

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Health Care Committee

BILL: CS/SB 2570

SPONSOR: Health Care Committee and Senator Jones

SUBJECT: Home Medical Equipment Providers

DATE: April 22, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Harkey</u>	<u>Wilson</u>	<u>HE</u>	<u>Fav/CS</u>
2.	_____	_____	<u>HA</u>	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill requires home medical equipment (HME) providers to be accredited by a national accrediting organization by January 1, 2006, as a prerequisite for licensure or licensure renewal. The Agency for Health Care Administration (AHCA) will no longer be required to perform licensure inspections since accredited providers are exempt from the licensure inspections, provided the accreditation is not provisional and AHCA receives a copy of the accreditation report. The bill also:

- Requires HME providers to be fully accessible to all patients between the hours of 9 a.m. and 5 p.m. and after hours for emergency service;
- Increases the amount of insurance that providers must have from \$250,000 to \$300,000 per claim;
- Removes the exemption from AHCA inspection for providers with medical oxygen retailer permits since all providers must be accredited and will be exempt from inspection;
- Creates definitions and requirements for high-tech medical equipment providers that offer ventilators and other life-sustaining equipment to patients;
- Requires all high-tech medical equipment providers to hire a respiratory therapist or registered nurse;
- Requires AHCA to adopt standards in rule for the designation of equipment as life sustaining or technologically advanced and for the designation of accrediting organizations; and
- Requires HME providers to notify consumers of their right to report fraud.

This bill amends ss. 400.925, 400.931, 400.933, 400.934, 400.935, and 400.95, F.S. The bill creates s. 400.936, F.S.

II. Present Situation:

Home Medical Equipment Providers

Home medical equipment providers deliver the appropriate medical equipment for a patient 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 called durable medical equipment.

Home medical equipment includes any product 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. This 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. It does not include prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner.

Licensure and Inspections of Home Medical Equipment Providers

According to AHCA, as of January 6, 2005, there were 2,122 licensed HME providers in Florida. The license is issued for a 2-year period. The fee is specified in the statutes as \$300 for license processing and \$400 for inspection for those not exempt from AHCA inspection. Under s. 400.933(2), F.S., those HME providers that are accredited or that have a medical oxygen retail establishment permit are exempt from AHCA licensure inspection. Only 168 or 8 percent of the 2,122 HME providers are currently accredited. Accrediting organizations are defined in s. 400.925(1), F.S., as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other national accreditation agencies whose standards for accreditation are comparable to those required for licensure. Most of the licensed HME providers, 1,544 or 73 percent, are exempt from inspection due to having a medical oxygen retail permit from the Department of Health. Currently the providers with such permits are inspected for oxygen, oxygen equipment and related supplies, but not the other medical equipment they sell or rent to consumers. The remaining 410 HME providers (19 percent) receive licensure inspections by AHCA field office staff.

In calendar year 2004, AHCA field office surveyors received 55 complaints alleging violations of state law and rules by HME providers. However, complaint investigations have increased by 50 percent in the past year due to the AHCA Medicaid office in Miami checking applicants for Medicaid 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.

Currently, providers must maintain safe premises, but they are not required to keep specified business hours or days of operation. However, s. 400.934(8), F.S., requires 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 under rule 59A-25.003(3)(c), F.A.C. A "life-supporting or life-sustaining device" is defined in rule at 59A-

25.001(9), FAC, and also defined in 21 Code of Federal Regulations part 860.3, as “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.” Also, the state rule 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.

HME providers are required to maintain trained personnel to handle orders and services in current law at s. 400.934(4), F.S., but the statutes do not require providers to employ a respiratory therapist or registered nurse. Section 400.934(2), F.S., requires HME providers to fulfill orders from their own inventory for at least one category of equipment.

HME 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 the same as the insurance required for home health agencies.

HME providers are also required to deliver to patients’ homes 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. There is no requirement to provide the AHCA toll free complaint line number. Thus, consumers are not informed that they can report complaints to AHCA.

According to AHCA, 139 HME providers are accredited by JCAHO and 29 home medical equipment providers are currently accredited by the Community Health Accreditation Program (CHAP) in Florida. 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. CHAP accreditation standards are based on four underlying principles:

- The organization’s structure and function consistently supports its consumer oriented philosophy, mission, and purpose.
- The organization consistently provides high-quality services and products.
- The organization has adequate human, financial, and physical resources to accomplish its stated mission and purpose.
- The organization is positioned for long-term viability.

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, HME 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.

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.

III. Effect of Proposed Changes:

Section 1. Amends s. 400.925, F.S., to revise the definition of *accrediting organizations* to add CHAP and ACHC to the definition.

The bill provides the following new definitions:

High-tech medical equipment provider means any home medical equipment company that provides life-sustaining equipment, technologically advanced equipment, or any other similar service or product to any patient.

Life-sustaining equipment means mechanical ventilators or other similar equipment that supports life or essential respiratory functions.

Technologically advanced equipment means equipment of such complexity that a licensed respiratory therapist or registered nurse must set it up and train the patient in its use.

From its own inventory means to provide the items or service directly to the patient.

Section 2. Amends s. 400.931, F.S., to add life-sustaining equipment and technologically advanced equipment to the list of categories of equipment that licensure applicants must report. The bill increases liability insurance requirements for HME providers from a minimum of \$250,000 to a minimum of \$300,000 per claim. The liability insurance requirement for contractors also is increased from a minimum of \$250,000 to a minimum of \$300,000 per claim. The bill deletes the authorization for a 90-day provisional license. New timeframes for licensure are established in s. 400.936, F.S., which is created in this bill.

Section 3. Amends s. 400.933, F.S., to delete the exemption of providers with medical oxygen retail establishment permits issued by the Department of Health, pursuant to ch. 499, F.S., from licensure inspection by AHCA. The bill authorizes AHCA to assess a survey fee of \$500 to cover the cost of complaint investigations that result from the finding of a violation that was the subject of the complaint and any follow-up visits conducted to verify the correction of the violation.

Section 4. Amends s. 400.934, F.S., to require that when receiving orders and filling orders, HME providers must furnish high-tech medical equipment and technologically advanced equipment from the provider's own inventory and not by contract, unless the contract is with an entity that is licensed and accredited. The bill requires providers who coordinate the filling and delivery of high-tech medical equipment orders to have a respiratory therapist or registered nurse on staff.

HME providers' premises must be open from 9 a.m. to 5 p.m. Weekends and holidays are not exempted, thus all providers must be open every day for those hours. Current law and rules do not define business hours. The bill also requires high-tech medical equipment providers to have at a minimum one licensed respiratory therapist who is either a certified respiratory therapist or a registered respiratory therapist, or a registered nurse on call after hours.

Section 5. Amends s. 400.935, F.S., to require AHCA to establish rules for designating equipment as life sustaining or technologically advanced and for the designation of appropriate accrediting organizations. Current rule at 59A-25.003(2)(a), FAC, already defines life supporting or life sustaining equipment. Technologically advanced equipment is not defined as such.

Section 6. Creates s. 400.936, F.S., to require all licensed HME providers, effective January 1, 2006, to submit to the agency proof of accreditation as a prerequisite for licensure or license renewal. Any provider that does not submit proof of accreditation will be issued a temporary license and will have 60 days to submit proof of application to an accrediting organization. In order to receive a permanent license the provider must submit proof of accreditation within 180 days after submitting an application. HME providers who are licensed as of January 1, 2006, will have a period of time lasting until their next licensure renewal date to become accredited, and AHCA may issue them a temporary license until the review of their accreditation.

The bill requires AHCA to adopt rules designating appropriate accrediting organizations whose standards for accreditation are comparable to those required by this part for licensure.

Section 7. Amends s. 400.95, F.S., to require home medical equipment providers to inform patients of the toll-free telephone number of the central abuse hot line for purposes of reporting fraud. The bill redesignates the hotline, in this statute only, as the “central fraud and abuse hotline,” so consumers can report fraud and abuse. However, the statewide central abuse hotline which is established in the Department of Children and Family Services is not responsible for receiving reports of fraud.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:**A. Tax/Fee Issues:**

The bill authorizes AHCA to assess a survey fee of \$500 to cover the cost of conducting complaint investigations.

B. Private Sector Impact:

According to AHCA, based on current figures, 1,954 or 92 percent of the currently licensed HME 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 1,000 or more. This inspection fee is paid to JCAHO every 3 years to maintain accreditation. According to AHCA, accreditation of all providers will require that the 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.

The bill requires high-tech equipment providers to maintain premises that are fully accessible to all patients from 9:00 am to 5:00 p.m. daily and to employ and also have on call a respiratory therapist or registered nurse. Currently not all premises are fully accessible, as not all providers have show rooms or operate stores for persons to come in and purchase the equipment. Some premises are service centers for cleaning and repairing equipment or responding to mail orders. In addition, requiring high-tech providers to hire a certified respiratory therapist, or a registered nurse may increase providers' business costs by not allowing them to contract with an respiratory therapist or registered nurse. Increasing the amount of liability insurance coverage from at least \$250,000 to \$300,000 will increase provider insurance costs, but may be beneficial to consumers.

AHCA anticipates that some businesses will not seek accreditation and thus no longer be able to be licensed. The bill may result in a reduction in the number of HME providers due to costs associated with gaining accreditation. HME providers are not evenly distributed across the state. In the 16 counties of the Gainesville area, there are currently 108 licensed HME providers. In Miami-Dade County, there are 1,175 licensed providers. To what extent competition would be affected, and whether it would be most affected in urban or rural areas, cannot be determined.

HME providers who violate licensure standards must pay a survey fee of \$500 to cover the cost of complaint investigations and any follow-up visits conducted to verify the correction of the violation.

C. Government Sector Impact:

At the end of state fiscal year 2003-2004, the HME 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 periods 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.

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. The bill authorizes AHCA to assess a survey fee of \$500 to cover the cost of complaint investigations that result from the finding of a violation that was the subject of the complaint and any follow-up visits conducted to verify the correction of the violation.

Contracted services for a Senior Human Services Program Specialist at \$20 per hour are requested for the AHCA Home Care Unit to complete the duties required in this bill for rule development, notifications, issuance of temporary licenses, and taking administrative action against those providers not in compliance. This contract employee would be paid \$41,600 the first year and \$20,800 the second year.

Projected HME Expenditures and Revenues under the Provisions of this Bill

Projected revenues in FY 2005-2006 = \$458,154

This is estimated at \$540,153.85 (no growth) less the \$82,000 in inspection fees that would have been charged. It is anticipated that there will be \$164,000 less for a two-year period, thus \$82,000 would not be received in the first year.

Projected expenses in FY 2005 -2006 = \$529,876

This is based on the 2003-2004 amount of \$434,619, plus \$15,212 for inflation at 3.5 percent, 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. Thus a projected deficit of \$71,722 will occur.

Projected revenues for FY 2006-2007 = \$307,440

While there will be some applications from new providers, 20 to 25 percent of the existing providers will not obtain accreditation. Thus, it is estimated that 15 percent less revenue will be received. In addition, \$82,000 from the second year of inspection fees referred to above will not be received.

Projected expenses in FY 2006 –2007 = \$521,435

The contractor would be needed the first six months (\$20 X 1040 hours = \$20,800), but other expenses would remain plus inflation of 3.5 percent. 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. Thus, a deficit of \$213,995 is projected.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
