

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 227 Intravenous Vitamin Treatment
SPONSOR(S): Healthcare Regulation Subcommittee, Garcia
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Healthcare Regulation Subcommittee	18 Y, 0 N, As CS	Osborne	McElroy
2) Health & Human Services Committee	15 Y, 0 N	Osborne	Calamas

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 settings, and for purposes 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 be 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 common IVT ingredients carry a risk of allergic reaction or possible drug interactions if the patient is taking other medications. 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 require immediate medical response.

CS/HB 227 requires providers to obtain a self-screening risk assessment questionnaire from a patient before administering IVT to the patient, 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 when IVT is administered, and to maintain a written plan for emergency care. The bill exempts IVT administered in a hospital or ambulatory surgical center from these requirements.

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.

CS/HB 227 has an insignificant, negative fiscal impact on DOH which current resources are sufficient to absorb, and no fiscal impact on local government.

The bill 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 outside of conventional medical settings and for unconventional purposes; 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 IVT infusion products are not otherwise regulated or based on evidence-based practice guidelines. 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 in mobile units⁷ that administer IVT to patients in their own homes.⁸ 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 applicable scope of practice and who possesses the

¹ WebMD, *IV Vitamin Therapy: Does It Work?* Available at <https://www.webmd.com/vitamins-and-supplements/iv-vitamin-therapy-does-it-work> (last visited January 12, 2024).

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 January 12, 2024).

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 January 12, 2024).

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 January 12, 2024).

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

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 January 12, 2024).

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 January 12, 2024).

Restore Hyper Wellness, *IV Drip Therapy*. Available at <https://www.restore.com/services/iv-drip-therapy> (last visited January 12, 2024).

Florida Mind Health Center, *IV Vitamin Therapy*. Available at <https://www.flmindhealth.com/iv-therapy/> (last visited January 12, 2024).

¹¹ The IV-Suite, *IV Pushes*. Available at <https://www.iv-suite.com/iv-pushes/> (last visited January 12, 2024).

¹² Mobile IV Medics, *Mobile IV Hydration Therapy in Florida*. Available at <https://mobileivmedics.com/service-areas/florida/> (last visited January 12, 2024).

appropriate 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 consult with their physicians prior to receiving treatment;²⁰ others require a telehealth consultation with their own medical professionals at the first visit.²¹ 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. The risks may be especially high for individuals with heart disease and kidney problems whose bodies are not capable processing the salts and fluids at the rapid rate they are being added to the body.²⁵ Some common IVT ingredients carry a risk of allergic reaction or possible drug interactions if the patient is taking other medications.²⁶ 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 require an immediate medical response.²⁷

Effect of the Bill

CS/HB 227 creates the "Stephanie Balais Act,"²⁸ regulating the administration of intravenous vitamin treatments by certain health care providers. The bill defines intravenous vitamin treatment (IVT) 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 specific health care providers: allopathic and osteopathic physicians, physician assistants, anesthesiologist assistants, registered nurses, including advanced

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 January 12, 2024).

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 January 12, 2024).

²¹ Restore Hyper Wellness, *FAQs: Learn More about IV Drip Therapy*. Available at <https://www.restore.com/services/iv-drip-therapy> (last visited January 12, 2024).

²² See Bounce Hydration, *Our IV Drip Menu*. Available at <https://www.bouncehydration.com/our-iv-drips> (last visited January 12, 2024).

Restore Hyper Wellness, *IV Drip Therapy*. Available at <https://www.restore.com/services/iv-drip-therapy> (last visited January 12, 2024).

Florida Mind Health Center, *IV Vitamin Therapy*. Available at <https://www.flmindhealth.com/iv-therapy/> (last visited January 12, 2024).

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 January 12, 2024).

²⁴ *Supra*, note 21.

²⁵ *Supra*, note 5.

²⁶ *Id.*

²⁷ *Supra*, note 2.

²⁸ Stephanie Balais was an aspiring nurse from Miami, Florida who passed away at age 25 following an IVT-associated incident in 2018. For more information about Stephanie Balais, or the nursing scholarship founded in her memory, see The Stephanie Balais Nursing Scholarship Foundation, available at <https://stephaniebalaisnsf.com/about-stephanie> (last visited January 13, 2024).

practice registered nurses, and licensed practical nurses.²⁹ Health care providers administering IVVT in a hospital or ambulatory surgical center licensed under ch. 395, F.S., are exempt from the requirements of the bill.

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 when IVVT is administered.

CS/HB 227 also requires that health care providers maintain a written plan for emergency care, which 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 Board of Nursing, Board of Medicine, and Board of Osteopathic Medicine (the Boards), to adopt rules to establish procedures for the safe administration of IVVT. Specifically, the bill directs the Boards to adopt rules pertaining to the following as they relate to the administration of IVVT:

- Education and training requirements;
- Patient self-screening risk assessment questionnaire;
- Information that must be provided to patients;
- Notification to be provided to a patient's designated physician;
- Administration and documentation requirements; and
- Protocols to follow in a health emergency.

Violation of the provisions of the bill constitute grounds for disciplinary action.

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.³⁰

²⁹ This list includes all health care providers licensed under chs. 458, 459, and 464, F.S.

³⁰ Department of Health, *Agency Bill Analysis for House Bill 227 (2024)*, p. 5. On file with the Health and Human Services Committee.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

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 requirements as prescribed in the bill and by the regulatory boards. Adhering to such safety requirements may increase the cost of administering intravenous vitamin treatments.

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 its provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On December 6, 2023, the Healthcare Regulation Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment created an exemption from the requirements of the bill for IVVT administered in hospital or ambulatory surgical center licensed under ch. 395, F.S.

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