

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 | | | |

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.

CS/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 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, 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

CS/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 unless they are providing IVVT in a hospital or ambulatory surgical center licensed under ch. 395, F.S., in which case they are exempt from the requirements of the bill.

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.

CS/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

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.