

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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BILL: SB 996

INTRODUCER: Senator Richter

SUBJECT: Home Medical Equipment

DATE: March 6, 2015

REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	<b>Favorable</b>
2.			AHS	
3.			FP	

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**I. Summary:**

SB 996 amends s. 400.93, F.S., to exempt physicians who sell or rent electrostimulation medical equipment to their patients in the course of their practice from the requirement to be licensed as a home medical equipment provider.

**II. Present Situation:**

**Home Medical Equipment Providers**

Part VII of ch. 400, F.S., requires the Agency for Health Care Administration (AHCA) to license and regulate any person or entity that holds itself out to the public as performing any of the following functions:

- Providing home medical equipment<sup>1</sup> and services;<sup>2</sup>
- Accepting physician orders for home medical equipment and services; or
- Providing home medical equipment that typically requires home medical services.<sup>3</sup>

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<sup>1</sup> Defined in s. 400.925, F.S., as any product as defined by the federal Food and Drug Administration's Drugs, Devices and Cosmetics Act, any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Home medical equipment includes oxygen and related respiratory equipment; manual, motorized, or customized wheelchairs and related seating and positioning, but does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need.

<sup>2</sup> Defined in s. 400.925, F.S., as equipment management and consumer instruction, including selection, delivery, set-up, and maintenance of equipment, and other related services for the use of home medical equipment in the consumer's regular or temporary place of residence.

<sup>3</sup> Section 400.93(1) and (2), F.S.

The following are exempt from the licensure requirement for home medical equipment providers:<sup>4</sup>

- Providers operated by the Department of Health (DOH) or the federal government;
- Nursing homes;
- Assisted living facilities;
- Home health agencies;
- Hospices;
- Intermediate care facilities;
- Homes for special services;
- Transitional living facilities;
- Hospitals;
- Ambulatory surgical centers;
- Manufacturers and wholesale distributors that do not sell directly to the consumer;
- Licensed health care practitioners who utilize home medical equipment in the course of their practice but do not sell or rent home medical equipment to their patients; and
- Pharmacies.

Currently there are 1,003 licensed home medical equipment providers, including those providers that are located out of the state but hold a Florida license.<sup>5</sup>

Any person or entity applying for a license as a home medical equipment provider must provide the AHCA with:

- A report of the medical equipment that will be provided, indicating whether it will be provided directly or by contract;
- A report of the services that will be provided, indicating whether the services will be provided directly or by contract;
- A list of the persons and entities with whom they contract;
- Documentation of accreditation, or an application for accreditation, from an organization recognized by the AHCA;
- Proof of liability insurance; and
- A \$300 application fee and a \$400 inspection fee, unless exempt from inspection.<sup>6</sup>

As a requirement of licensure, home medical equipment providers must comply with a number of minimum standards including, but not limited to:

- Offering and providing home medical equipment and services, as necessary, to consumers who purchase or rent any equipment that requires such services;
- Providing at least one category of equipment directly from their own inventory;
- Responding to orders for other equipment from either their own inventory or from the inventory of other contracted companies;
- Maintaining trained personnel to coordinate orders and scheduling of equipment and service deliveries;

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<sup>4</sup> Section 400.93(5), F.S.

<sup>5</sup> See AHCA, Florida Health Finder, *Home Health Care in Florida*, (printed list of home medical equipment providers on file with Senate Committee on Health Policy).

<sup>6</sup> Section 400.931, F.S.

- Ensuring that their delivery personnel are appropriately trained;
- Ensuring that patients are aware of their service hours and emergency service procedures;
- Answering any questions or complaints a consumer has about an item or the use of an item;
- Maintaining and repairing, either directly or through contract, items rented to consumers;
- Maintaining a safe premises;
- Preparing and maintaining a comprehensive emergency management plan that must be updated annually and provide for continuing home medical equipment services for life-supporting or life-sustaining equipment during an emergency;
- Maintaining a prioritized list of patients who need continued services during an emergency;<sup>7</sup>
- Complying with AHCA rules on minimum qualifications for personnel, including ensuring that all personnel have the necessary training and background screening;<sup>8</sup> and
- Maintaining a record for each patient that includes the equipment and services the provider has provided and which must contain:
  - Any physician's order or certificate of medical necessity;
  - Signed and dated delivery slips;
  - Notes reflecting all services, maintenance performed, and equipment exchanges;
  - The date on which rental equipment was retrieved; and,
  - Any other appropriate information.<sup>9</sup>

Licensed home medical equipment providers are subject to periodic inspections, including biennial licensure inspections, inspections directed by the federal Centers for Medicare and Medicaid Services, and licensure complaint investigations. A home medical equipment provider may submit a survey or inspection by an accrediting organization in lieu of a licensure inspection if the provider's accreditation is not provisional and the AHCA receives a report from the accrediting organization. A copy of a valid medical oxygen retail establishment permit issued by the DOH may also be submitted in lieu of a licensure inspection.<sup>10</sup>

### **Electrostimulation Medical Equipment**

Devices that provide electrical stimulation can be used medically to treat a number of symptoms and conditions. Electrical stimulators can provide direct, alternating, pulsed, and pulsed waveforms of energy to the human body through electrodes that may be indwelling, implanted in the skin, or used on the surface of the skin.<sup>11</sup> Such devices may be used to exercise muscles, demonstrate a muscular response to stimulation of a nerve, relieve pain, relieve incontinence, and provide test measurements.<sup>12</sup>

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<sup>7</sup> Section 400.934, F.S.

<sup>8</sup> AHCA, Rule 59A-25.004, F.A.C. All home medical equipment provider personnel are also subject to a level 2 background screening per s. 400.953, F.S.

<sup>9</sup> Section 400.94, F.S.

<sup>10</sup> Section 400.933, F.S.

<sup>11</sup> United Healthcare Medical Policy, *Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation*, p. 4, (December 1, 2014) [https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Electrical\\_Stim\\_Tx\\_Pain\\_Muscle\\_Rehab.pdf](https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Electrical_Stim_Tx_Pain_Muscle_Rehab.pdf), (last visited Mar. 6, 2015).

<sup>12</sup> Id.

Functional electrical stimulation (FES), also known as therapeutic electrical stimulation (TES), is used to prevent or reverse muscular atrophy and bone loss by stimulating paralyzed limbs. FES is designed to be used as a part of a self-administered, home-based rehabilitation program for the treatment of upper limb paralysis. An FES system consists of a custom-fitted device and control unit that allows the user to adjust the stimulation intensity and a training mode which can be gradually increased to avoid muscle fatigue.<sup>13</sup>

A second type of electrical stimulation is Transcutaneous Electrical Nerve Stimulation, or TENS. TENS is the application of electrical current through electrodes placed on the skin for pain control. It has been used to treat a variety of painful conditions, but there is “much controversy over which conditions to treat with TENS and the adequate parameters to use.”<sup>14</sup> Despite this controversy, there is some clinical evidence that TENS is able to relieve certain types of pain and “experimental pain studies and clinical trials are beginning to refine parameters of stimulation to obtain the best pain relief.”<sup>15</sup> For example, studies have shown that TENS increases the pressure and heat pain thresholds in people who are healthy and reduces mechanical and heat hyperalgesia in arthritic animals.<sup>16</sup>

Other types of electrical stimulation include interferential therapy (IFT) and neuromuscular electrical stimulation (NMES). IFT uses two alternating currents simultaneously applied to the affected area through electrodes and which is proposed to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. NMES involves the application of electrical currents through the skin to cause muscle contractions and is used to promote the restoration of nerve supply, prevent or slow atrophy, relax muscle spasms, and to promote voluntary control of muscles in patients who have lost muscle function.<sup>17</sup>

### III. Effect of Proposed Changes:

The bill amends s. 400.93, F.S., to exempt physicians who sell or rent electrostimulation medical equipment to their patients in the course of their practice from the requirement to be licensed as a home medical equipment provider.

The bill establishes an effective date of July 1, 2015.

### IV. Constitutional Issues:

#### A. Municipality/County Mandates Restrictions:

None.

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<sup>13</sup> Supra note 11.

<sup>14</sup> Effectiveness of Transcutaneous Electrical Nerve Stimulation for Treatment of Hyperalgesia and Pain, *Curr Rheumatol Rep.* Dec 2008; 10(6): 492–499, found at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2746624/>, (last visited Mar. 6, 2015).

<sup>15</sup> *Id.*

<sup>16</sup> Effects of Transcutaneous Electrical Nerve Stimulation on Pain, Pain Sensitivity, and Function in People With Knee Osteoarthritis: A Randomized Controlled Trial, *Physical Therapy* 2012 Jul; 92(7): 898–910 found at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3386514/>, (last visited Mar. 6, 2015).

<sup>17</sup> Supra note 11

**B. Public Records/Open Meetings Issues:**

None.

**C. Trust Funds Restrictions:**

None.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

Any exempted physicians may see a positive fiscal impact from SB 996 due to no longer having to pay licensure and inspection fees or meet the licensure requirements of part VII of ch. 400, F.S.

**C. Government Sector Impact:**

The AHCA may experience a negative fiscal impact due to fewer licensed home medical equipment providers.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 400.93 of the Florida Statutes.

**IX. Additional Information:****A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

**B. Amendments:**

None.