HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 725 Intravenous Vitamin Treatment **SPONSOR(S):** Healthcare Regulation Subcommittee, Garcia

TIED BILLS: IDEN./SIM. BILLS: SB 754

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	17 Y, 0 N, As CS	Osborne	McElroy
2) Health & Human Services Committee	17 Y, 0 N	Osborne	Calamas

SUMMARY ANALYSIS

Intravenous Vitamin Therapy (IVVT) 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. IVVT 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. IVVT is not regulated by the U.S. Food and Drug Administration (FDA).

IVVT 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. IVVT may pose a variety of risks depending on an individual's health status. IVVT 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 IVVT without a reviewing a patient's current bloodwork; for example, sudden changes in electrolyte balances can cause fatal cardiac arrythmias and other complications that must be responded to immediately.

CS/HB 725 creates s. 456.0302, F.S., relating to administering intravenous vitamin treatment. The bill defines intravenous vitamin treatments, requires patients complete a self-screening risk assessment questionnaire prior to receiving IVVT, and prohibits health care providers from administering IVVT to patients for whom it would be unsafe based on their answers to the questionnaire.

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 to notify a patient's designated physician if IVVT 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, and no fiscal impact on local government.

CS/HB 725 provides an effective date of July 1, 2023.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0725b.HHS

DATE: 4/11/2023

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Intravenous Vitamin Treatment

Intravenous Vitamin Therapy (IVVT) 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. 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 requires 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

IVVT differs from traditional applications of IV therapy in that it is frequently used among 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 IVVT for healthy individuals and it is not regulated by the U.S. Food and Drug Administration (FDA).5 Nonetheless, use of IVVT 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 IVVT popularity among young adults. 6 IVVT is commonly marketed by providers as a hangover cure. 7 and as such post-party IVVT treatments have been popularized among some young adults, sometimes referred to as "club kids," seeking an efficient recovery after a night of partying.8

IVVT may be administered in primary care or integrative medical centers, or found in stand-alone retail locations, commonly known as drip bars or medical spas, and mobile units⁹ that administer IVVT to patients in their own homes. 10 IVVT infusion products are not regulated or based on evidence-based practice guidelines. Retail venues administering IWT commonly advertise "menus" from which a patient can choose their treatment.¹¹ IVVT contents may include saline, amino acids, B-12, vitamin C, "anti-nausea medicines," and zinc, among other micronutrients, vitamins, and "medicinal treatments." "12"

WebMD, IV Vitamin Therapy: Does It Work? Available at https://www.webmd.com/vitamins-and-supplements/iv-vitamin-therapy-doesit-work (last visited March 27, 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 March 27, 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 March 27, 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-vitamintherapy.html (last visited March 27, 2023).

⁶ Bobb, B. Kendall Jenner's Health Scare Might Make You Think Twice About Getting Your Vitamins Intravenously, Voque Magazine. On file with the House Health and Human Services Committee.

⁷ See, Crave Aesthetics, Party Drip. Available at https://cravemedspa.com/iv-vitamin-drip/party-drip/ (last visited April 6, 2023).

⁸ See, UrgentMed Urgent Care. Can A Vitamin IV Actually Cure a Hangover? Available at https://urgentmednetwork.com/can-vitamin-

iv-therapy-actually-cure-hangover/#:~:text=Plus%2C%20the%20cocktail%20of%20vitamins,speeds%20up%20your%20recovery%20time. (last visited April 6, 2023). See also, Storm, C., I Tried a Service That Promises to Fix Your Hangover with an IV Drip – Here's What it Was Like. (2015) Business Insider. Available at https://www.businessinsider.com/i-tried-hangover-club-iv-drip-2015-2 (last visited April 6, 2023). 9 Jones Health Law, Establishing a Mobile IV Therapy Clinic in Florida. Available at https://www.joneshealthlaw.com/establishing-amobile-iv-therapy-clinic-in-florida/ (last visited March 27, 2023). ¹⁰ *Id*.

¹¹ Supra, note 2.

¹² See Bounce Hydration, Our IV Drip Menu. Available at https://www.bouncehydration.com/our-iv-drips (last visited March 27, 2023). Restore Hyper Wellness, IV Drip Therapy. Available at https://www.restore.com/services/iv-drip-therapy (last visited March 27, 2023). Florida Mind Health Center, IV Vitamin Therapy, Available at https://www.flmindhealth.com/iv-therapy/ (last visited March 27, 2023). STORAGE NAME: h0725b.HHS PAGE: 2

Cost of treatment ranges widely from \$90¹³ to over \$300¹⁴ for treatments lasting between 45 and 90 minutes.

Under current law, IVVT may be administered by any licensed health care provider who may administer intravenous therapies within their scope of practice and possesses the appropriate certifications and training. This includes physicians, ¹⁵ physician assistants, ¹⁶ registered nurses and advanced practice registered nurses, ¹⁷ anesthesiologist assistants under the direct supervision of an anesthesiologist, ¹⁸ medical assistants under the direct supervision of a physician, ¹⁹ and licensed practical nurses under the direction of a registered nurse. ²⁰ The licensure and regulation of these health care providers is overseen by their respective regulatory boards under the Department of Health (DOH). ²¹

IVVT is an elective treatment that does not require physician referral. Procedures vary widely between facilities; some suggest patients consult with their physician prior to receiving treatment, ²² others require a telehealth consultation with their own "medical professionals" upon first visit, ²³ and most require a medical questionnaire and liability waiver or consent form be completed prior to treatment. ²⁴ Some facilities require that patients over 65 years of age provide a recent basic metabolic panel lab²⁵ prior to receiving IVVT. ²⁶

IVVT 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.²⁷ Some ingredients could cause an allergic reaction or interact with other medications that a patient is taking.²⁸ There are additional risks associated with administering IVVT without a reviewing a patient's current bloodwork; for example, sudden changes in electrolyte balances can cause fatal cardiac arrythmias other complications that must be responded to immediately.²⁹

Effect of the Bill

CS/HB 725 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

¹³ The IV-Suite, IV Pushes. Available at https://www.iv-suite.com/iv-pushes/ (last visited March 27, 2023).

¹⁴ Mobile IV Medics, Mobile IV Hydration Therapy in Florida. Available at https://mobileivmedics.com/service-areas/florida/ (last visited March 27, 2023).

¹⁵ See, chs. 458 and 459, F.S.

¹⁶ See, chs. 458 and 459, F.S.

¹⁷ See, Ch. 464, F.S.

¹⁸ S. 458.3475(3), F.S.

¹⁹ 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 March 27, 2023).

²⁰ Rule 64B9-12.004, F.A.C.

²¹ 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.

²² Midtown Movement and Medicine, IV Vitamin Therapy Provides Full Body Rejuvenation. Available at https://midtownmovementtlh.com/our-services/iv-infusion-therapy (last visited March 28, 2023).

²³ Restore Hyper Wellness, FAQs: Learn More about IV Drip Therapy. Available at https://www.restore.com/services/iv-drip-therapy (last visited March 28, 2023).

²⁴ See Bounce Hydration, *Our IV Drip Menu*. Available at https://www.bouncehydration.com/our-iv-drips (last visited March 27, 2023). Restore Hyper Wellness, *IV Drip Therapy*. Available at https://www.restore.com/services/iv-drip-therapy (last visited March 27, 2023). Florida Mind Health Center, *IV Vitamin Therapy*. Available at https://www.flmindhealth.com/iv-therapy (last visited March 27, 2023).

²⁵ A basic metabolic panel is a common blood test measuring the glucose, calcium, blood urea nitrogen, creatine, sodium, potassi um, bicarbonate, and chloride in a person's blood. *See also*, Cleveland Clinic, *Basic Metabolic Panel (BMP)*. Available at https://mv.clevelandclinic.org/health/diagnostics/22020-basic-metabolic-panel-bmp (last visited March 28, 2023).

²⁶ Supra, note 23.

²⁷ Supra, note 5.

²⁸ Id.

²⁹ Supra, note 2.

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, 30 and 464, F.S. 31

Under the bill, health care providers must 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.

CS/HB 725 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 to notify a patient's designated physician if IVVT was administered.

CS/HB 725 also requires health care providers to 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, 32 the Board of Nursing, Board of Medicine, and Board of Osteopathic Medicine, to develop rules implementing the 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, 2023.

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, 2023.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

DOH will incur insignificant, negative expenditures related to rulemaking which current resources are able to absorb.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

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³⁰ 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.

³¹ 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.

³² 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.

	Expenditures:None.	
C.	DIRECT ECONOMIC IMPACT ON PRIVATE SECTO)R:
D.	FISCAL COMMENTS: None.	

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Revenues: None.

- 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