still relied on heavily for addressing human trafficking and IMBs; however, these approaches have been shown to be ineffective in holding traffickers accountable and decreasing the risk of victimization.⁵²

Police response to human trafficking has been criticized for not being victim-oriented; few victims of human trafficking are identified by police as they often do not self-identify as victims, fear retribution from their exploiter, and mistrust the authorities.⁵³ Obtaining a conviction for human trafficking related crimes relies heavily on victim testimony which has proven difficult to obtain in IMB-related cases.⁵⁴ As a result very few police actions have resulted in prosecutions for human trafficking, thus signaling very little accountability for traffickers.⁵⁵

Under certain circumstances, IMBs may also be identified as a public nuisance and enjoined.⁵⁶ When such a nuisance exists, the Attorney General, state attorney, city attorney, county attorney, or any citizen of the county where the nuisance exists may bring a nuisance abatement action in the name of the state to enjoin the nuisance, the person maintaining it, and the owner or agent of the premises where the nuisance is located.⁵⁷ Such actions may result in a permanent injunction requiring the establishment to cease operation or abate any such nuisance.

Massage establishments may be declared a public nuisance under current law if they are operating outside of legal hours, serving as a person's principal domicile,⁵⁸ or are unable to provide the required identification and licensure documents upon the request of a law enforcement officer or DOH investigator.⁵⁹

Regulatory Response to IMBs

Florida has implemented several regulatory measures in an effort to obstruct the operation of IMBs without interfering with legitimate massage establishments. These regulations include:

- Massage establishments are not authorized to operate between 12am and 5am;⁶⁰
- Sexual misconduct⁶¹ is explicitly prohibited in massage establishments;⁶²
- Advertisements must include the license number of the individual massage therapist or establishment being advertised;⁶³
- Persons employed in a massage establishment must be able to produce government identification upon request by a DOH or law enforcement investigator;⁶⁴ and

⁵¹ *Supra*, note 47.

⁵² Vries, I. de, & Farrell, A. (2022). *Explaining the Use of Traditional Law Enforcement Responses to Human Trafficking Concerns in Illicit Massage Businesses*. *Justice Quarterly*, 1-26. doi:10.1080/07418825.2022.2051587

⁵³ Farrell, A., et al., (2019). *Failing victims? Challenges of the police response to human trafficking*. *Criminology & Public Policy*, 18: 649–673. Available at <https://onlinelibrary.wiley.com/doi/epdf/10.1111/1745-9133.12456> (last visited November 27, 2023).

⁵⁴ *Supra*, note 52.

⁵⁵ *Supra*, note 53.

⁵⁶ S. 823.05, F.S.

⁵⁷ S. 60.05, F.S.

⁵⁸ See, s. 480.0475, F.S.

⁵⁹ See, s. 480.0535, F.S.

⁶⁰ S. 480.0475, F.S.

⁶¹ Rule 64B7-26.010, F.A.C. specifies that the statutory prohibition of sexual misconduct extends to sexual activity occurring within any massage establishment.

⁶² S. 480.0485, F.S.

⁶³ S. 480.0465, F.S.

⁶⁴ S. 480.0535, F.S.

- Massage establishments are required to have a set procedure for reporting suspected human trafficking and conspicuously post a sign with the relevant procedures.⁶⁵

Discipline of Massage Therapists and Establishments

The Board has disciplinary authority over massage therapists and massage establishment licenses.⁶⁶ The purpose of imposing fines and penalties is to protect the public by assuring compliance with an agency's rules.⁶⁷ DOH is required to inspect licensed massage establishments on an annual or more frequent basis. Such inspections include, but are not limited to, assessing whether the establishment is in compliance with the requirements for facilities operation, personnel, safety, sanitary requirements, and existing insurance coverage.⁶⁸

Section 456.073, F.S., outlines the process for disciplinary proceedings for professionals licensed under DOH, including massage therapists. Disciplinary proceedings begin when a complaint is filed. DOH investigates complaints for legal sufficiency,⁶⁹ and if DOH determines a complaint to be legally sufficient all investigative findings are submitted to a panel to be assessed for probable cause.⁷⁰ Upon making a finding of probable cause, DOH is required to file a formal complaint, and may choose to prosecute the complaint pursuant to Chapter 120, F.S.⁷¹

The case may be referred to the Board for a hearing, or to the Division of Administrative Hearings to be heard before an administrative law judge if there are any disputed issues of material fact.⁷² A judge may submit a recommended order,⁷³ but the final determination of whether or not a licensee has violated the laws and rules regulating the profession is a conclusion to be determined by the Board.⁷⁴ The Board considers the findings of fact and conclusions of law contained in the formal complaint, reviews the investigative materials, and determines the appropriate penalty for the violation.

The Board has established disciplinary guidelines specifying the range of penalties based upon the severity and repetition of specific offenses.⁷⁵ The board is provided some discretion to deviate from disciplinary guidelines based on mitigating or aggravating circumstances.⁷⁶ Dependent upon the severity of the massage therapist's or establishment's infraction, the Board may impose any of the following pursuant to the Board's disciplinary guidelines: letter of concern, reprimand, fines, license with conditions, probation, suspension, revocation and/or fines.⁷⁷

During fiscal year 2022-23, 229 Administrative Complaints were filed related to massage therapists and massage establishments.⁷⁸ Of those complaints, 70 were related to sexual misconduct.⁷⁹

⁶⁵ S. 480.043, F.S.

⁶⁶ S. 480.046, F.S.

⁶⁷ S. 120.695, F.S.

⁶⁸ Rule 64B7-26.004, F.A.C.

⁶⁹ S. 456.073(1), F.S.; a complaint is legally sufficient if it contains ultimate facts that show that a violation of Ch. 456, F.S., of any of the practice acts relating to the professions regulated by the department, or of any rule adopted by the department or a regulatory board in the department has occurred.

⁷⁰ S. 456.073(4), F.S.

⁷¹ *Id.*

⁷² S. 456.073(5), F.S.

⁷³ See, s. 120.52, F.S.

⁷⁴ *Supra*, note 72

⁷⁵ See s. 456.079, F.S.

⁷⁶ *Id.*

⁷⁷ Rule 64B7-30, F.A.C

⁷⁸ Department of Health, Agency Bill Analysis for House Bill 197 (2024), p. 3. On file with the Healthcare Regulation Subcommittee.

⁷⁹ *Id.*

Emergency/Summary Suspensions

Under current law, DOH is authorized to issue an emergency suspension, restriction, or limitation of a license if the following criteria are met:⁸⁰

- The procedure provides at least the same procedural protection as is given by other statutes, the State Constitution, or the United States Constitution;
- The agency takes only that action necessary to protect the public interest under the emergency procedure; and
- The agency states in writing at the time of, or prior to, its specific action the specific facts and reasons for finding an *immediate danger to the public health, safety, or welfare* and its reasons for concluding that the procedure used is fair under the circumstances.

The State Surgeon General, or their designee, is required to conduct any proceedings for the purposes of a summary (emergency) suspension or restriction of a health care practitioner or facility license.⁸¹

DOH is required to immediately suspend the license of any health care practitioner who has plead guilty or nolo contendere to or has been convicted of the following offenses:

- Felony Medicare or Medicaid fraud under ch. 409, F.S.;
- Felony fraud under ch. 817, F.S.;
- Felony drug offenses under ch. 893, F.S., and equivalent charges under federal law;
- Misdemeanors or felonies under federal law relating to the Medicaid program;
- Felonies under s. 784.086, F.S., relating to reproductive battery; and
- Felonies under ch. 782, F.S., relating to homicide.

DOH also has the authority to immediately suspend the license of any health care practitioner who tests positive for any drug on any government or private-sector preemployment or employer-order confirmed drug test, provided that the health care practitioner does not have a lawful prescription for the drug.

Summary Suspension of Massage Therapist and Massage Establishment Licenses

DOH is required to suspend the license of a massage therapist or establishment when a therapist, or a person with any ownership interest in a massage establishment has pled guilty or nolo contendere to, or has been convicted of any offense related to prostitution or related acts under s. 796.07, F.S., or a felony under:⁸²

- Section 787.01, F.S., relating to kidnapping;
- Section 787.02, F.S., relating to false imprisonment;
- Section 787.025, F.S., relating to luring or enticing a child;
- Section 787.06, F.S., relating to human trafficking;
- Section 787.07, F.S., relating to human smuggling;
- Section 794.011, F.S., relating to sexual battery;
- Section 794.08, F.S., relating to female genital mutilation;
- Former section 796.03, F.S., relating to procuring a person under the age of 18 for prostitution;
- Former section 796.04, F.S., relating to forcing, compelling, or coercing another to become a prostitute;
- Section 796.05, F.S., relating to deriving support from the proceeds of prostitution;
- Section 796.07(4)(a)3, F.S., relating to a felony of the third degree for a third or subsequent violation of section 796.07, F.S., relating to prohibiting prostitution and related acts;

⁸⁰ S. 120.60(6), F.S.

⁸¹ S. 456.073(8), F.S.

⁸² S. 456.074(4), F.S.

- Section 800.04, F.S., relating to lewd or lascivious offenses committed upon or in the presence of persons less than 16 years of age;
- Section 825.1025(2)(b), F.S., relating to lewd or lascivious offenses committed upon or in the presence of an elderly or disabled person;
- Section 827.071, F.S., relating to sexual performance by a child;
- Section 847.0133, F.S., relating to the protection of minors;
- Section 847.0135, F.S., relating to computer pornography;
- Section 847.0138, F.S., relating to the transmission of material harmful to minors to a minor by electronic device or equipment; and
- Section 847.0145, F.S., relating to the selling or buying of minors.

Under current law, DOH cannot issue a summary suspension absent a conviction or the entry of a guilty or nolo contendere plea by the licensee.

Between January 1, 2020, and December 31, 2022:⁸³

- 13 massage establishment licenses were revoked related to sexual misconduct
- 23 massage establishment licenses were revoked for aiding and abetting unlicensed massage therapists

Massage establishments are also required to maintain a designated establishment manager (DEM) on file with DOH as a condition of their licensure. DOH is authorized to issue a summary suspension to an establishment who fails to identify a new DEM within 10 days of terminating the previous DEM.⁸⁴

Under current law, DOH is required to annually report to the Legislature the total number of administrative complaints and description of disciplinary actions taken against health care professionals and establishments licensed and regulated by DOH.⁸⁵ Such figures are required to be categorized by profession, but not by the cause for the complaint or disciplinary action, such as sexual misconduct or failure to maintain a DEM.

Effect of the Bill

Investigations and Enforcement

PCS for HB 197 significantly expands DOH's authority to issue emergency orders suspending the license of a massage therapist and massage establishment.

The bill requires DOH to issue an emergency order suspending the license of the offending massage therapist *and* the affiliated massage establishment upon qualifying circumstances. Under current law DOH has the discretion to suspend the license of the massage therapist *or* establishment dependent on the facts of a specific case.

The bill also expands the type of events which constitute cause for the emergency suspension of a license. The bill requires DOH to issue an emergency suspension upon the arrest of *any* massage establishment employee for committing or attempting, soliciting, or conspiring to commit an offense listed in s. 465.074, F.S. This expands the requirements of current law which require an emergency suspension only *after* a massage therapist or individuals involved in the management or ownership of the establishment has been convicted or found guilty of a qualifying offense.

⁸³ *Supra*, note 78.

⁸⁴ S. 480.043(12), F.S.

⁸⁵ S. 456.026, F.S. See also, Department of Health, Division of Medical Quality Assurance Annual Report and Long-Range Plan (2023). Available at <https://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/MQAAnnualReport2022-2023.pdf> (last visited December 4, 2023).

The bill requires DOH to issue an emergency order suspending the license of any licensee upon a finding that probable cause exists to believe that the licensee has committed sexual misconduct⁸⁶ and that such violation constitutes an immediate danger to the public.

The bill requires DOH investigators to request valid government identification from all employees in the establishment at the time of inspection. If any employee of a massage establishment is unable to provide a valid form of government identification, the bill requires DOH to notify a federal immigration office of such.

The bill also expands DOH's reporting requirements regarding massage therapists and establishments. Under current law, the number of complaints, investigations, and disciplinary actions taken are required to be reported for all professions regulated by DOH, but the cause of action is not required to be reported. Under the bill, DOH must separately categorize complaints, investigations, and disciplinary actions against massage therapists and establishments by the specific statutory violations being alleged.

The bill expands the circumstances under which a massage establishment may be declared a public nuisance; under the bill, massage establishments violating regulations pertaining to sexual activity in a massage establishment and the maintenance of certain records may be declared a nuisance and abated or enjoined.

Requirements of Massage Therapists and Establishments

The bill expressly prohibits any sexual activity in a massage establishment, as opposed to specifically sexual *misconduct*, and prohibits the use of an establishment to arrange for sexual activity in another location. The bill broadly defines sexual activity to include any direct or indirect contact by any employee or person, or between any employees or persons, with the intent to abuse, humiliate, harass, degrade, or arouse, or gratify the sexual desire of, any employee or person, or which is likely to cause such abuse, humiliation, harassment, degradation, or arousal, or sexual gratification.

Under the bill, massage establishments are generally required to:

- Cover no more than 50 percent of any outside windows into the reception area;
- Ensure that outside windows into the reception area allow for at least 35 percent light penetration;
- Post signage outside of the establishment including the establishment's name, license number, and telephone number as provided to DOH;
- Maintain specified employee records in English or Spanish;
- Conspicuously display 2-inch by 2-inch photos of all employees with licensure information; and
- Maintain complete records of each service provided, with the full name, address, and telephone number of the patient for at least one year after the provision of the service.

The bill provides exemptions to certain requirements for massage establishments within public lodging establishments as defined in s. 509.013(4), F.S., and facilities wherein a health care practitioner licensed under chs. 457, 458, 459, or 460, F.S.,⁸⁷ employs a massage therapist. The bill also permits health care practitioners licensed under these sections to serve as the designated establishment manager of a massage establishment.

The bill requires employees of a massage establishment are required to be fully clothed while in the establishment. Massage establishments within a public lodging establishment as defined in s.

⁸⁶ See s. 456.063(1), F.S. Sexual misconduct in the practice of a health care profession means violation of the professional relationship through which the health care practitioner uses such relationship to engage or attempt to engage the patient or client, or an immediate family member, guardian, or representative of the patient or client in, or to induce or attempt to induce such person to engage in, verbal or physical sexual activity outside the scope of the professional practice of such health care profession.

⁸⁷ Health care practitioners licensed under these sections include acupuncturists, allopathic physicians, osteopathic physicians, and chiropractic physicians.

509.013(4), F.S., and chartered with the American Association for Nude Recreation⁸⁸ as a clothing-optional establishment are exempt from this requirement.

The bill requires all advertisements for a massage therapist or establishment to include the physical address and telephone number of the establishment as provided to DOH. Massage establishments with more than five locations are exempt from this requirement. Massage therapists, establishments, and employees of massage establishments are prohibited from advertising in any medium or website that expressly or implicitly advertises prostitution, escort, or other sexual services. The bill deletes the statutory clause allowing new massage establishments with pending licensure to advertise using the license number of a massage therapist.

The bill changes quorum of Board of Massage Therapy from four members to a majority of members of the Board.

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

B. SECTION DIRECTORY:

- Section 1:** Amends s. 456.026, F.S., relating to annual report concerning finances, administrative complaints, disciplinary actions, and recommendations.
- Section 2:** Amends s. 456.074, F.S., relating to certain health care practitioners; immediate suspension of license.
- Section 3:** Amends s. 480.033, F.S., relating to definitions.
- Section 4:** Amends s. 480.035, F.S., relating to the Board of Massage Therapy.
- Section 5:** Amends s. 480.043, F.S., relating to massage establishments; requisites; licensure; inspection; human trafficking awareness training and policies.
- Section 6:** Amends s. 480.0465, F.S., relating to advertisement.
- Section 7:** Amends s. 480.0475, F.S., relating to massage establishments; prohibited practices.
- Section 8:** Amends s. 480.0535, F.S., relating to documents required while working in a massage establishment.
- Section 9:** Amends s. 823.05, F.S., relating to places and groups engaged in certain activities declared a nuisance; abatement and enjoinder.
- Section 10:** 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:

According to DOH, it will experience a significant increase in workload associated with additional complaints, investigations, and prosecution cases resulting from the provisions of the bill. DOH expects 8 additional full-time equivalent positions will be required to implement the bill.

DOH estimates the total annual cost to be \$1,034,032 in the following categories:⁸⁹

- Salary - \$846,102/Recurring
- Salary Rate – 593,954 Units of Rate
- Expense - \$71,000/Recurring + \$53,272/Non-Recurring
- Human Resources - \$2,878/Recurring

⁸⁸ See the American Association for Nude Recreation – Florida Region website for more information. Available at <https://aanr-florida.org/> (last visited November 28, 2023).

⁸⁹ Department of Health, Agency Bill Analysis for House Bill 197 (2024), p. 11. On file with the Healthcare Regulation Subcommittee.

- Contracted Services - \$5,100/Recurring \$55,680/Non-Recurring

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Massage therapy establishments may experience a negative fiscal impact as a result of the requirements of the bill.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Massage Therapy has the rulemaking authority necessary to adopt the rules pursuant to this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
 2 An act relating to health care practitioners and
 3 massage therapy; amending s. 456.026, F.S.; requiring
 4 the Department of Health to report specific data;
 5 amending s. 456.074, F.S.; authorizing the Department
 6 of Health to immediately suspend the license of
 7 certain health care practitioners and massage
 8 establishments in certain circumstances; amending s.
 9 480.033, F.S.; revising and providing definitions;
 10 amending s. 480.035, F.S.; revising quorum
 11 requirements for the Board of Massage Therapy;
 12 amending s. 480.043, F.S.; revising certain rules the
 13 board is required to adopt; revising the timeframe in
 14 which establishment owners must report specified
 15 information to the department; prohibiting sexual
 16 activity and certain devices in massage
 17 establishments; specifying prohibited conduct by
 18 establishment owners and employees; providing
 19 requirements for outside windows and signs in massage
 20 establishments; providing exceptions; providing
 21 employee dress code requirements; requiring
 22 establishments to maintain certain employment records
 23 in English or Spanish; requiring that specified
 24 information be recorded before an employee may provide
 25 services or treatment; requiring massage

26 establishments to conspicuously display a photo and
 27 specified information for each employee; requiring
 28 that such photos and information be displayed before
 29 an employee may provide services or treatment;
 30 providing for such requirements in massage
 31 establishments within public lodging establishments;
 32 requiring massage establishments to maintain customer
 33 and patient records for services and treatment
 34 provided in the massage establishment in English or
 35 Spanish; providing that medical records satisfy
 36 certain requirements; requiring massage establishments
 37 to maintain such records for a specified timeframe;
 38 requiring massage establishments to collect and record
 39 specified information; requiring massage
 40 establishments to confirm the identification of a
 41 customer or patient before providing services or
 42 treatment; amending s. 480.0465, F.S.; revising
 43 advertising requirements for massage therapists and
 44 massage establishments; amending s. 480.0475, F.S.;
 45 prohibiting establishments from sheltering or
 46 harboring, or being used as sleeping quarters for, any
 47 person; amending s. 480.0535, F.S.; requiring
 48 Department of Health investigators to request valid
 49 government identification from all employees while in
 50 a massage establishment; specifying additional

51 documents a person operating a massage establishment
 52 must immediately present, upon request, to department
 53 investigators and law enforcement officers; requiring
 54 the department to notify a federal immigration office
 55 if specified persons fail to provide valid government
 56 identification; amending s. 823.05, F.S.; conforming a
 57 cross-reference; providing an effective date.
 58

59 Be It Enacted by the Legislature of the State of Florida:
 60

61 Section 1. Section 456.026, Florida Statutes, is amended
 62 to read:

63 456.026 Annual report concerning finances, administrative
 64 complaints, disciplinary actions, and recommendations.—

65 (1) The department is directed to prepare and submit a
 66 report to the President of the Senate and the Speaker of the
 67 House of Representatives by November 1 of each year. In addition
 68 to finances and any other information the Legislature may
 69 require, the report shall include statistics and relevant
 70 information, profession by profession, detailing:

71 (a)~~(1)~~ The revenues, expenditures, and cash balances for
 72 the prior year, and a review of the adequacy of existing fees.

73 (b)~~(2)~~ The number of complaints received and investigated.

74 (c)~~(3)~~ The number of findings of probable cause made.

75 (d)~~(4)~~ The number of findings of no probable cause made.

76 ~~(e)(5)~~ The number of administrative complaints filed.

77 ~~(f)(6)~~ The disposition of all administrative complaints.

78 ~~(g)(7)~~ A description of disciplinary actions taken.

79 ~~(h)(8)~~ A description of any effort by the department to

80 reduce or otherwise close any investigation or disciplinary

81 proceeding not before the Division of Administrative Hearings

82 under chapter 120 or otherwise not completed within 1 year after

83 the initial filing of a complaint under this chapter.

84 ~~(i)(9)~~ The status of the development and implementation of

85 rules providing for disciplinary guidelines pursuant to s.

86 456.079.

87 ~~(j)(10)~~ Such recommendations for administrative and

88 statutory changes necessary to facilitate efficient and cost-

89 effective operation of the department and the various boards.

90 (2) The report shall separately categorize all complaints,

91 investigations, probable cause and disciplinary actions against

92 a massage therapist or massage establishment licensed under

93 chapter 480 related to a violation of section:

94 (a) 480.043(12);

95 (b) 480.043(13);

96 (c) 480.043(14) (a) - (f);

97 (d) 480.0465;

98 (e) 480.0475;

99 (f) 480.0485; and

100 (g) 480.0535.

101 Section 2. Subsection (4) of section 456.074, Florida
 102 Statutes, is amended and a new subsection (7) is added to that
 103 section to read:

104 456.074 Certain health care practitioners; immediate
 105 suspension of license.—

106 (4) The department shall issue an emergency order
 107 suspending the license of a massage therapist and ~~or~~
 108 establishment as those terms are defined in chapter 480 upon
 109 receipt of information that the massage therapist; ~~the~~
 110 designated establishment manager as defined in chapter 480; an
 111 employee of the establishment; a person with an ownership
 112 interest in the establishment; ~~or,~~ or, for a corporation that has
 113 more than \$250,000 of business assets in this state, the owner,
 114 officer, or individual directly involved in the management of
 115 the establishment has been arrested for committing or
 116 attempting, soliciting, or conspiring to commit, or convicted or
 117 found guilty of, or has entered a plea of guilty or nolo
 118 contendere to, regardless of adjudication, a violation of s.
 119 ~~796.07(2)(a) which is reclassified under s. 796.07(7)~~ or a
 120 felony offense under any of the following provisions of state
 121 law or a similar provision in another jurisdiction:

- 122 (a) Section 787.01, relating to kidnapping.
- 123 (b) Section 787.02, relating to false imprisonment.
- 124 (c) Section 787.025, relating to luring or enticing a
 125 child.

- 126 (d) Section 787.06, relating to human trafficking.
- 127 (e) Section 787.07, relating to human smuggling.
- 128 (f) Section 794.011, relating to sexual battery.
- 129 (g) Section 794.08, relating to female genital mutilation.
- 130 (h) Former s. 796.03, relating to procuring a person under
- 131 the age of 18 for prostitution.
- 132 (i) Former s. 796.035, relating to the selling or buying
- 133 of minors into prostitution.
- 134 (j) Section 796.04, relating to forcing, compelling, or
- 135 coercing another to become a prostitute.
- 136 (k) Section 796.05, relating to deriving support from the
- 137 proceeds of prostitution.
- 138 (l) Section 796.07(4)(a)3., relating to a felony of the
- 139 third degree for a third or subsequent violation of s. 796.07,
- 140 relating to prohibiting prostitution and related acts.
- 141 (m) Section 800.04, relating to lewd or lascivious
- 142 offenses committed upon or in the presence of persons less than
- 143 16 years of age.
- 144 (n) Section 825.1025(2)(b), relating to lewd or lascivious
- 145 offenses committed upon or in the presence of an elderly or
- 146 disabled person.
- 147 (o) Section 827.071, relating to sexual performance by a
- 148 child.
- 149 (p) Section 847.0133, relating to the protection of
- 150 minors.

151 (q) Section 847.0135, relating to computer pornography.

152 (r) Section 847.0138, relating to the transmission of
 153 material harmful to minors to a minor by electronic device or
 154 equipment.

155 (s) Section 847.0145, relating to the selling or buying of
 156 minors.

157 (7) The department shall issue an emergency order
 158 suspending the license of any licensee upon a finding of the
 159 State Surgeon General that probable cause exists to believe that
 160 the licensee has committed sexual misconduct as defined and
 161 prohibited in s. 456.063(1), or the applicable practice act, and
 162 that such violation constitutes an immediate danger to the
 163 public.

164 Section 3. Subsections (1) through (6) of section 480.033,
 165 Florida Statutes, are renumbered as subsections (2) through (7),
 166 respectively, subsections (7) through (12), are renumbered as
 167 subsections (9) through (14), respectively, present subsection
 168 (6) is amended, and new subsections (1), (8), and (15) are added
 169 to that section, to read:

170 480.033 Definitions.—As used in this act:

171 (1) "Advertising medium" means any newspaper; airwave or
 172 computer transmission; telephone directory listing, other than
 173 an in-column listing consisting only of a name, physical
 174 address, and telephone number; business card; handbill; flyer;
 175 sign, other than a building directory listing all building

176 tenants and their room or suite numbers; or any other form of
 177 written or electronic advertisement.

178 (7)-(6) "Designated establishment manager" means a massage
 179 therapist who holds a clear and active license without
 180 restriction; a health care practitioner licensed under chapter
 181 457; or a physician licensed under chapter 458, chapter 459, or
 182 chapter 460 who is responsible for the operation of a massage
 183 establishment in accordance with the provisions of this chapter,
 184 and who is designated the manager by the rules or practices at
 185 the establishment.

186 (8) "Employee" means any person, including, but not
 187 limited to, independent contractors or lessees of a massage
 188 establishment, whose duties involve any aspect or capacity of
 189 the massage establishment, including, but not limited to,
 190 preparing meals and cleaning regardless of whether such person
 191 is compensated for the performance of such duties. The term does
 192 not include a person who is exclusively engaged in the repair or
 193 maintenance of the massage establishment or the delivery of
 194 goods to the establishment.

195 (15) "Sexual activity" means any direct or indirect
 196 contact by any employee or person, or between any employees or
 197 persons, with the intent to abuse, humiliate, harass, degrade,
 198 or arouse, or gratify the sexual desire of, any employee or
 199 person, or which is likely to cause such abuse, humiliation,
 200 harassment, degradation, or arousal, or sexual gratification:

- 201 (a) With or without the consent of the employee or person.
- 202 (b) With or without verbal or nonverbal communication that
- 203 the sexual activity is undesired.
- 204 (c) With or without the use of any device or object.
- 205 (d) With or without the occurrence of penetration, orgasm,
- 206 or ejaculation.
- 207 (e) Including, but not limited to, intentional contact
- 208 with the genitalia, groin, femoral triangle, anus, buttocks,
- 209 gluteal cleft, breast or nipples, mouth, or tongue.
- 210 (f) Including, but not limited to, the intentional removal
- 211 of any drape without specific written informed consent of the
- 212 patient.

213 Section 4. Subsection (5) of section 480.035, Florida
 214 Statutes, is amended to read:

215 480.035 Board of Massage Therapy.—

216 (5) The board shall hold such meetings during the year as
 217 it may determine to be necessary, one of which shall be the
 218 annual meeting. The chair of the board shall have the authority
 219 to call other meetings at her or his discretion. A quorum of the
 220 board shall consist of not less than a majority of the current
 221 membership of the board ~~four members~~.

222 Section 5. Subsection (14) of section 480.043, Florida
 223 Statutes, is renumbered as subsection (15), subsection (3) and
 224 present subsection (14) are amended, and a new subsection (14)
 225 is added to that section, to read:

226 480.043 Massage establishments; requisites; licensure;
 227 inspection; human trafficking awareness training and policies.-

228 (3) The board shall adopt rules governing the operation of
 229 massage establishments and their facilities, employees
 230 ~~personnel~~, safety and sanitary requirements, financial
 231 responsibility, insurance coverage, and the license application
 232 and granting process.

233 (14) In order to provide the department and law
 234 enforcement agencies the means to more effectively identify
 235 persons engaging in human trafficking at massage establishments,
 236 the following apply:

237 (a) Sexual activity in a massage establishment is
 238 prohibited. An establishment owner or employee may not engage in
 239 or allow any person to engage in sexual activity in the
 240 establishment or use the establishment to make arrangements to
 241 engage in sexual activity in another location. Used or unused
 242 condoms are prohibited in a massage establishment.

243 (b) If there is an outside window or windows into the
 244 massage establishment's reception area, the outside window or
 245 windows must allow for at least 35 percent light penetration and
 246 no more than 50 percent of the outside window or windows may be
 247 obstructed with signage, blinds, curtains, or other
 248 obstructions, allowing the public to see the establishment's
 249 reception area. A sign must be posted on the front window of the
 250 establishment that includes the name and license number of the

251 message establishment and the telephone number that has been
 252 provided to the department as part of licensure of the
 253 establishment. This paragraph does not apply to:

254 1. A message establishment within a public lodging
 255 establishment as defined in s. 509.013(4).

256 2. A message establishment located within a county or
 257 municipality that has an ordinance that prescribes requirements
 258 related to business window light penetration or signage
 259 limitations if compliance with this paragraph would result in
 260 noncompliance with such ordinance.

261 (c) All employees within the message establishment must be
 262 fully clothed and such clothing must be fully opaque and made of
 263 nontransparent material that does not expose the employee's
 264 genitalia. This requirement does not apply to an employee,
 265 excluding a massage therapist, of a public lodging
 266 establishment, as defined in s. 509.013(4), that is licensed as
 267 a clothing-optional establishment and chartered with the
 268 American Association for Nude Recreation.

269 (d) A message establishment must maintain a complete set
 270 of legible records in English or Spanish, which must include
 271 each employee's start date of employment, full legal name, date
 272 of birth, home address, telephone number, and employment
 273 position and a copy of the employee's government identification
 274 required under s. 480.0535. All information required under this
 275 paragraph must be recorded before the employee may provide any

276 service or treatment to a client or patient.

277 (e) A massage establishment must conspicuously display a 2
 278 inch by 2 inch photo for each employee, which, for massage
 279 therapists, must be attached to the massage therapist's license.
 280 Such display must also include the employee's full legal name
 281 and employment position. All information required under this
 282 paragraph must be displayed before the employee may provide any
 283 service or treatment to a client or patient. A massage
 284 establishment within a public lodging establishment as defined
 285 in s. 509.013(4) may satisfy this requirement by displaying the
 286 photos and required information in an employee break room or
 287 other room that is used by employees, but is not used by clients
 288 or patients.

289 (f) A massage establishment must maintain a complete set
 290 of legible records in English or Spanish, which must include the
 291 date, time, and type of service or treatment provided; the full
 292 legal name of the employee who provided the service or
 293 treatment; and the full legal name, home address, and telephone
 294 number of the client or patient. Medical records may satisfy
 295 this requirement if the records include the specified
 296 information. A copy of the client's or patient's photo
 297 identification may be used to provide the full legal name and
 298 home address of the client or patient. Records required under
 299 this paragraph must be maintained for at least 1 year after a
 300 service or treatment is provided. All information required under

301 this paragraph must be collected and recorded before any service
 302 or treatment is provided to a client or patient. The
 303 establishment must confirm the identification of the client or
 304 patient before any service or treatment is provided to the
 305 client or patient.

306 ~~(15)-(14)~~ Except for the requirements of subsection (13),
 307 this section does not apply to a practitioner ~~physician~~ licensed
 308 under chapter 457 or a physician licensed under, chapter 458,
 309 chapter 459, or chapter 460 who employs a licensed massage
 310 therapist to perform massage therapy on the practitioner's or
 311 physician's patients at his or her ~~the physician's~~ place of
 312 practice. This subsection does not restrict investigations by
 313 the department for violations of chapter 456 or this chapter.

314 Section 6. Section 480.0465, Florida Statutes, is amended
 315 to read:

316 480.0465 Advertisement; prohibitions.—

317 (1) Each massage therapist or massage establishment
 318 licensed under this act shall include the number of the license
 319 in any advertisement of massage therapy services appearing in
 320 any advertising medium, including, but not limited to, a
 321 newspaper, airwave transmission, telephone directory, Internet,
 322 or other advertising medium. Pending licensure of a new massage
 323 establishment under s. 480.043(7), the license number of a
 324 licensed massage therapist who is an owner or principal officer
 325 of the establishment may be used in lieu of the license number

326 ~~for the establishment.~~ The advertisement must also include the
 327 physical address of the massage establishment and the telephone
 328 number that has been provided to the department as part of the
 329 licensing of the establishment. However, the inclusion of the
 330 physical address and telephone number is not required for an
 331 advertisement by a massage establishment whose establishment
 332 owner operates more than five locations in this state.

333 (2) A massage therapist, an establishment owner, an
 334 employee, or any third party directed by the establishment owner
 335 or employee, may not place, publish, or distribute, or cause to
 336 be placed, published, or distributed, any advertisement in any
 337 advertising medium which states prostitution services, escort
 338 services, or sexual services are available.

339 (3) A massage therapist, an establishment owner, an
 340 employee, or any third party directed by the massage therapist,
 341 establishment owner, or employee may not place, publish, or
 342 distribute, or cause to be placed, published, or distributed,
 343 any online advertisement on any website known for advertising
 344 prostitution services, escort services, or sexual services.

345 Section 7. Subsection (2) of section 480.0475, Florida
 346 Statutes, is amended to read:

347 480.0475 Massage establishments; prohibited practices.—

348 (2) A person operating a massage establishment may not use
 349 or permit the establishment to be used as a principal or
 350 temporary domicile, to shelter or harbor, or as sleeping or

351 napping quarters for any person unless the establishment is
 352 zoned for residential use under a local ordinance.

353 Section 8. Section 480.0535, Florida Statutes, is amended
 354 to read:

355 480.0535 Documents required while working in a massage
 356 establishment; penalties; reporting.—

357 (1) In order to provide the department and law enforcement
 358 agencies the means to more effectively identify, investigate,
 359 and arrest persons engaging in human trafficking, an employee ~~a~~
 360 ~~person employed by a massage establishment~~ and any person
 361 performing massage therapy in a massage establishment ~~therein~~
 362 must immediately present, upon the request of an investigator of
 363 the department or a law enforcement officer, valid government
 364 identification while in the establishment. An investigator of
 365 the department must request valid government identification from
 366 all employees while in the establishment. A valid government
 367 identification for the purposes of this section is:

368 (a) A valid, unexpired driver license issued by any state,
 369 territory, or district of the United States;

370 (b) A valid, unexpired identification card issued by any
 371 state, territory, or district of the United States;

372 (c) A valid, unexpired United States passport;

373 (d) A naturalization certificate issued by the United
 374 States Department of Homeland Security;

375 (e) A valid, unexpired alien registration receipt card

376 (green card); or
 377 (f) A valid, unexpired employment authorization card
 378 issued by the United States Department of Homeland Security.
 379 (2) A person operating a massage establishment must:
 380 (a) Immediately present, upon the request of an
 381 investigator of the department or a law enforcement officer:
 382 1. Valid government identification while in the
 383 establishment.
 384 2. A copy of the documentation specified in paragraph
 385 (1)(a) for each employee and any person performing massage
 386 therapy in the establishment.
 387 3. A copy of the documents required under s.
 388 480.043(14)(d) and (f).
 389 (b) Ensure that each employee and any person performing
 390 massage therapy in the massage establishment is able to
 391 immediately present, upon the request of an investigator of the
 392 department or a law enforcement officer, valid government
 393 identification while in the establishment.
 394 (3) A person who violates any provision of this section
 395 commits:
 396 (a) For a first violation, a misdemeanor of the second
 397 degree, punishable as provided in s. 775.082 or s. 775.083.
 398 (b) For a second violation, a misdemeanor of the first
 399 degree, punishable as provided in s. 775.082 or s. 775.083.
 400 (c) For a third or subsequent violation, a felony of the

401 third degree, punishable as provided in s. 775.082, s. 775.083,
 402 or s. 775.084.

403 (4) The department shall notify a federal immigration
 404 office if a person operating a massage establishment, an
 405 employee, or any person performing massage therapy in a massage
 406 establishment fails to provide valid government identification
 407 as required under this section.

408 Section 9. Subsection (3) of section 823.05, Florida
 409 Statutes, is amended to read:

410 823.05 Places and groups engaged in certain activities
 411 declared a nuisance; abatement and enjoinder.-

412 (3) A massage establishment as defined in s. 480.033 which
 413 operates in violation of s. 480.043(14)(a) or (f), s. 480.0475,
 414 or s. 480.0535(2) is declared a nuisance and may be abated or
 415 enjoined as provided in ss. 60.05 and 60.06.

416 Section 10. This act shall take effect July 1, 2024.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 227 Intravenous Vitamin Treatment

SPONSOR(S): Garcia

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		Osborne	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Intravenous Vitamin Therapy (IVT) is a relatively recent medical trend that involves administering a high dose mixture of vitamins, minerals, electrolytes, and other fluids directly into a patient's bloodstream. IVT differs from traditional applications of IV therapy in that it is frequently used among otherwise healthy individuals outside of conventional medical setting with goals ranging from achieving a general feeling of wellness to curing a hangover. IVT is not regulated by the U.S. Food and Drug Administration (FDA).

IVT is an elective treatment that does not require physician referral; as such, it may be provided without first obtaining a patient's complete medical history or recent bloodwork. IVT may pose a variety of risks depending on an individual's health status. IVT can especially dangerous for individuals with heart disease and kidney problems whose bodies are not capable processing the salts and fluids that are being rapidly added to the body. Some ingredients could cause an allergic reaction or interact with other medications that a patient is taking. There are additional risks associated with administering IVT without a reviewing a patient's current bloodwork; for example, sudden changes in electrolyte balances can cause fatal cardiac arrhythmias and other complications that must be responded to immediately.

HB 227 requires patients complete a self-screening risk assessment questionnaire prior to receiving IVT, and prohibits health care providers from administering IVT to patients for whom it would be unsafe based on their answers to the questionnaire.

The bill requires health care providers administering IVT to provide patients with information regarding potential side effects and risks of IVT, instructions on when to seek medical attention, and a visit summary. The bill requires health care providers to notify a patient's designated physician if IVT was administered, and to maintain a written plan for emergency care.

The bill directs the Board of Medicine, Board of Osteopathic Medicine, and the Board of Nursing, within the Department of Health (DOH), to adopt rules to implement the provisions of the bill.

The bill has an insignificant, negative fiscal impact on DOH which current resources are sufficient to absorb. The bill has no fiscal impact on local government.

HB 227 provides an effective date of July 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Intravenous Vitamin Treatment

Intravenous Vitamin Therapy (IVT) is a relatively recent medical trend that involves administering a high dose mixture of vitamins, minerals, electrolytes, and other fluids directly into a patient's bloodstream.¹ Traditionally, intravenous (IV) therapy is used in conventional medical settings for the management of fluids and electrolytes for patients who cannot swallow, are dehydrated, or have other conditions that require timely correction of fluid or electrolyte imbalance.² In these settings, there are clinical guidelines to direct the medical professional in the type of fluid, rate, and volume, at which the fluid should be administered based on the needs of the patient.³

IVT differs from traditional applications of IV therapy in that it is frequently used by otherwise healthy individuals, with unconventional goals such as achieving a general feeling of wellness, obtaining clearer skin, fighting a cold, or curing a hangover.⁴ There is very little evidence of the benefit of IVT for healthy individuals and it is not regulated by the U.S. Food and Drug Administration (FDA).⁵ Nonetheless, use of IVT by high-profile celebrities, such as Kendall Jenner and Chrissy Teigen, as a means of curing or mitigating the effects of high-stress events or late-night parties has contributed to an increase in IVT popularity among young adults.⁶

IVT may be administered in primary care or integrative medical centers, or found in stand-alone retail locations known as drip bars or medical spas and mobile units⁷ that administer IVT to patients in their own homes.⁸ IVT infusion products are not regulated or based on evidence-based practice guidelines. Retail venues administering IVT commonly advertise "menus" from which a patient can choose their treatment.⁹ IVT contents may include saline, amino acids, B-12, vitamin C, "anti-nausea medicines," and zinc, among other micronutrients, vitamins, and "medicinal treatments."¹⁰ Cost of treatment ranges widely from \$90¹¹ to over \$300¹² for treatments lasting between 45 and 90 minutes.

Under current law, IVT may be administered by any licensed health care professional who may administer intravenous therapies within their scope of practice and possesses the appropriate

¹ WebMD, *IV Vitamin Therapy: Does It Work?* Available at <https://www.webmd.com/ivitamins-and-supplements/iv-vitamin-therapy-does-it-work> (last visited November 13, 2023).

² Dayal, S. & Kolasa, K. (2021). *Consumer Intravenous Vitamin Therapy: Wellness Boost or Toxicity Threat?* Nutrition Today, 56:5. Available at

https://www.researchgate.net/publication/354838784_Consumer_Intravenous_Vitamin_Therapy_Wellness_Boost_or_Toxicity_Threat (last visited November 13, 2023).

³ See, American Academy of Pediatrics, *Clinical Practice Guideline: Maintenance Intravenous Fluids in Children*. Available at <https://publications.aap.org/pediatrics/article/142/6/e20183083/37529/Clinical-Practice-Guideline-Maintenance?autologincheck=redirected> (last visited November 13, 2023).

⁴ *Supra*, note 2.

⁵ AARP. *The Truth Behind Trendy IV Therapy*. Available at <https://www.aarp.org/health/drugs-supplements/info-2022/iv-vitamin-therapy.html> (last visited November 13, 2023).

⁶ Bobb, B. *Kendall Jenner's Health Scare Might Make You Think Twice About Getting Your Vitamins Intravenously*. Vogue Magazine. On file with the Florida House of Representative's Healthcare Regulation Subcommittee.

⁷ Jones Health Law, *Establishing a Mobile IV Therapy Clinic in Florida*. Available at <https://www.joneshealthlaw.com/establishing-a-mobile-iv-therapy-clinic-in-florida/> (last visited November 13, 2023).

⁸ *Id.*

⁹ *Supra*, note 2.

¹⁰ See Bounce Hydration, *Our IV Drip Menu*. Available at <https://www.bouncehydration.com/our-iv-drips> (last visited November 13, 2023). Restore Hyper Wellness, *IV Drip Therapy*. Available at <https://www.restore.com/services/iv-drip-therapy> (last visited November 13, 2023). Florida Mind Health Center, *IV Vitamin Therapy*. Available at <https://www.flmindhealth.com/iv-therapy/> (last visited November 13, 2023).

¹¹ The IV-Suite, *IV Pushes*. Available at <https://www.iv-suite.com/iv-pushes/> (last visited November 13, 2023).

¹² Mobile IV Medics, *Mobile IV Hydration Therapy in Florida*. Available at <https://mobileivmedics.com/service-areas/florida/> (last visited November 13, 2023).

certifications and training. This includes physicians,¹³ physician assistants,¹⁴ registered nurses and advanced practice registered nurses,¹⁵ anesthesiologist assistants under the direct supervision of an anesthesiologist,¹⁶ medical assistants under the direct supervision of a physician,¹⁷ and licensed practical nurses under the direction of a registered nurse.¹⁸ The licensure and regulation of these health care providers is overseen by their respective regulatory boards under the Department of Health (DOH).¹⁹

IVT is an elective treatment that does not require physician referral. Procedures vary widely between facilities; some suggest patients to consult with their physician prior to receiving treatment,²⁰ others require a telehealth consultation with their own “medical professionals” upon first visitation,²¹ and most require a medical questionnaire and liability waiver or consent form be completed prior to treatment.²² Some facilities require that patients over 65 years of age provide a recent basic metabolic panel lab²³ prior to receiving IVT.²⁴

IVT may pose a variety of risks depending on an individual’s health status. It is especially dangerous for individuals with heart disease and kidney problems whose bodies are not capable processing the salts and fluids that are being rapidly added to the body.²⁵ Some ingredients could cause an allergic reaction or interact with other medications that a patient is taking.²⁶ There are additional risks associated with administering IVT without reviewing a patient’s current bloodwork; for example, sudden changes in electrolyte balances can cause fatal cardiac arrhythmias other complications that must be responded to immediately.²⁷

Effect of the Bill

HB 227 creates s. 456.0302, F.S., to regulate intravenous vitamin treatments. The bill defines intravenous vitamin treatment (IVVT) as a procedure in which high concentrations of vitamins and minerals are administered directly into a person’s bloodstream, allowing rapid absorption of higher doses of the vitamins and minerals than if received through food or supplements. The requirements of the bill apply to health care providers licensed under chs. 458, 459,²⁸ and 464, F.S.²⁹

¹³ See, Chs. 458 and 459, F.S.

¹⁴ See, Chs. 458 and 459, F.S.

¹⁵ See, Ch. 464, F.S.

¹⁶ S. 458.3475(3), F.S.

¹⁷ Board of Medicine, *Final Order On Petition for Declaratory Statement*. Available at https://www.floridahealth.gov/licensing-and-regulation/declaratory_documents/medical/doh-09-0320.pdf (last visited November 13, 2023).

¹⁸ Rule 64B9-12.004, F.A.C.

¹⁹ See, Chs. 458 and 459, F.S., the Board of Medicine and Board of Osteopathic Medicine regulate allopathic and osteopathic physicians and the health care providers that practice under physician supervision. See also, Ch. 464, F.S., the Board of Nursing regulates registered nurses, advanced practice registered nurses, and the health care providers that practice under their supervision.

²⁰ Midtown Movement and Medicine, *IV Vitamin Therapy Provides Full Body Rejuvenation*. Available at <https://midtownmovementllh.com/our-services/iv-infusion-therapy/> (last visited November 13, 2023).

²¹ Restore Hyper Wellness, *FAQs: Learn More about IV Drip Therapy*. Available at <https://www.restore.com/services/iv-drip-therapy> (last visited November 13, 2023).

²² See Bounce Hydration, *Our IV Drip Menu*. Available at <https://www.bouncehydration.com/our-iv-drips> (last visited November 13, 2023). Restore Hyper Wellness, *IV Drip Therapy*. Available at <https://www.restore.com/services/iv-drip-therapy> (last visited November 13, 2023). Florida Mind Health Center, *IV Vitamin Therapy*. Available at <https://www.flmindhealth.com/iv-therapy/> (last visited November 13, 2023).

²³ A basic metabolic panel is a common blood test measuring the glucose, calcium, blood urea nitrogen, creatine, sodium, potassium, bicarbonate, and chloride in a person’s blood. See also, Cleveland Clinic, *Basic Metabolic Panel (BMP)*. Available at <https://my.clevelandclinic.org/health/diagnostics/22020-basic-metabolic-panel-bmp> (last visited November 13, 2023).

²⁴ *Supra*, note 21.

²⁵ *Supra*, note 5.

²⁶ *Id.*

²⁷ *Supra*, note 2.

²⁸ Chs. 458 and 459, F.S., regulate the licensure of allopathic and osteopathic physicians, and practitioners that operate under the supervision of physicians, including physician assistants, anesthesiologist assistants, and medical assistants.

²⁹ Ch. 464, F.S., regulates the licensure of registered nurses, advanced practice registered nurses, and practitioners that operate under the supervision of registered nurses including licensed practical nurses and certified nursing assistants.

The bill requires health care providers to obtain a complete self-screening assessment questionnaire from a patient prior to administering IVVT. Health care providers may not administer IVVT to patients for whom it would be unsafe based on the results of the questionnaire or otherwise.

The bill requires health care providers administering IVVT to provide patients with information regarding potential side effects and risks of IVVT, instructions on when to seek medical attention, and a visit summary. The bill requires health care providers notify a patient's designated physician if IVVT is administered.

HB 227 also requires that health care providers maintain a written plan for emergency care. The plan must include the following:

- The name and address of hospital closest to the location at which the intravenous vitamin treatment is being performed;
- Reasons for which an emergency transfer of a patient may be required; and
- Medical services to be used in the event of a health emergency.

The bill directs the regulatory boards responsible for the licensure and regulation of the specified health care providers,³⁰ the Board of Nursing, Board of Medicine, and Board of Osteopathic Medicine, to develop rules implementing provisions of the bill. This includes the adoption of a self-screening risk assessment questionnaire, information that must be provided to patients prior to receiving IVVT, notification to be provided to a patient's designated physician, procedures for safely administering IVVT, and protocols to follow in a health emergency. The Boards must also develop requirements for education and training requirements for health care providers authorized to administer IVVT, as well as, administrative and documentation requirements regarding the administration of IVVT.

Violation of the provisions of the bill constitute grounds for disciplinary action by DOH and the practitioner's respective regulatory board.

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

B. SECTION DIRECTORY:

Section 1: Provides a name for the act: "Stephanie Balais Act."

Section 2: Creates s. 456.0302, F.S., relating to administering intravenous vitamin treatment.

Section 3: 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:

The bill has an insignificant, negative fiscal impact on DOH which current resources are sufficient to absorb.³¹

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

³⁰ Those health care providers licensed under Chs. 458, 459, and 464, F.S., including allopathic and osteopathic physicians and the providers under physician supervision, and professional nurses and the providers acting under their supervision.

³¹ Department of Health, Agency Bill Analysis for House Bill 227 (2024), p. 5. On file with the Healthcare Regulation Subcommittee.

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Businesses whose model is based upon the administration of elective intravenous vitamin treatments will be required to adhere to safety regulations as prescribed in the bill and delegated to the regulatory boards. Such regulations may increase the cost of administering intravenous vitamin treatments and negatively impact the profit margins of these businesses.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
 2 An act relating to intravenous vitamin treatment;
 3 providing a short title; creating s. 456.0302, F.S.;
 4 providing definitions; providing requirements for
 5 persons administering intravenous vitamin treatment;
 6 requiring the Board of Nursing, the Board of Medicine,
 7 and the Board of Osteopathic Medicine to adopt rules
 8 establishing procedures to administer intravenous
 9 vitamin treatment and emergency protocols; providing
 10 penalties; providing an effective date.

11
 12 Be It Enacted by the Legislature of the State of Florida:

13
 14 Section 1. This act may be cited as the "Stephanie Balais
 15 Act."

16 Section 2. Section 456.0302, Florida Statutes, is created
 17 to read:

18 456.0302 Administering intravenous vitamin treatment.—

19 (1) As used in this section, the term:

20 (a) "Health care provider" means a person licensed under
 21 chapter 458, chapter 459, or chapter 464.

22 (b) "Intravenous vitamin treatment" means a procedure in
 23 which high concentrations of vitamins and minerals are
 24 administered directly into a person's bloodstream, allowing
 25 rapid absorption of higher doses of the vitamins and minerals

26 than if received through food or supplements.

27 (2) A health care provider administering intravenous
28 vitamin treatment shall:

29 (a) Obtain a complete self-screening risk assessment
30 questionnaire from a patient before administering intravenous
31 vitamin treatment. The health care provider must use a form
32 adopted by rule by the applicable board.

33 (b) Provide a patient with information related to
34 potential side effects and risks of intravenous vitamin
35 treatment and instructions on when to seek medical attention.

36 (c) Provide a patient with a visit summary.

37 (d) Notify a patient's designated physician that an
38 intravenous vitamin treatment was administered.

39 (e) Have a written plan for the provision of emergency
40 care. A copy of the emergency plan must be kept at the location
41 offering intravenous vitamin treatment. The plan must include
42 all of the following:

43 1. The name and address of the hospital closest to the
44 location at which the intravenous vitamin treatment is being
45 performed.

46 2. Reasons for which an emergency transfer of a patient
47 may be required.

48 3. Medical services to be used in the event of a health
49 emergency.

50 (3) A health care provider may not administer intravenous

51 vitamin treatment to a patient if the provider determines that
52 it is unsafe to administer such treatment based upon the results
53 of the self-screening risk assessment questionnaire or
54 otherwise.

55 (4) The respective boards shall adopt rules establishing
56 procedures to safely administer intravenous vitamin treatment
57 and establish protocols to follow in the event of a health
58 emergency, including, but not limited to, requirements for:

59 (a) Education and training requirements for health care
60 providers authorized to administer intravenous vitamin
61 treatment.

62 (b) Self-screening risk assessments.

63 (c) Information that a health care provider must provide
64 to a patient before administering intravenous vitamin treatment.

65 (d) Documentation regarding the process of administering
66 intravenous vitamin treatment.

67 (e) Notification that must be provided to a patient's
68 designated physician if intravenous vitamin treatment is
69 administered.

70 (f) Evaluation and review of the administration practices
71 used to administer intravenous vitamin treatment.

72 (5) Violation of this section constitutes grounds for
73 disciplinary action under this chapter and chapter 458, chapter
74 459, or chapter 464, as applicable.

75 Section 3. This act shall take effect July 1, 2024.

Amendment No. 1

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED (Y/N)
ADOPTED AS AMENDED (Y/N)
ADOPTED W/O OBJECTION (Y/N)
FAILED TO ADOPT (Y/N)
WITHDRAWN (Y/N)
OTHER

1 Committee/Subcommittee hearing bill: Healthcare Regulation
2 Subcommittee

3 Representative Garcia offered the following:

4
5 **Amendment (with title amendment)**
6 Between lines 74 and 75, insert:
7 (6) The requirements of this section do not apply to intravenous
8 vitamin treatments provided in facilities licensed under chapter
9 395.

10
11
12
13
14
15
16

T I T L E A M E N D M E N T

Remove line 10 and insert:
penalties; providing an exemption for certain licensed
facilities; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

SPONSOR(S): Bell

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee		DesRochers	McElroy
2) Health & Human Services Committee			

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.

HB 201 expands current law on emergency prescription refills to authorize a pharmacist to dispense a standard unit of dispensing or a 30-day supply of insulin and insulin-related supplies or equipment up to three 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, 4}

- 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.^{5, 6} As a result, the pancreas stops making insulin.⁷ Without insulin, glucose cannot get into the cells and blood glucose rises above normal.⁸ People with type 1 diabetes need to take insulin every day to stay alive.⁹ Type 1 diabetes typically occurs in children and young adults, although it can appear at any age.¹⁰ Having a parent or sibling with the disease may increase the chance of developing type 1 diabetes.¹¹

Symptoms of type 1 diabetes are serious and usually happen quickly, over a few days to weeks, and can include:¹²

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).

⁴ 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).

⁵ *Supra*, FN 1.

⁶ 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.

⁷ *Supra*, FN 1.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

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

Sometimes the first symptoms of type 1 diabetes are signs of a life-threatening condition called diabetic ketoacidosis (DKA).¹³ The condition develops when the body cannot produce enough insulin.¹⁴ Without enough insulin, the body begins to break down fat as fuel.¹⁵ This causes a buildup of acids in the bloodstream called ketones; if left untreated, the buildup can lead to DKA.¹⁶ Symptoms of DKA include:¹⁷

- 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.¹⁸ Different types of insulin start to work at different speeds, and the effects of each last a different length of time.¹⁹ Insulin can be taken in several ways; common options include a needle and syringe, insulin pen, or insulin pump.²⁰

Some people who have trouble 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.²¹ Pramlintide, given by injection, helps keep blood glucose levels from going too high after eating.²² Few people with type 1 diabetes take pramlintide, however. Another diabetes medicine, metformin, may help decrease the amount of insulin necessary.²³

Type 2 Diabetes

Type 2 diabetes, the most common type of diabetes, occurs when blood glucose is too high.²⁴ In type 2 diabetes, the body does not make enough insulin or does not use insulin well enough.²⁵ Too much glucose then stays in the blood, and not enough reaches the cells.²⁶

Type 2 diabetes can develop at any age, even during childhood.²⁷ However, type 2 diabetes occurs most often in middle-aged and older people.²⁸ 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.²⁹ Diabetes

¹³ *Id.*

¹⁴ *Supra*, FN 3.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Supra*, FN 1.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Supra*, FN 4

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

is more common in people who are African American, Hispanic/Latino, American Indian, Asian American, or Pacific Islander.³⁰

Physical inactivity and certain health problems such as high blood pressure affects a person's chances of developing type 2 diabetes.³¹ A person is also more likely to develop type 2 diabetes if they have prediabetes or had gestational diabetes when they were pregnant.³² Symptoms of type 2 diabetes include:³³

- 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.³⁴ Many people have no symptoms.³⁵ Some people do not find out they have the disease until they have diabetes-related health problems.³⁶

Type 2 diabetes is caused by several factors, including:³⁷

- 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.³⁸ Diabetes is also linked to other health problems such as sleep apnea, depression, some types of cancer, and dementia.³⁹

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

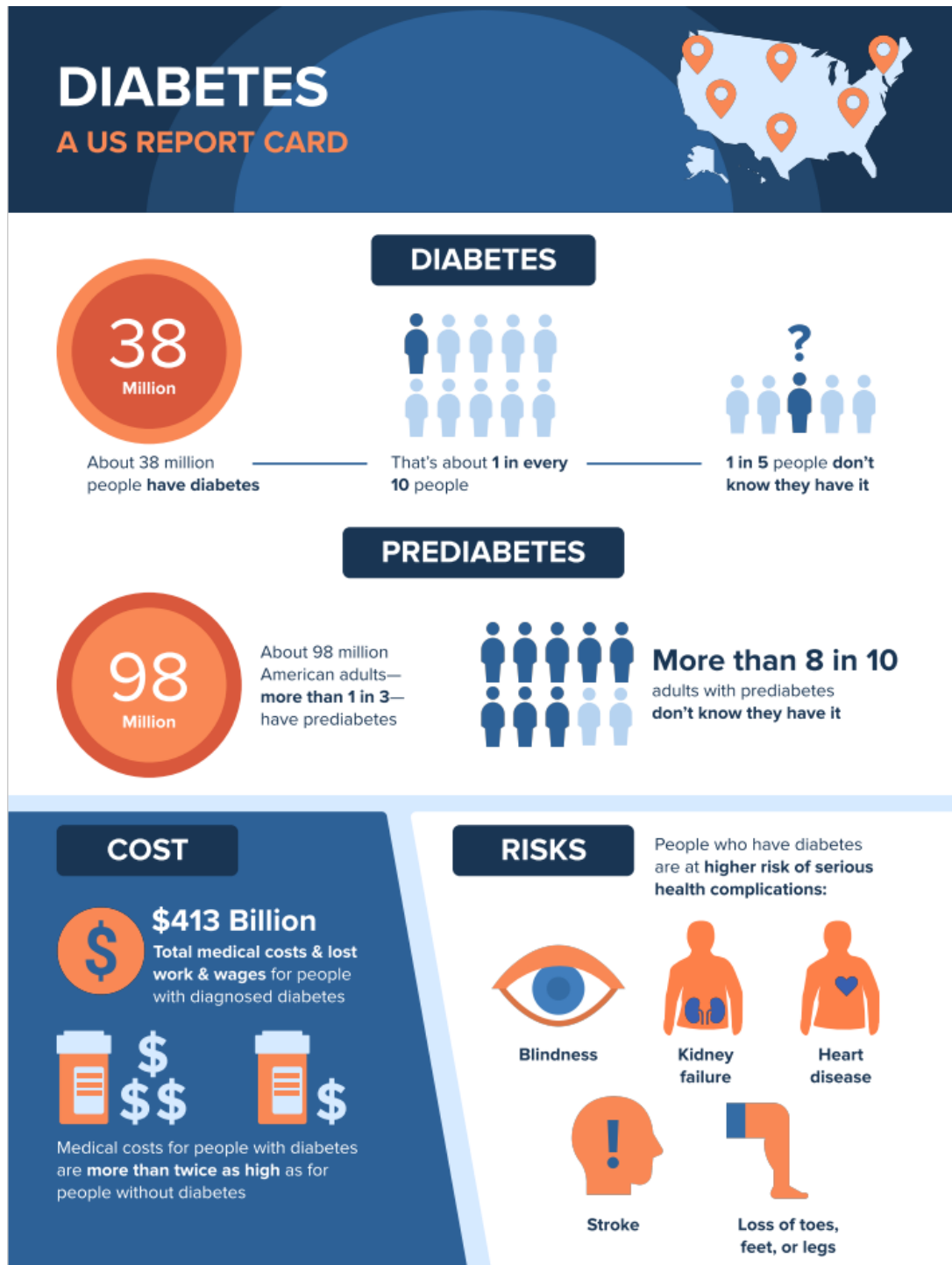
³⁷ *Id.*

³⁸ 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).

³⁹ *Supra*, FN 3.

Diabetes in the United States

Diabetes is the eighth leading cause of death in the United States.⁴⁰ Below is a snapshot of diabetes prevalence and health care costs in the U.S.⁴¹



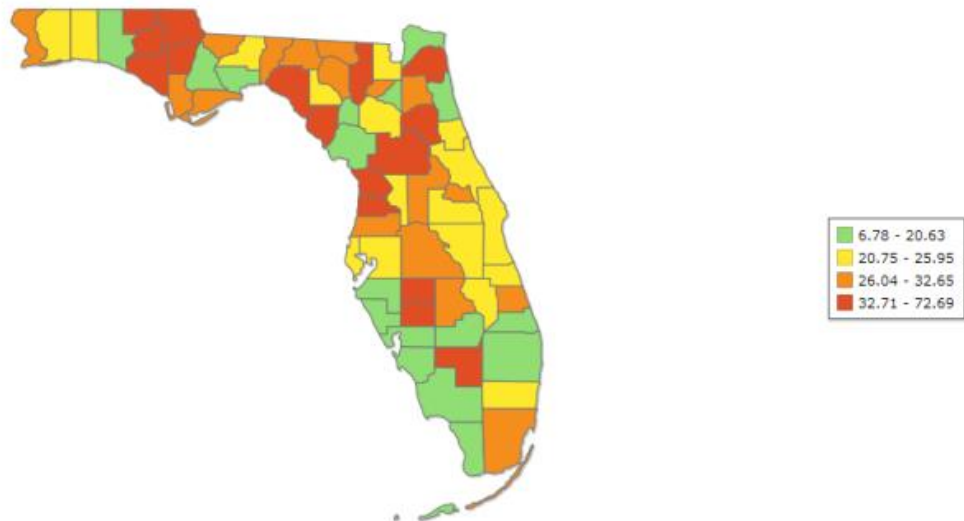
Diabetes in Florida

⁴⁰ 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.htm> (last visited Nov. 27, 2023).

⁴¹ 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).

Current through 2021, diabetes was the seventh leading cause of death in Florida – claiming 8,032 lives.⁴² 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 proportion in the standard population before being summed together.⁴³ In 2021, the age-adjusted deaths from diabetes rate per 100,000 population in Florida was 24.2.⁴⁴

Age-adjusted Deaths From Diabetes, Rate Per 100,000 Population, 2021



45

The American Diabetes Association estimates that 2,071,045 Floridians, or 11.6% of the adult population, have diagnosed diabetes.⁴⁶ Diagnosed diabetes costs approximately \$25 billion in Florida each year.⁴⁷ People with diabetes have medical expenses about 2.3 times higher than those without diabetes.⁴⁸

⁴² 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.LLeadingCausesOfDeathProfile> (last visited Nov. 27, 2023).

⁴³ 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).

⁴⁴ 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 Nov. 27, 2023).

⁴⁵ *Id.*

⁴⁶ 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).

⁴⁷ *Id.*

⁴⁸ *Id.*

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.⁴⁹

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.⁵⁰

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).⁵¹

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 levels steady between meals and overnight. Inhaler device dosages are not as precise as other insulin administration devices.⁵²

Pharmacists

Pharmacist Licensure

Pharmacy is the third largest health profession behind nursing and medicine.⁵³ The Board of Pharmacy (Board), in conjunction with the Department of Health (DOH), regulates the practice of pharmacy under ch. 465, F.S.⁵⁴ To be licensed as a pharmacist in Florida, a person must:⁵⁵

- 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;⁵⁶

⁴⁹ 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).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ American Association of Colleges of Pharmacy, *About AACP*, available at <https://www.aacp.org/about-aacp> (last visited Nov. 27, 2023).

⁵⁴ ss. 465.004 and 465.005, F.S.

⁵⁵ 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.

⁵⁶ 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

- 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:⁵⁷

- 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;⁵⁸
- Administering vaccines to adults;⁵⁹
- Administering epinephrine injections;⁶⁰ and
- Administering antipsychotic medications by injection.⁶¹

A pharmacist may only dispense controlled substances, including insulin, upon a written, oral, or electronic prescription.⁶²

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.⁶³

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.⁶⁴ The formulary may only include:⁶⁵

- 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.

A pharmacist may order, within his or her professional judgment and subject to the stated conditions:⁶⁶

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

⁵⁷ s. 465.003(22), F.S.

⁵⁸ A Class III institutional pharmacy are those pharmacies affiliated with a hospital. See s. 465.019(2)(d), F.S.

⁵⁹ See s. 465.189, F.S.

⁶⁰ *Id.*

⁶¹ s. 465.1893, F.S.

⁶² s. 893.04, FS

⁶³ s. 465.003(22), F.S.

⁶⁴ s. 465.186, F.S.

⁶⁵ *Id.*

- 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 Prescription Refills

Current law authorizes a pharmacist to dispense, if the pharmacist is unable to readily obtain refill authorization from a prescriber, a one-time refill of up to a 72-hour supply of the prescribed medication or a one-time refill of one vial of insulin to treat diabetes.⁶⁷ 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 up to a 30-day supply if the Governor declares a state of emergency in the areas affected by the order if:⁶⁸

- 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.

Effect of the Bill

HB 201 expands current law to authorize a pharmacist to dispense a standard unit of dispensing or a 30-day supply of insulin and insulin-related supplies or equipment up to three times per calendar year, if the pharmacist is unable to readily obtain refill authorization from a prescriber.

⁶⁶ Rule 64B16-27.220, F.A.C.

⁶⁷ S. 465.0275(1), F.S.

⁶⁸ S. 465.0275(2), F.S.

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 Department of Health has sufficient rulemaking authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
 2 An act relating to emergency refills of insulin and
 3 insulin-related supplies or equipment; amending s.
 4 465.0275, F.S.; authorizing an emergency refill of
 5 specified amounts of insulin and insulin-related
 6 supplies or equipment a specified number of times per
 7 year; amending s. 893.04, F.S.; conforming a provision
 8 to changes made by the act; providing an effective
 9 date.

10
 11 Be It Enacted by the Legislature of the State of Florida:

12
 13 Section 1. Paragraph (b) of subsection (1) of section
 14 465.0275, Florida Statutes, is amended to read:

15 465.0275 Emergency prescription refill.—

16 (1) In the event a pharmacist receives a request for a
 17 prescription refill and the pharmacist is unable to readily
 18 obtain refill authorization from the prescriber, the pharmacist
 19 may dispense:

20 (b) An ~~A one-time~~ emergency refill of a standard unit of
 21 dispensing or a 30-day supply ~~one vial~~ of insulin and insulin-
 22 related supplies or equipment to treat diabetes mellitus, not to
 23 exceed 3 times per calendar year.

24 Section 2. Subsection (3) of section 893.04, Florida
 25 Statutes, is amended to read:

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26 893.04 Pharmacist and practitioner.—

27 (3) Notwithstanding subsection (1), a pharmacist may
28 dispense a one-time emergency refill of up to a 72-hour supply
29 of the prescribed medication for any medicinal drug other than a
30 medicinal drug listed in Schedule II, or a standard unit of
31 dispensing or a 30-day supply ~~up to one vial~~ of insulin and
32 insulin-related supplies or equipment to treat diabetes
33 mellitus, not to exceed 3 times per calendar year, in compliance
34 with s. 465.0275.

35 Section 3. This act shall take effect July 1, 2024.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	___	(Y/N)
ADOPTED AS AMENDED	___	(Y/N)
ADOPTED W/O OBJECTION	___	(Y/N)
FAILED TO ADOPT	___	(Y/N)
WITHDRAWN	___	(Y/N)
OTHER	_____	

1 Committee/Subcommittee hearing bill: Healthcare Regulation
2 Subcommittee

3 Representative Skidmore offered the following:

4

5 **Amendment**

6 Remove everything after the enacting clause and insert:

7 Section 1. Section 1. Paragraph (b) of subsection (1) of
8 section 465.0275, Florida Statutes, is amended to read:

9 465.0275 Emergency prescription refill.—

10 (1) In the event a pharmacist receives a request for a
11 prescription refill and the pharmacist is unable to readily
12 obtain refill authorization from the prescriber, the pharmacist
13 may dispense:

14 (b) An ~~A one-time~~ emergency refill of ~~one vial~~ of insulin
15 and insulin-related supplies or equipment to treat diabetes

Amendment No.

16 mellitus, not to exceed 3 nonconsecutive times per calendar
17 year.

18 Section 2. Subsection (3) of section 893.04, Florida
19 Statutes, is amended to read:

20 893.04 Pharmacist and practitioner.—

21 (3) Notwithstanding subsection (1), a pharmacist may
22 dispense a one-time emergency refill of up to a 72-hour supply
23 of the prescribed medication for any medicinal drug other than a
24 medicinal drug listed in Schedule II, or emergency refill up to
25 one vial of insulin and insulin-related supplies or equipment to
26 treat diabetes mellitus, not to exceed 3 nonconsecutive times
27 per calendar year, in compliance with s. 465.0275.

28 Section 3. This act shall take effect July 1, 2024