

STORAGE NAME: h0247b.hcl

DATE: March 31, 1999

**HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE LICENSING & REGULATION
ANALYSIS**

BILL #: HB 247

RELATING TO: Home Medical Equipment Providers

SPONSOR(S): Representative Goode

COMPANION BILL(S): CS/SB 276(l), HB 245(c), and SB 674(c)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:

- (1) HEALTH CARE LICENSING & REGULATION YEAS 9 NAYS 0
 - (2) HEALTH CARE SERVICES
 - (3) GOVERNMENTAL RULES & REGULATIONS
 - (4) HEALTH & HUMAN SERVICES APPROPRIATIONS
 - (5)
-

I. SUMMARY:

The bill requires licensure and establishes reasonable standards that home medical equipment [HME] providers must meet in order to conduct business in Florida. It defines HME providers as those who provide durable medical equipment and services related to the use of this equipment in a patient's home. It creates a two year licensure period with exemptions for certain entities already subject to licensure under Florida law. The exemptions include nursing homes, home health agencies, intermediate care facilities, hospitals and ambulatory surgical centers, and certain other licensed health care providers.

The bill requires that HME personnel who instruct patients on the operation of equipment to be trained. HME providers are to inform patients of operating hours, equipment warranties, and complaint procedures for after normal business hours. HME suppliers are required to provide equipment and services in accordance with a patient's plan of care or prescription, honor warranties, maintain equipment, and keep patient records.

The Agency for Health Care Administration (Agency) is to be the regulatory entity, and the bill creates authority to charge fees, conduct applicant criminal history and abuse registry background checks, perform on-site inspections, and assess administrative penalties.

This bill has an estimated fiscal impact of \$645,816 and 13 FTE's on state government, no fiscal impact on local government and an indeterminate impact on the private sector.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Currently, there are no existing laws that regulate the requirements for an individual or entity to start up and operate a medical equipment company in Florida to serve the general public.

There are approximately 8,800 Medicare-enrolled Durable Medical Equipment providers in the State of Florida. As of 12/30/98, there were 2,639 Medicaid-enrolled Durable Medical Equipment providers in Florida.

The Medicaid and Medicare programs in Florida have identified widespread fraud and quality concerns in the medical equipment industry. Procedures have been implemented to deter the enrollment of and payment to fraudulent providers through investigations by the Agency for Health Care Administration and other contributing organizations.

There have been significant concerns about the quality of care provided by these DME providers and their fraudulent activities. Many instances have been identified where medical equipment providers have delivered sophisticated life sustaining medical equipment to Medicaid patients and yet the provider offered no training on the operation of the equipment.

The Agency has taken significant steps to reduce the ability of fraudulent DME providers from enrolling in Medicaid, including stronger enrollment criteria and re-enrollment of all DME providers. These efforts have resulted in a reduction in the number of Florida Medicaid DME providers from 4,500 to 2,639. The Health Care Financing Administration (HCFA) has also implemented program safeguards to bar fraudulent providers from participating in the Medicare program.

B. EFFECT OF PROPOSED CHANGES:

This bill ensures the safety of Florida's citizens by creating a regulatory mechanism through the Agency for Health Care Administration for home medical equipment providers. It also creates a standard for licensure and regulation of medical equipment providers.

It establishes minimum standards for all providers subject to licensure, including maintaining trained personnel to provide HME services, assuring that patients are made aware of service hours and emergency service procedures, honoring all warranties, and answering any questions or complaints a consumer has about an item.

C. APPLICATION OF PRINCIPLES:

1. Less Government:

- a. Does the bill create, increase or reduce, either directly or indirectly:

- (1) any authority to make rules or adjudicate disputes?

Yes, the ability to create rules to implement the provisions of the new licensure law is included.

- (2) any new responsibilities, obligations or work for other governmental or private organizations or individuals?

The bill gives the Agency for Health Care Administration responsibility to administer this program. Businesses subject to licensure will have a responsibility to comply with licensure requirements and standards.

- (3) any entitlement to a government service or benefit?

No.

- b. If an agency or program is eliminated or reduced:

- (1) what responsibilities, costs and powers are passed on to another program, agency, level of government, or private entity?

N/A

- (2) what is the cost of such responsibility at the new level/agency?

N/A

- (3) how is the new agency accountable to the people governed?

N/A

2. Lower Taxes:

- a. Does the bill increase anyone's taxes?

No.

- b. Does the bill require or authorize an increase in any fees?

The bill requires a licensure and inspection fee of DME providers subject to licensure. All applicants must pay a biennial license processing fee. Those not exempt from standard licensure inspection will pay a fee for inspection. Those exempt from standard license inspection will not have to pay the inspection fee.

- c. Does the bill reduce total taxes, both rates and revenues?

No.

d. Does the bill reduce total fees, both rates and revenues?

No.

e. Does the bill authorize any fee or tax increase by any local government?

No, the only fees created are directly associated with the agency's cost of processing licensure including inspection.

3. Personal Responsibility:

a. Does the bill reduce or eliminate an entitlement to government services or subsidy?

No.

b. Do the beneficiaries of the legislation directly pay any portion of the cost of implementation and operation?

No. The beneficiaries are the users of medical equipment and the payers of health care who are expected to benefit from the deterrence of fraud. Although the cost of this regulation is borne by HME businesses, the cost will likely be passed on to the primary payers of these products and services which are Medicare, Medicaid, private insurance, and consumers.

4. Individual Freedom:

a. Does the bill increase the allowable options of individuals or private organizations/associations to conduct their own affairs?

No. The bill reduces the independence of home medical equipment providers who will now be subject to government regulation.

b. Does the bill prohibit, or create new government interference with, any presently lawful activity?

Yes. The bill makes it illegal to operate a home medical equipment business without a valid license.

5. Family Empowerment:

a. If the bill purports to provide services to families or children:

(1) Who evaluates the family's needs?

N/A

(2) Who makes the decisions?

N/A

(3) Are private alternatives permitted?

N/A

(4) Are families required to participate in a program?

N/A

(5) Are families penalized for not participating in a program?

N/A

b. Does the bill directly affect the legal rights and obligations between family members?

N/A

c. If the bill creates or changes a program providing services to families or children, in which of the following does the bill vest control of the program, either through direct participation or appointment authority:

(1) parents and guardians?

N/A

(2) service providers?

N/A

(3) government employees/agencies?

Yes. To protect families from fraud, unsafe or inadequate services.

D. STATUTE(S) AFFECTED:

Creates Part X of ch. 400, F.S.

E. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates Part X of Chapter 400, F.S., relating to home medical equipment providers.

Section 400.92, F.S., describes the legislative intent of this bill to provide licensure of home medical equipment providers and enforce basic standards that will insure quality home medical equipment, products and services.

Section 400.925, F.S., defines “home medical equipment” as any product defined by the Federal Drug Administration’s Drugs, Devices, and Cosmetic Act reimbursed under Medicare Durable Medical Equipment benefits, or reimbursed under the Florida Medicaid Durable Medical Equipment program, including oxygen products and equipment.

Section 400.93, F.S., establishes exemption status for nursing homes, home health agencies, hospices, hospitals, ambulatory surgical centers, intermediate care facilities, homes for special services, transitional living facilities, pharmacies, manufacturers and wholesale distributors. Provides for a two-year licensure period. Establishes the act of operating without a license as unlawful for those subject to this legislation.

Section 400.931, F.S., requires an application for licensure to include equipment and services offered, those with whom the provider contracts, demonstration of financial ability to operate which may be satisfied by submission of a \$50,000 surety bond, professional and commercial liability insurance, and compliance with Ch. 435, level 2 background screening requirements for the general manager and the financial officer. Also, any owner, officer, director, agent, managing employee, general manager, affiliated person, or any partner or shareholder having at least 5 percent interest of the licensee may also be screened if there is probable cause to believe that the individual was convicted of an offense prohibited under the level 2 standards in ch. 435.

Level 2 requirements include an abuse registry check through the Florida Department of Children and Family Services and criminal checks through the Florida Department of Law Enforcement and the Federal Bureau of Investigation.

Provides for a 90-day provisional license for new applicants during which time an inspection demonstrating substantial compliance must occur and screening results are received. Requires an application for renewal of license and change of ownership. Creates authority to collect biennial licensure and inspection fees. Permits AHCA to deny or revoke the license if the applicant has falsely represented a material fact in the application or has prior Medicaid or Medicare action taken against them.

Section 400.932, F.S., establishes administrative penalties and specifies the actions that are grounds for such penalties, providing for fines not to exceed \$5,000 per day, per violation. Establishes ability to impose a moratorium, the mandated cessation or suspension of the offering of equipment, when any action by the HME provide represents a threat to public health or safety.

Section 400.933, F.S., establishes the provision for inspections related to licensure, complaints, and direction from the federal Health Care Financing Administration. Provides for the acceptance of the survey or inspection of an accrediting organization, or acceptance of a valid medical oxygen retail establishment permit issued by the Department of Health in lieu of periodic licensure inspection by the agency.

Section 400.934, F.S., establishes minimum standards for all suppliers subject to licensure.

Section 400.935, F.S., creates authority to adopt rules establishing minimum standards relating to all entities of the agency.

Section 400.94, F.S., establishes minimum requirements for maintaining clinical records.

Section 400.95, F.S., requires home medical equipment suppliers to notify patients of a toll-free telephone number for the central abuse registry for reporting abuse of patients.

Section 400.953, F.S., requires background screening of home medical equipment provider personnel.

Section 400.955, F.S., establishes background screening requirements for home medical equipment supplier personnel, as defined in Ch. 435. Prohibits the use of information obtained during screening for any other purpose than to determine good moral character for employment.

Section 400.96, F.S., creates authority to institute injunctive proceedings.

Section 400.965, F.S., requires compliance with state and federal laws prohibiting patient referrals and rebates as a condition of licensure.

Section 2. Requires existing home medical equipment providers subject to licensure to submit application and fees by December 31, 1999.

Section 3. Appropriates 13 FTEs and \$701,370 from the Health Care Trust Fund to the agency to implement provisions of this act.

Section 4. Provides an effective date of July 1, 1999.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

	1999-00
1. <u>Non-recurring Effects:</u>	
Professional Staff- 12@\$2,132	25,584
Support Staff- 1 @ \$1,1469	1,469
Total Expenses (12)	27,053
Operating Capitol Outlay	
Professional Staff- 12@ \$3,167	38,004
Support Staff- 1 @ 3,247	3,247
Total Non-recurring OCO for 13 FTEs	41,251
Total Non-recurring Effects Health Care Trust Fund	68,304

2. <u>Recurring Effects:</u>	1999-00	2000-01
Licensure Processing Fees (\$300)	981,000	98,100
Inspection Fees (\$400)	588,800	58,800
Administrative Fines	50,000	50,000
Total Revenues Health Care Trust Fund	1,619,800	206,900
Expenditures:		
Full Time Equivalent Staff	13 FTE	13 FTE
Salaries and Benefits		
1 Administrative Secretary	20,769	27,693
1 Senior Human Services	34,427	45,903
1 Program Administrator	41,247	54,995
1 Health/Services Facilities Consultant	38,794	51,725
8 R.N. Specialists	36,976	49,302
1 Senior Attorney	36,976	49,302
Total Salaries and Benefits for 13 FTEs	449,133	598,844
Office Expenses for FTEs Professional Staff-11 @ \$11,057	121,627	121,627
Support Staff-1 @ \$1,752	6,752	6,752
Total Recurring Expenses for 13 FTEs	128,379	128,379
Total Recurring Expenditures	577,512	727,223
3. <u>Long Run Effects Other Than Normal Growth:</u>		
None.		
4. <u>Total Revenues and Expenditures:</u>		
Health Care Trust Fund		
Revenues:		
Total Revenues	1,619,800	206,900
Expenditures:		
Total Salaries and Benefits	449,133	598,844
Total Expenses	155,432	128,379
Operating Capital Outlay	41,251	0
Total Expenditures	645,816	727,223
Summary:		
Total Revenues	1,619,800	206,900
Prior Fiscal Year Revenue (carried over)		973,984

Less: Expenditures	(645,816)	(727,223)
Total Balance	973,984	453,661

B. FISCAL IMPACT ON LOCAL GOVERNMENTS AS A WHOLE:

1. Non-recurring Effects:

None.

2. Recurring Effects:

None.

3. Long Run Effects Other Than Normal Growth:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

1. Direct Private Sector Costs:

Each applicant will pay a licensure fee, up to \$300 for initial licensure and biennial renewal. The applicants subject to inspection will pay an inspection fee, up to \$400, biennially.

The costs associated with background screening will be borne by those subject to screening. The cost for level 1 screening includes \$6 for the Department of Children and Family Services abuse registry and \$15 for the Florida Department of Law Enforcement, totaling \$21. The cost for level 2 screening includes the same \$6 for abuse registry plus \$39 for the Federal Bureau of Investigation, totaling \$45.

2. Direct Private Sector Benefits:

This bill provides assurance that businesses subject to this licensure will meet minimal acceptable standards, and serve as a deterrent to fraud.

3. Effects on Competition, Private Enterprise and Employment Markets:

Minimum standards for licensure should even the playing field in terms of quality, since all providers will be required to meet the same minimum standards.

Background screening will effect the employability of individuals who have been convicted of certain crimes, keeping them out of an industry that has become an easy prey for fraud, and keeping individuals with abuse or neglect backgrounds out of patients' homes. This employment exemption is not expected to have a major impact on employment markets in general.

D. FISCAL COMMENTS:

Per the Agency for Health Care Administration, licensure fees for the first year are estimated to be from 3,270 providers. Licensure fees expected in the second fiscal year are for new businesses applying for licensure (10% growth) of 327.

Year 1 fees are based on 3,270 providers x \$300 = \$981,000 in licensure fees. Based on an estimate that 45% of all providers will require standard licensure inspections (3,270 x 45% = 1,472 providers).
1,472 providers x \$400 = \$588,800 in inspection fees
Administrative fines \$50,000
Total estimated revenues: \$1,619,800

Year 2 fees are based on an estimated 10% increase, 5% on growth in this industry and 5% on unidentified providers from first year:
3270 providers x 10% growth = 327 providers x \$300 = \$98,100 in licensure fees.
327 providers x 45% subject to inspection = 147 providers x \$400 = \$58,800 in inspection fees.
Administrative fines \$50,000.
Total estimated revenues: \$206,900

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require counties or municipalities to spend funds or to take and action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

On March 29, the Committee on Health Care Licensing & Regulation adopted two amendments:

Amendments 1 requires HME providers to adhere to state law and rules or federal law and regulations and;

Amendment 2 provides assisted living facilities with exemption status.

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VII. SIGNATURES:

COMMITTEE ON HEALTH CARE LICENSING & REGULATION:

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