

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS**

**BILL #:** PCS for HB 725 Intravenous Vitamin Treatment by Garcia

**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**

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, with unconventional goals such as achieving a general feeling of wellness, obtaining clearer skin, fighting a cold, or 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.

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. 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 arrhythmias and other complications that must be responded to immediately.

The PCS for HB 725 creates s. 456.0302, F.S., relating to administering intravenous vitamin treatment. The PCS 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 PCS requires patients be provided information regarding potential side effects and risks of IVVT, instructions on when to seek medical attention, and a visit summary. The PCS requires health care providers to notify a patient’s designated physician that IVVT was administered. The PCS also requires that health care providers maintain a written plan for emergency care.

The PCS directs the Board of Medicine, Board of Osteopathic Medicine, and the Board of Nursing to adopt rules to implement the provisions of the PCS.

The bill has an insignificant negative fiscal impact on the Department of Health, and no fiscal impact on local government.

The PCS provides an effective date of July 1, 2023.

# 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

IVT 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.<sup>4</sup> 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).<sup>5</sup> 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 units<sup>6</sup> that administer IVT to patients in their own homes.<sup>7</sup>

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.<sup>8</sup> IVT contents may include saline, amino acids, B-12, vitamin C, "anti-nausea medicines," and zinc, among other micronutrients, vitamins, and "medicinal treatments."<sup>9</sup> Cost of treatment ranges widely from \$90<sup>10</sup> to over \$300<sup>11</sup> 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 certifications and training. This includes physicians,<sup>12</sup> physician assistants,<sup>13</sup> registered nurses and advanced practice registered nurses,<sup>14</sup> anesthesiologist assistants under the direct supervision of an

<sup>1</sup> WebMD, *IV Vitamin Therapy: Does It Work?* Available at <https://www.webmd.com/ivitamins-and-supplements/iv-vitamin-therapy-does-it-work> (last visited March 27, 2023).

<sup>2</sup> 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](https://www.researchgate.net/publication/354838784_Consumer_Intravenous_Vitamin_Therapy_Wellness_Boost_or_Toxicity_Threat) (last visited March 27, 2023).

<sup>3</sup> 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).

<sup>4</sup> *Supra*, note 2.

<sup>5</sup> AARP. *The Truth Behind Trendy IV Therapy*. Available at <https://www.aarp.org/health/drugs-supplements/info-2022/iv-vitamin-therapy.html> (last visited March 27, 2023).

<sup>6</sup> 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 March 27, 2023).

<sup>7</sup> *Id.*

<sup>8</sup> *Supra*, note 2.

<sup>9</sup> 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).

<sup>10</sup> The IV-Suite, *IV Pushes*. Available at <https://www.iv-suite.com/iv-pushes/> (last visited March 27, 2023).

<sup>11</sup> Mobile IV Medics, *Mobile IV Hydration Therapy in Florida*. Available at <https://mobileivmedics.com/service-areas/florida/> (last visited March 27, 2023).

<sup>12</sup> See, chs. 458 and 459, F.S.

<sup>13</sup> See, chs. 458 and 459, F.S.

<sup>14</sup> See, Ch. 464, F.S.

anesthesiologist,<sup>15</sup> medical assistants under the direct supervision of a physician,<sup>16</sup> and licensed practical nurses under the direction of a registered nurse.<sup>17</sup>

IVVT 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,<sup>18</sup> others require a telehealth consultation with their own “medical professionals” at their first visit,<sup>19</sup> and most require a medical questionnaire and liability waiver or consent form be completed prior to treatment.<sup>20</sup> Some facilities require that patients over 65 years of age provide a recent basic metabolic panel lab<sup>21</sup> prior to receiving IVVT.<sup>22</sup>

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.<sup>23</sup> Some ingredients could cause an allergic reaction or interact with other medications that a patient is taking.<sup>24</sup> There are additional risks associated with administering IVVT 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.<sup>25</sup>

### Effect of the Bill

The PCS for HB 725 creates s. 456.0302, F.S., relating to administering intravenous vitamin treatment. The PCS 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 PCS apply to health care providers licensed under chs. 458, 459, and 464, F.S.

The PCS for HB 725 requires that patients complete a self-screening risk assessment questionnaire prior to receiving IVVT. A health care provider may not administer IVVT to a patient if it would be unsafe to do so based upon the patient’s answers to the questionnaire.

The PCS requires patients be provided information regarding potential side effects and risks of IVVT, instructions on when to seek medical attention, and a visit summary. The PCS requires health care providers to notify a patient’s designated physician that IVVT was administered.

The PCS 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

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<sup>15</sup> S. 458.3475(3), F.S.

<sup>16</sup> 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](https://www.floridahealth.gov/licensing-and-regulation/declaratory_documents/medical/doh-09-0320.pdf) (last visited March 27, 2023).

<sup>17</sup> Rule 64B9-12.004, F.A.C.

<sup>18</sup> Midtown Movement and Medicine, *IV Vitamin Therapy Provides Full Body Rejuvenation*. Available at <https://midtownmovementllh.com/our-services/iv-infusion-therapy/> (last visited March 28, 2023).

<sup>19</sup> 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).

<sup>20</sup> 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).

<sup>21</sup> 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 March 28, 2023).

<sup>22</sup> *Supra*, note 19.

<sup>23</sup> *Supra*, note 5.

<sup>24</sup> *Id.*

<sup>25</sup> *Supra*, note 2.

- Medical services to be used in the event of a health emergency.

The PCS instructs the Board of Nursing, Board of Medicine, and Board of Osteopathic Medicine to develop rules implementing the provisions of the PCS. 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.

The PCS 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:**

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

2. Other:

None.

**B. RULE-MAKING AUTHORITY:**

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

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

None.

**IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES**