HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 179 CS Home Medical Equipment Providers
SPONSOR(S): Robaina
TIED BILLS: **IDEN./SIM. BILLS:** SB 2570

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

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.

HB 179 CS requires mandatory accreditation for all home medical equipment providers. It increases the amount of insurance coverage, mandates that businesses be operated daily from 9 to 5, and requires high-tech medical equipment providers to hire a respiratory therapist or registered nurse. The bill provides that high-tech medical equipment providers must fill all orders for equipment directly from their own inventory and can not contract with another entity to fill orders, unless such entity is also licensed and accredited. The bill provides that all home medical equipment providers must submit proof of accreditation as a prerequisite to licensure or renewal.

The bill provides the Agency for Health Care Administration the authority to asses a survey fee of $500 to cover the cost to conduct complaint investigations.

The bill exempts home medical providers from inspections as long as they are accredited by an approved accrediting organization. Providers that are issued a medical oxygen retail permit by the Department of Health are no longer exempt from inspections conducted by the Agency for Health Care Administration.

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

This bill has a fiscal impact see “Fiscal Analysis.”

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government-The bill provides additional requirements for rule making 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, F.S., was created to regulate the home medical equipment (HME) industry.

Definitions
HB 179 amends the definition of an "accrediting organization" to require that it must be nationally recognized.

The bill adds a definition of a "high-tech medical equipment provider" that is any home medical equipment company that provides life-sustaining equipment, technically advanced equipment, or any other similar service or product to any patient.

The bill also defines "life-sustaining equipment." The definition refers to equipment that provides mechanical ventilation, 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.[1]

Application Information and Liability Insurance
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. The bill increases the liability insurance coverage from $250,000 to $300,000 per claim.

Exemptions
The bill provides that home medical equipment providers that are accredited by approved organizations are exempt from AHCA inspections. 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 the Agency for Health Care Administration.

Inventory, Staffing and Hours of Operation
The bill provides that high-tech medical equipment providers must fill all orders for equipment directly from their own inventory and can not contract with another entity to fill orders, unless such entity is also licensed and accredited.

[1] 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."

The bill also provides that high-tech equipment providers must have at least one licensed respiratory therapist or a registered nurse on staff, who must be on-call after hours to provide emergency services to the public.

The bill provides that home medical equipment providers must be open for business between the hours of 9 a.m. to 5 p.m.

Accreditation

The bill provides that 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 the Agency for Health Care Administration. The bill authorizes the Agency for Health Care Administration to adopt rules designating appropriate accrediting organizations.

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

Fraud

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.

BACKGROUND

Accreditation Organizations

Section 400.925(1), F.S., 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.

Community Health Accreditation Program (CHAP)

CHAP accredits home and community-based health care organizations. The Center 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.

Accreditation Commission for Health Care (ACHC)

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

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 sometimes used synonymously as 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. This includes oxygen and related respiratory equipment; 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.

Section 409.906(10), F.S., provides that AHCA may authorize and pay for certain durable medical equipment and supplies provided to a Medicaid recipient when medically necessary.

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.

Section 400.933(2), F.S., exempts home medical equipment providers from AHCA licensure inspection if they are accredited or hold a medical oxygen retail establishment permit. Only 168 or 8% of the 2,122 home medical equipment providers are currently accredited.

Home Medical Equipment Providers that have a Medical Oxygen Retail Permit
Currently, most licensed home medical equipment providers, 1,544 or 73%, are exempt from inspection since they have a medical oxygen retail permit issued by the Department of Health. The providers with medical oxygen retail permits are inspected for oxygen, oxygen equipment and related supplies, but not the medical equipment they sell or rent to consumers.

According to AHCA, the cost to obtain a 2-year medical oxygen retail permit is $600. Only 7.18% of home medical equipment providers with a medical oxygen permit are accredited by JCAHO or CHAP.

Only 410 home medical equipment providers (19%) receive licensure inspections by AHCA field office staff.

Staffing, Inventory, and Liability Insurance Requirements
A home medical equipment provider is required to maintain trained personnel to handle orders and services according to s. 400.934(4), F.S. Current statute does not require providers to employ a respiratory therapist or registered nurse. Section 400.934(2), F.S., requires home medical equipment providers to fulfill orders from their own inventory for at least one category of equipment.

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 s. 400.931(6), F.S. This is identical to the insurance coverage required of home health agencies.

Home medical equipment providers are also required to provide to patients with the statewide toll free telephone number for the Central Abuse Hotline to report abuse, neglect, or exploitation, as required in s. 400.95, F.S. The reporting of fraud is not a responsibility of the Department of Children and Families hotline. There is no requirement to provide the AHCA toll free complaint line numbers, consumers are not informed that they can report complaints to AHCA.

Hours of Operation
Current law requires providers to maintain safe premises but does not define business hours or days of operation. Section 400.934(8), F.S., does require providers to arrange for emergency services after normal business hours. AHCA requires emergency service for life-supporting or life-sustaining

equipment 24 hours per day, seven days per week in state rule at 59A-25.003(3)(c), Florida Administrative Code (F.A.C.).

Complaints
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% 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.

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. Created 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:

Projected Revenues:	**2004-2005**	**2005-2006**	**2006-2007**
	$540,154	$458,154 *	$389,440 **

1) Revenues are from licensing and inspection fees, late application fines, relocation without timely notification fines, and a few fines for inspection deficiencies.

2) AHCA estimates revenue for 2005-2006 at $540,153.85 (no growth) less the $82,000 in inspection fees that would have been charged. AHCA anticipates that there will be $164,000 less for a two-year period, thus $82,000 would not be received in the first year.*

3) AHCA estimates for 2006-2007 there will be some applications from new providers, 20 to 25% of the existing providers will not obtain accreditation. AHCA estimates that 15% less revenue will be received. **

2. Expenditures:

Projected Expenditures:	2004-2005	2006-2007	2006-2007
	$434,619	$529,876*	$521,435**

1) Cost of AHCA central office and field office staff, mailing and printing costs related to the issuance of licenses, and travel and other related costs for the investigation of complaints and licensure inspections. This amount is from the Health Care Trust Fund- Final Distributions.

2) Based on the 2004-2005 estimates of $434,619, plus $15,212 for inflation at 3.5%, and $5,000 for provider notification of mandatory accreditation and rule public notices; plus Home Care Unit contract employee costs of $41,600 for the first year ($20 X 2,080 hours) and the services charges to general revenue of $33,445.24. A projected deficit of $71,722 will occur.*

3) A contractor would be needed the first six months ($20 X 1040 hours = $20,800), but other expenses would remain plus inflation of 3.5%. Last year's expenses of $496,431 + inflation $17,375 – minus half of contractor amount from prior year ($20,800) and the services charges to general revenue of $28,429.12. A deficit of $131,995 is projected.**

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% of the currently licensed home medical equipment providers will have to become accredited in order 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 1-50 consumers to $9,790 for a large provider with a daily census of 1000+. This inspection fee is paid to JCAHO every 3 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 also 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:

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% 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 may offset the loss of the inspection 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 in order 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:

AHCA expressed concern that the agency will have difficulty covering the cost of investigating complaints. Assessing a complaint investigation fee may be advantageous to recoup associated expenses.

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 2 technical amendments sponsored by Representative Robaina. The Committee Substitute differs from the original bill as filed in that the:

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; and
- 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.