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DATE: February 22, 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
 - (2) HEALTH CARE SERVICES
 - (3) GOVERNMENTAL RULES & REGULATIONS
 - (4) HEALTH & HUMAN SERVICES APPROPRIATIONS
 - (5)
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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. Through concentrated detection and investigation efforts by the Agency for Health Care Administration, Medicare's Operation Restore Trust Initiative and the Thirteenth Statewide Grand Jury, durable medical equipment (DME) Medicaid and Medicare provider participation requirements and pre-payment procedures have been implemented to prevent enrollment of and payment to fraudulent providers.

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.

Although the cost of health care fraud can only be estimated, according to the National Health Care Anti-Fraud Association (NHCAA), in May 1992, citing health insurance industry sources, the U. S. General Accounting Office (GAO) reported to Congress that fraud loss amounts to an estimated 10% of the nation's total annual health care expenditures. NHCAA also reports that national health care expenditures in 1993 totaled \$884.2 billion. Blue Cross/Blue Shield (BC/BS), of South Carolina is responsible for investigating durable medical equipment fraud in the Southeast region of the United States, which consists of 14 Southeastern states, Puerto Rico and the Virgin Islands. BC/BS estimates that 50% of DME fraud complaints for the region originate in Dade and Broward counties. One-third of their investigating staff is devoted to complaints from Dade and Broward, one-third to the rest of Florida and Puerto Rico, and one-third to the other 13 states and the Virgin Islands. This information indicates that DME fraud in Florida may be far in excess of the national average of 10%.

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. The Florida Medicaid program spent approximately \$36 million on DME reimbursement in fiscal year 97/98. Even with the Agency's and HCFA's efforts which have created barriers to DME fraud, it is not unreasonable to use the national 10% average to estimate that fraud will cost \$3.6 million in the Medicaid program alone this year.

B. EFFECT OF PROPOSED CHANGES:

The home medical equipment (HME) licensing legislation creates a regulatory mechanism through the Agency for Health Care Administration for home medical equipment providers. It creates standards 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.

This bill defines home medical equipment products typically considered to be durable medical equipment when the product requires related support services by the provider. These services are equipment management, consumer instruction, including selection, delivery, set-up, and maintenance of equipment, and other related services for use of the product at home.

It establishes administrative penalties, and fines not to exceed \$5,000 per day, per violation. Establishes the ability to impose a moratorium, the mandated cessation or suspension of the offering of equipment, when any condition in the HME providers' business operations represents a threat to public health or safety.

This bill has a fiscal impact on state government of \$645,816 and 13 FTEs.

The bill takes effect on July 1, 1999.

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 terms used in this bill. 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. Home medical equipment does not include prosthetics or customized orthotics.

Defines "home medical equipment services" as management and consumer instruction, including selection, delivery, set-up, maintenance of equipment, and other related services for use of home medical equipment in the consumer's regular or temporary place of residence.

"Home medical equipment providers" are defined as those offering home medical equipment (HME) products and services, or HME products that require HME service.

Section 400.93, F.S., defines those subject to licensure, exempting 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 when not selling directly to consumers, providers operated by the federal government, and licensed health care professionals who utilize HME in the course of their practice, but do not sell HME to patients. 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. These include: providing at least one category of equipment directly; filling orders from its own inventory; maintaining trained personnel to provide HME services; assuring that patients are made aware of service hours and emergency service procedures; honoring all warranties express and implied under applicable state law; answering any questions or complaints a consumer has about an item or use of an item that they buy or rent; maintaining and repairing items rented to consumers; accepting returns of substandard or unsuitable items from consumers; disclosing consumer information to each consumer who rents or purchases items, including all applicable warranty information and the provider standards to which it must conform. In addition, the standards include; maintaining patient payment and service records and ensuring their confidentiality; designating appropriate staff as intake coordinators; assuring that order intake personnel are appropriately trained in the types of equipment and products, commonly occurring medical conditions, service procedures, third-party billing, and insurance requirements and coverage; train intake coordinators in a basic understanding of patient and caregiver needs; provision of home care patient crisis management; procedures for maintaining a record of employment history, including background screening of all home medical equipment provider personnel; maintaining safe premises; and maintaining compliance with all other state and federal laws.

Section 400.935, F.S., creates authority to adopt rules establishing minimum standards relating to training requirements of personnel, licensure application and renewal, licensure and inspection fees, financial ability to operate, administration of a HME provider, maintenance of patient records, provision of equipment and services in accordance with plans of treatment, standards for contractual arrangements, physical location, and identification of HME that typically requires an HME service.

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. Level 1 requirements include abuse registry checks through the Florida Department of Children and Family Services and criminal checks through the Federal Bureau of Investigation. Provides for exemptions to prevent disqualification from employment. Requires screening for employees hired on or after July 1, 1999, the effective date of this bill. Within 54 days of the start of employment, the employee must submit information necessary to conduct the required screening. Employment must be probationary status pending the results of screening, and must be terminated for non-compliance. Allows use of screening results for up to two years. 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. Provides for these providers to be deemed to meet licensure requirements until the agency acts upon their application. They are prevented from operating without a license after that date.

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:

	FY 1999-00	2000-01
1. <u>Non-recurring Effects:</u>		
Professional Staff- 12@\$2,132	25,584	0
Support Staff- 1 @ \$1,1469	1,469	0
Total Expenses (12)	27,053	0
Operating Capitol Outlay		
Professional Staff- 12@ \$3,167	38,004	0
Support Staff- 1 @ 3,247	3,247	0
Total Non-recurring OCO for 13 FTEs	41,251	0
Total Non-recurring Effects Health Care Trust Fund	68,304	0
2. <u>Recurring Effects:</u>		
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. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

Health Care Trust Fund

Revenues:

Total Revenues	1,619,800	206,900
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Expenditures:

Total Salaries and Benefits	449,133	598,844
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Total Expenses	155,432	128,379
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Operating Capital Outlay	41,251	0
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Total Expenditures	645,816	727,223
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Summary:

Total Revenues	1,619,800	206,900
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Prior Fiscal Year Revenue (carried over)		973,984
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Less: Expenditures	(645,816)	(727,223)
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Total Balance	973,984	453,661
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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:

The licensure fees collected will impact those subject to licensure. Each applicant will pay a licensure fee, up to \$300 for initial licensure and biennial renewal. Each applicant subject to inspection will pay an inspection fee, up to \$400, biennially. Providers are also subject to administrative fines for non-compliance.

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:

None.

VII. SIGNATURES:

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