HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1305 Home Medical Equipment Providers
SPONSOR(S): Eagle
TIED BILLS: **IDEN./SIM. BILLS:** SB 996

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	12 Y, 0 N	Guzzo	Poche
2) Health Care Appropriations Subcommittee	9 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee	16 Y, 0 N	Guzzo	Calamas

SUMMARY ANALYSIS

Home medical equipment providers are licensed and regulated by the Agency for Health Care Administration (AHCA) under part VII of ch. 400, F.S. The licensure requirements for home medical equipment providers apply to any person or entity that holds itself out to the public as providing home medical equipment and services or accepts physician orders for home medical equipment and services. Certain individuals and entities are exempt from the licensure requirements, including:

- Nursing homes;
- Assisted living facilities;
- Home health agencies;
- Hospices;
- Intermediate care facilities;
- Hospitals;
- Manufacturers and wholesale distributors;
- Pharmacies; and
- 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.

Electrostimulation medical equipment can be used to treat a number of medical symptoms and conditions. Electrical stimulators can provide direct, alternating, and pulsed waveforms of energy to the human body through electrodes that may be implanted in the skin or used on the surface of the skin. 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.

The bill amends s. 400.93, F.S., to exempt physicians licensed under chapters 458 and 459, F.S., and chiropractors licensed under ch. 460, F.S., who sell or rent electrostimulation medical equipment to their patients in the course of their practice from licensure as a home medical equipment provider.

The bill will have an insignificant negative fiscal impact on AHCA resulting from a reduction in licensure fees collected.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Home Medical Equipment Providers

Home medical equipment providers are licensed and regulated by the Agency for Health Care Administration (AHCA), under part VII of ch. 400, F.S., and Chapter 59A-25, F.A.C. A home medical equipment license is required for any person or entity that:

- Holds itself out to the public as providing home medical equipment[1] and services;[2]
- Accepts physician orders for home medical equipment and services; or
- Provides home medical equipment that typically requires home medical services.[3]

Section 400.931, F.S., requires any person or entity applying for a home medical equipment provider license to submit certain information to AHCA with the application, including:

- A report of the medical equipment and services that will be provided, and whether the equipment will be provided directly or by contract;
- A list of the persons and entities with whom the applicant contracts;
- Documentation of accreditation, or an application for accreditation, from an accrediting organization recognized by AHCA;
- Proof of liability insurance; and
- An application fee of $300 and an inspection fee of $400[4].

Section 400.934, F.S., requires home medical equipment providers to comply with minimum standards of operation relating to topics such as services, training and personnel, and emergency standards.

A home medical equipment provider must offer and provide home medical equipment and services, as necessary, to consumers who purchase or rent any equipment that requires such services, and must provide at least one category of equipment directly from their own inventory.[5] A home medical equipment provider is required to respond to orders for other equipment from either their own inventory or from the inventory of other contracted companies and must maintain and repair, either directly or through contract, items rented to consumers.[6]

Home medical equipment providers are required to maintain trained personnel to coordinate orders and scheduling of equipment and service deliveries and must ensure that their delivery personnel are appropriately trained.[7] Home medical equipment providers are required to ensure that all personnel have the necessary training and background screening.[8]

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[1] 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 product 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; motorized scooters; personal transfer systems; and specialty beds, for use by a person with a medical need. Home medical equipment does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner.

[2] 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 customer's regular or temporary place of residence.

[3] S. 400.93(1) and (2), F.S.

[4] S. 400.933, F.S.; Provides that the home medical equipment provider is exempt from the inspection fee if a survey or inspection has been conducted by an accrediting organization.

[5] S. 400.934(1) and (2), F.S.

[6] S. 400.934(3) and (11), F.S.

[7] S. 400.934(4) and (5), F.S.

[8] S. 400.934(16), F.S.

A home medical equipment provider must comply with certain emergency standards, including:

- Ensuring that patients are aware of service hours and emergency service procedures;
- 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;

Home medical equipment providers are also required to maintain a record for each patient that includes the equipment and services provided, 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.[9]

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.[10] Currently there are 779 licensed home medical equipment providers in Florida.[11]

Certain individuals and entities are considered exempt from licensure, including:

- 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 patient; and
- Pharmacies.[12]

[9] S. 400.94, F.S.
[10] S. 400.932, F.S.
[11] AHCA , Florida Health Finder, *Facility/Provider Search, Home Medical Equipment Providers*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (search conducted March 15, 2015).
[12] S. 400.93(5), F.S.

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, and pulsed waveforms of energy to the human body through electrodes that may be implanted or used on the surface of the skin.[13] 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.[14]

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.[15]

A second type of electrical stimulation is Transcutaneous Electrical Nerve Stimulation (TENS). A TENS device consists of an electrical signal generator that transmits pulses of electrical current to electrodes on the skin.[16] The TENS unit is programmable and the generators are capable of delivering stimulation in different rates and intensities. Conventional TENS devices have a high stimulation frequency and low intensity. Pulsed burst TENS devices use low-intensity stimulation in high-frequency bursts.

Other types of electrical stimulation include interferential therapy (IFT) and neuromuscular electrical stimulation (NMES). IFT uses two alternating currents applied to the affected area through electrodes to relieve musculoskeletal pain and increase healing in soft tissue injuries and bone fractures. NMES applies electrical currents through the skin to cause muscle contractions and 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.[17]

Effect of Proposed Changes

The bill amends s. 400.93, F.S., to exempt physicians licensed under Chapters 458 and 459, F.S., and chiropractors licensed under ch. 460, F.S., who sell or rent electrostimulation medical equipment to their patients in the course of their practice from home medical equipment provider licensure requirements. The bill permits physicians and chiropractors to sell or rent this type of home medical equipment directly to their patients without incurring a fee for licensure or licensure renewal.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 400.93, F.S., relating to licensure required; exemptions; unlawful acts; penalties.
Section 2: Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

[13] 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 (last viewed March 15, 2015).
[14] Id.
[15] Id.
[16] United Healthcare Medical Policy, *Transcutaneous Electrical Nerve Stimulation (TENS) for the Treatment of Nausea and Vomiting,* p. 2, (November 1, 2014) https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/TENS_Tx_Nausea_Vomiting.pdf (last viewed March 15, 2015).
[17] Supra at FN 8, pg. 5.

1. Revenues:

   AHCA may experience a decrease in revenues resulting from a reduction in the number of physicians and chiropractors paying licensure fees to sell or rent electrostimulation medical equipment directly to their patients. The exact amount is uncertain but not significant.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Licensed physicians and chiropractors who sell or rent electrostimulation medical equipment to their patients will not have to pay licensure and licensure renewal fees.

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 government.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rulemaking is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES