

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 179 CS

Home Medical Equipment Providers

**SPONSOR(S):** Robaina

**TIED BILLS:**

**IDEN./SIM. BILLS:** SB 2570

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REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	10 Y, 0 N, w/CS	Hamrick	Mitchell
2) Health Care Appropriations Committee		Speir	Massengale
3) Governmental Operations Committee			
4) Health & Families Council			
5) _____			

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### SUMMARY ANALYSIS

Regulation of the home medical equipment industry was established in 1999 following a Grand Jury investigation that uncovered fraudulent practices in the home medical equipment industry specifically related to Medicare and Medicaid.

House Bill 179 CS furthers regulation of the home medical equipment industry by implementing the following:

- Requires mandatory accreditation for all home medical equipment providers.
- Increases the liability insurance coverage from \$250,000 to \$300,000 per claim.
- Mandates that businesses be operated daily from 9 to 5.
- Requires certain providers to hire a respiratory therapist or registered nurse.
- Places conditions on fulfillment of certain orders.
- Requires all home medical equipment providers to submit proof of accreditation as a prerequisite to licensure or renewal.
- Provides the Agency for Health Care Administration the authority to assess a survey fee of \$500 to cover the cost of conducting complaint investigations.
- Exempts home medical providers from inspections as long as they are accredited by an approved accrediting organization.
- Removes the inspection exemption from providers that are issued a medical oxygen retail permit by the Department of Health.

The bill appears to have an insignificant fiscal impact to the state.

The bill provides an effective date of July 1, 2005.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. HOUSE PRINCIPLES ANALYSIS:

**Provide limited government**-The bill provides additional requirements for rulemaking authority, enforcement, staffing and implementation by the Agency for Health Care Administration.

#### B. EFFECT OF PROPOSED CHANGES:

The Agency for Health Care Administration (AHCA) regulates the home medical equipment licensing program. This program was established in 1999 following a Grand Jury investigation that uncovered fraudulent practices in the home medical equipment industry specifically related to Medicare and Medicaid. In 1999, part X of chapter 400, Florida Statutes, was created to regulate the home medical equipment (HME) industry.

#### **Accreditation Organizations**

Section 400.925(1), Florida Statutes, defines accrediting organizations as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other nationally accredited organizations. This bill will add two other national organizations to the definition: the Community Health Accreditation Program (CHAP) and Accreditation Commission for Health Care, Inc. (ACHC). According to AHCA, 139 home medical equipment providers are accredited by JCAHO and 29 home medical equipment providers are currently accredited by CHAP in Florida.

CHAP accredits home and community-based health care organizations. The Centers for Medicare and Medicaid Services (CMS) has granted "*deeming*" authority to CHAP to evaluate Medicare certified home health and hospice organizations on its behalf. The six areas evaluated by CHAP are quality assurance, antidiscrimination, access to services, confidentiality, and accuracy of enrollee records, information on advance directives, and provider participation rules.

The Accreditation Commission for Health Care, Inc. (ACHC) was established in 1986, and began offering its services nationwide in 1996. ACHC has accreditation programs that include home health agencies, home medical equipment services, home infusion, hospice, women's health, rehabilitation technology supplier services, specialty pharmacy, respiratory nebulizer medication programs and medical supply provider services. ACHC has eight categories of standards, which are organization and administration, program/service operations, fiscal management, personnel management, client service/care management, quality outcomes/improvement, risk management and scope of services.

#### **Home Medical Equipment Providers**

Home medical equipment providers usually select the appropriate medical equipment for a patient, deliver the equipment to the patient's home, assemble the equipment, instruct the patient about its use, and perform maintenance on the equipment as specified by the manufacturer and regulatory bodies. Home medical equipment is synonymous with durable medical equipment.

Home medical equipment includes any product defined by the Federal Drug Administration's Drugs, Devices and Cosmetics Act, as any products reimbursed under the Medicare Part B Durable Medical Equipment benefits, or any products reimbursed under the Florida Medicaid durable medical equipment program. Section 409.906(10), Florida Statutes, provides that AHCA may only pay for medically necessary durable medical equipment and supplies. This includes oxygen and related respiratory equipment, and manual, motorized or customized wheelchairs and related seating and positioning. It 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.

### **Licensure and Inspections of Home Medical Equipment Providers**

As of January 6, 2005, there were 2,122 licensed home medical equipment providers in Florida. Licensure as a home medical equipment provider is issued for 2 years. The fee is specified in the statutes as \$300 for license processing and \$400 for inspection for those not exempt from the AHCA inspection.

The bill adds two categories to the list of home medical equipment that must be reported on applications for a home medical equipment license, which are life-sustaining equipment and technologically advanced equipment. Life-sustaining equipment is defined as, "mechanical ventilators or other equipment that is essential to the restoration or continuation of a bodily function important to the continuation of human life." This is similar to federal regulation and state rule.<sup>1</sup> Technologically advanced equipment is defined as, "equipment of such complexity that a licensed respiratory therapist or registered nurse must set it up and train the patient in its use."

Section 400.933(2), Florida Statutes, exempts home medical equipment providers from AHCA licensure inspection if they are accredited or hold a medical oxygen retail establishment permit. There are currently 168 accredited home medical equipment providers. There are 1,544 home medical equipment providers with a medical oxygen retail permit issued by the Department of Health. Therefore, only 410 (19 percent) of the home medical equipment providers receive licensure inspection as a result of these exemptions. The bill deletes the provision that home medical providers with a medical oxygen retail permit from the Department of Health are exempt from inspections conducted by AHCA.

The bill requires that after January 1, 2006, all home medical equipment providers must submit proof of accreditation as a prerequisite to licensure or renewal. The bill also provides that a provider may have 180 days to submit proof and may receive a 60-day temporary license. This allows a home medical equipment provider time to submit proof of accreditation to AHCA. The bill authorizes AHCA to adopt rules designating appropriate accrediting organizations.

### **Staffing, Inventory, and Liability Insurance Requirements**

The bill places defines high-tech medical equipment providers as "any home medical equipment company that provides life-sustaining equipment, technically advanced equipment, or any other similar service or product to any patient" and adds new service requirements to their businesses.

Currently, a home medical equipment provider is required to maintain trained personnel to handle orders and services according to section 400.934(4), Florida Statutes. Current statute does not require providers to employ a respiratory therapist or registered nurse. This bill requires high-tech equipment providers to have at least one certified respiratory therapist or a registered nurse on staff to provide emergency services to the public.

Section 400.934(2), Florida Statutes, requires home medical equipment providers to fulfill orders from their own inventory for at least one category of equipment. This bill provides that high-tech medical

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<sup>1</sup> See 59A-25.001(9) defines "Life-supporting or life-sustaining device", as defined in 21 Code of Federal Regulations part 860.3, is a device that "is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life."

In 59A-25.003(2)(a), F.A.C, states that "apnea monitors, enteral feeding pumps, infusion pumps, portable home dialysis equipment, and ventilator equipment and supplies for all related equipment, including oxygen equipment and related respiratory equipment, are considered life-supporting or life-sustaining equipment."

equipment providers must fill all orders for equipment directly from their own inventory and cannot contract with another entity to fill orders, unless such entity is also licensed and accredited.

Home medical equipment providers are required to obtain professional and commercial liability insurance in the amount not less than \$250,000 per claim according to section 400.931(6), Florida Statutes. This is identical to the insurance coverage required of home health agencies. This bill increases the minimum liability coverage to \$300,000 per claim.

### **Hours of Operation**

Current law requires providers to maintain safe premises, but does not define business hours or days of operation. The bill provides that home medical equipment providers must be open for business between the hours of 9 a.m. to 5 p.m.

### **Complaints**

Home medical equipment providers are also required to provide patients with the statewide toll-free telephone number for the Central Abuse Hotline to report abuse, neglect or exploitation, as required in section 400.95, Florida Statutes. The reporting of fraud is not a responsibility of the Department of Children and Family Services hotline. There is no requirement to provide the AHCA toll-free complaint line numbers, and consumers are not informed that they can report complaints to AHCA. The bill amends language to include "fraud or fraudulent" to the language providers present to patients about the toll-free telephone number for the central fraud and abuse hotline.

In calendar year 2004, AHCA field office surveyors received 55 complaints alleging violation of state law and rules by home medical equipment providers. Complaint investigations have increased by 50 percent in the past year because the AHCA Medicaid office in Miami has begun checking applicants for Medicaid compliance and reporting violations of state law and rules. Complaint reports have included failure to repair and maintain equipment, poor infection control, untrained staff, administrative concerns, and unlicensed activity.

The bill provides AHCA the authority to assess a survey fee of \$500 to cover the cost to conduct complaint investigations.

#### **C. SECTION DIRECTORY:**

**Section 1.** Amends s. 400.925, F.S., revising and providing definitions.

**Section 2.** Amends s. 400.931, F.S., providing additional categories of equipment that applicants must report and increasing liability insurance requirements.

**Section 3.** Amends s. 400.933, F.S., revising requirements for licensure inspections and investigations.

**Section 4.** Amends s. 400.934, F.S., revising minimum requirements for licensure.

**Section 5.** Amends s. 400.935, F.S., requiring AHCA to provide additional regulatory standards by rule.

**Section 6.** Creates s. 400.936, F.S., requiring proof of accreditation as a prerequisite for licensure, renewal or temporary licensure, and providing authority to make rules relating to the designation of accrediting organizations.

**Section 7.** Amends s. 400.95, F.S., requiring home medical equipment providers to notice toll-free telephone numbers on products so consumers can report fraud and abuse.

**Section 8.** Provides an effective date of July 1, 2005.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:	<u>2005-2006</u>	<u>2006-2007</u>
Revenues from licensing, fees and fines	\$497,154	\$379,581
2. Expenditures:	<u>2005-2006</u>	<u>2006-2007</u>
Program Expenditures	\$454,831	\$472,206
Contractual Services	\$ 41,600	\$ 20,800
General Revenue Service Charge	<u>\$ 36,292</u>	<u>\$ 25,290</u>
Total Recurring Expenditures	\$532,723	\$518,296
Total General Revenue Need as a result of the bill	\$35,569	\$138,715

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

According to AHCA, based on current figures, 1,954 or 92 percent of the currently licensed home medical equipment providers will have to become accredited to continue to be licensed if the bill passes. Accreditation is costly. Providers must pay an inspection fee for accreditation. The JCAHO website reveals the 2005 cost of inspection ranges from \$3,565 for a very small provider with a daily census of 1 to 50 consumers to \$9,790 for a large provider with a daily census of 1,000+. This inspection fee is paid to JCAHO every three years to maintain accreditation.

According to AHCA, accreditation of all providers will require 1,544 providers that have oxygen permits and only receive inspections regarding their oxygen from the Department of Health will have to pass a more extensive inspection from an accrediting organization that would check all services and equipment, not just the oxygen.

Also, the bill requires high-tech equipment providers to employ and have on call a respiratory therapist or registered nurse who should provide more professional involvement with the equipment and services, which would benefit consumers.

AHCA anticipates that some businesses will not seek accreditation and thus no longer be able to be licensed. To what extent competition would be affected cannot be determined.

### D. FISCAL COMMENTS:

According to AHCA, the bill does not provide for fees from regulated entities to cover the projected expenditures. General Revenue funding of \$174,284 would be required to provide for projected expenditures. Given AHCA's budget, this appears to be an insignificant amount.

At the end of state fiscal year 2003-2004, the home medical equipment licensing program had a cumulative deficit of \$562,577; thus, the current fees have not covered AHCA's actual costs. Recently, the revenues exceeded the expenses by \$70,154, reducing the cumulative deficit to the amount previously indicated. AHCA staff believes this revenue increase is primarily due to the increase in the assessment of late application fines since many providers have failed to submit renewal applications according to the time frames required in law.

Since 410 of the 2,122 providers paid the \$400 inspection fee, the exemption of all licensees from payment of the inspection fee will result in a projected revenue loss of \$164,000 for a two-year period if the number of providers does not increase. Historical growth in this program has been approximately 10 percent per year. However, due to the requirement for accreditation, this growth rate will likely not continue and the number of providers will likely decrease. Without the continued receipt of the inspection fees, the projected revenues may not cover costs, especially in coming years. The bill provides AHCA the authority to assess a \$500 complaint investigation fee, which AHCA estimates will generate \$39,000 in fees.

According to AHCA in FY 1999-2000, thirteen positions were established: seven field office surveyors for inspections and complaint investigations, four central office licensing staff (two professionals, one secretary and one supervisor) and one attorney. Mandatory accreditation for licensure requires more central office staff time to notify providers, review accreditation submissions, issue temporary licenses, follow up to obtain proof of accreditation to issue permanent licenses and take action against those that do not obtain accreditation yet continue to operate. AHCA would need to hire a Senior Human Services Program Specialist at \$20 per hour for the Home Care Unit to complete the duties required in this bill. This contract employee would be paid \$41,600 the first year and \$20,800 the second year.

## II. COMMENTS

### A. CONSTITUTIONAL ISSUES:

#### 1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

#### 2. Other:

None.

### B. RULE-MAKING AUTHORITY:

The bill authorizes AHCA to promulgate new rules.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

Both AHCA and the Florida Association of Medical Equipment Services (FAMES) are concerned that it would be difficult to implement the mandatory accreditation within six months of the effective date of this bill. The accrediting organizations (JCAHO, CHAP or ACHC) would have to accredit 1,956 HME providers within the allotted time frame. Home medical equipment providers that are not accredited by January 1, 2006, would be forced to close. The committee substitute provides that a HME must have a reasonable period of time to comply with the accreditation requirements. The time period must not exceed the next licensure renewal date.

The Executive Committee of FAMES has stated that it was not appropriate for the state to mandate operating hours. The committee is concerned that the hours provided in the bill are too vague and do not take into consideration lunch, holidays, or weekend hours.

#### **IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES**

On April 6, 2005, the Health Care Regulation Committee adopted a strike-all amendment and two technical amendments sponsored by Representative Robaina. The committee substitute differs from the original bill as filed in that the strike-all and 2 amendments addressed several technical concerns and the following:

- Amends the definitions of accrediting organizations, high-tech medical equipment provider, from its own inventory, and life-sustaining equipment.
- Removes the language requiring a survey to be conducted for provisional licenses, since accredited home medical equipment providers are exempt from AHCA inspections.
- Provides AHCA the authority to assess a \$500 complaint investigation survey fee.
- Provides that high-tech medical equipment providers may only contract with other entities, if they are also licensed and accredited.
- Provides that any home medical equipment provider must be given a reasonable period of time to comply with the accreditation requirement.
- Provides applicants that have submitted proof of accreditation, completed the licensure application, and paid the required fees may be issued a temporary license until the accreditation process is complete. This will provide AHCA and providers more time to comply with mandatory accreditation.

This analysis is drafted to the committee substitute.