HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: HB 1183 Home Medical Equipment Providers
SPONSOR(S): Maggard and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 1742

FINAL HOUSE FLOOR ACTION: 116 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

HB 1183 passed the House on March 11, 2020, as CS/SB 1742.

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, for example, hospitals, nursing homes, hospices and pharmacies. Licensed health care practitioners who utilize home medical equipment in the course of practice but do not sell or rent home medical equipment to their patients are also exempt from licensure.

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.

The bill was approved by the Governor on June 24, 2020, ch. 2020-78, L.O.F., and the effective date is July 1, 2020.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Current Situation

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

[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.

appropriately trained.[7] Home medical equipment providers are required to ensure that all personnel have the necessary training and background screening.[8]

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;[9]
- 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;[10] and
- Maintaining a prioritized list of patients who need continued services during an emergency.[11]

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.[12]

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.[13] Currently there are 1,164 licensed home medical equipment providers in Florida.[14]

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; and
- Pharmacies.[15]

Licensed health care practitioners are also exempt from licensure, but only if they do not sell or rent home medical equipment to their patients.

<u>Electrostimulation Medical Equipment</u>

[7] S. 400.934(4) and (5), F.S.
[8] S. 400.934(16), F.S.
[9] S. 400.934(6), F.S.
[10] S. 400.934(20)(a), F.S.
[11] S. 400.934(21), F.S.
[12] S. 400.94, F.S.
[13] S. 400.932, F.S.
[14] AHCA , Florida Health Finder, *Facility/Provider Search, Home Medical Equipment Providers*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (search conducted March 17, 2020).
[15] S. 400.93(5), F.S.

Neuromuscular electrical stimulation (NMES) devices can be used to stimulate the muscle of a patient with muscle atrophy. They can also be used to enhance functional activity in neurologically impaired patients, which is commonly known as functional electrical stimulation (FES). There are two types of NMES: transcutaneous (surface) and percutaneous (partially implanted systems).[16]

Transcutaneous Electrical Nerve Stimulation (TENS) involves placing four electrodes on the skin, which passes a current through the skin to stimulate the appropriate muscles. TENS devices can be used for physical therapy in partially paralyzed patients. For example, a TENS device can be used to enhance flexibility of the foot of a partially paralyzed stroke patient to improve the patient's gate.[17] In addition to eliciting contraction of skeletal muscles TENS devices have been used in a variety of other applications, such as to contract the heart muscle (cardiac pacemakers), alleviate pain (TENS units), improve bladder control, control epileptic seizures, prevent progress of scoliosis, improve blood circulation, control respiration, and stimulate the auditory nerve and visual cortex.[18]

A percutaneous device is implanted into the body with leads and parts of the device remaining outside the body. Percutaneous leads require surgery and have been designed as either intramuscular electrodes that are embedded into the fibers of the muscle or epimysial electrodes that lay on the surface of the muscle.[19]

Effect of the Bill

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.[20] 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 maintains the limited exemption for other types of practitioners, who may not sell or rent such equipment without a home medical equipment provider license.

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[16] Jeffrey Shuren, MD, JD, Federal Centers for Medicare & Medicaid Services, *Decision Memo for Neuromuscular Electrical Stimulation for Spinal Cord Injury (CAG-00153R),* available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=55&TAId=5&NCDId=244&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=STI&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAQAAA& (last viewed March 17, 2020).

[17] 21 C.F.R., s. 882.5810.

[18] Sigmedics, Inc., Rehabilitation Technology for the Neurologically Impaired, *FAQ What is Functional Neuromuscular Stimulation*, available at https://www.sigmedics.com/faq (last visited March 17, 2020).

[19] Supra FN 16.

[20] In 2015, the Florida Legislature passed HB 1305, which was identical to this bill; however, the bill was vetoed by Governor Scott. In a June 2015 letter from former Governor Rick Scott to former Secretary of State Kenneth Detzner, Governor Scott explained his decision to repeal the bill: "while I agree with the Legislature's attempt to deregulate and remove burdensome regulations, carve outs add additional levels of complexity to regulatory requirements while allowing outdated regulations to remain on the books. Carve outs also present an unfair advantage to certain entities competing within the same industry". Available at https://www.flgov.com/wp-content/uploads/2015/06/Transmittal-Letter-6.10.15-HB-1305.pdf (last visited March 17, 2020).

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

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 is not expected to be 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.