

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 276

SPONSOR: Senator Brown-Waite

SUBJECT: Home Medical Equipment Providers; Regulation

DATE: February 17, 1999 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Carter</u>	<u>Wilson</u>	<u>HC</u>	<u>Favorable/CS</u>
2.	_____	_____	<u>FP</u>	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____

I. Summary:

Committee Substitute for Senate Bill 276 creates part X of chapter 400, Florida Statutes (F.S.), requiring biennial licensure of home medical equipment providers and establishing basic standards to ensure the provision of quality equipment, products and services by such providers. A licensure fee of up to \$300 and an inspection fee of up to \$400 is required of all applicants. Home medical equipment providers are persons or entities, except for certain exempted entities, that sell or rent the following to consumers: oxygen and related respiratory equipment, customized wheelchairs and related seating and positioning, or any products reimbursed under Medicare Part B Durable Medical Equipment benefits or the Florida Medicaid durable medical equipment program. Home medical equipment providers may also supply home medical equipment services such as equipment management and consumer instruction in the consumer’s regular or temporary place of residence. However, the following are explicitly excluded from home medical equipment provider regulation: prosthetics or orthotics or any splints, braces, or aids custom fabricated by a licensed health care practitioner. The bill delegates to the Agency for Health Care Administration the responsibilities of licensing and oversight of home medical equipment providers. A key prerequisite of licensure under this bill is background screening of applicants requesting authorization to serve as home medical equipment providers *and* home medical equipment provider personnel. An appropriation of \$701,370 and 13 full-time-equivalent positions are provided for in the bill.

This bill creates sections 400.92, 400.925, 400.93, 400.931, 400.932, 400.933, 400.934, 400.935, 400.94, 400.95, 400.953, 400.955, 400.96, and 400.965, Florida Statutes, and two undesignated sections of law.

II. Present Situation:

Home medical equipment is often referred to as “durable medical equipment.” Throughout this section of the analysis, reference will be made to durable medical equipment or DME, because of the considerable references to and use of information provided in the Thirteenth Statewide Grand

Jury (Grand Jury) reports. However, reference to home medical equipment or HME will be used in all other sections of the analysis, to conform to the terminology used in Senate Bill 276. The terms are used interchangeably.

In its May 6, 1996, report entitled *Medicaid Fraud in the Area of Durable Medical Equipment*, case number 86,726, in the Florida Supreme Court, the Grand Jury defined DME as *equipment that can be used repeatedly, serves a medical purpose, and is appropriate for use in a patient's home. DME typically consists of, but is not limited to, oxygen delivery systems, wheelchairs, orthotics, bandages, prosthetic devices, hospital beds, crutches, and commodes.* A partial listing obtained from various sites through the Internet indicate all of the following are marketed as either DME or HME: diabetic bracelets and other supplies for diabetics; four-wheeled walkers; mobility aids such as walkers, electric scooters, lift chairs and lift beds, stair lifts, and elevating devices; bath safety equipment; canes; intercoms; emergency and nurse-call systems; adaptive clothing; vacuum regulators; range-of-motion splints; respiratory disposables; drug infusion equipment; bed alarms, chair alarms, and other fall prevention devices; respiratory therapy equipment; and physical therapy equipment.

The listed equipment, as well as unlisted equipment and related services, may or may not be paid for by private insurers, the Medicare program, or the Medicaid program. However, subsection 409.906(10), F.S., empowers the Agency for Health Care Administration (AHCA) to *authorize and pay for certain durable medical equipment and supplies provided to a Medicaid recipient as medically necessary.* The Grand Jury stated that:

In order for the provider to file a claim for Medicaid funds, the equipment must have been ordered by a physician through what is known as a Certificate of Medical Necessity, or CMN. Upon receipt of the CMN, the provider may supply the equipment to the Medicaid recipient and bill the State pursuant to a schedule of allowable costs. The allowable costs are determined by the Agency [AHCA]. In some instances, the cost is in the form of a rental for a particular piece of equipment, such as a hospital bed, but then a cap is imposed on the total number of billings that can be submitted for a specific patient.

Several types of licensed health care providers offer DME supplies and services. For example, hospitals, home health agencies, and pharmacies may provide such equipment, supplies, and services. Additionally, a significant number of businesses operate to furnish customers or patients DME equipment, supplies, and services on a retail basis. They may or may not manufacture such equipment, and although they may offer instruction on how to use the equipment or supplies they do not develop the plan of treatment or make a determination of patient therapeutic needs as a function of their operations. It is not known how many DME businesses are located in Florida or how many operate in Florida from outside the state. Currently, DME providers are not regulated under Florida law.

The Grand Jury was convened in January 1996, to investigate cases involving fraud against the government, with an emphasis on Medicaid fraud. The Grand Jury, which was in existence until June 1997, issued four substantive reports, the theme of which was the state's need to be ever vigilant to prevent unscrupulous providers from entering the Medicaid Program. As to the Grand Jury's findings, DME providers were specifically the subject of the initial report of the Grand

Jury, dated May 6, 1996, and a review of actions, to date, to address the Grand Jury's concerns was included in the third interim report on Medicaid fraud filed on December 11, 1996. Virtually all of the recommendations raised in the initial report have been implemented, either administratively by AHCA under its then existing rulemaking authority or by subsequent specific legislative action. The third report of the Grand Jury, in reviewing efforts to implement its previous recommendations, refers to AHCA's desire to license DME providers; the Grand Jury endorsed this proposal.

In its May 6, 1996, report the Grand Jury stated, "We have learned that the methods of fraud are varied and innovative, ranging from non-existent providers to forged supporting documentation. This type of fraud is also expensive. Agency [AHCA] representatives estimate that \$3.5 million is stolen from the DME program annually." The Grand Jury also stated:

We have found significant abuse in this program, from the initial application process to the final payment stage. Our investigations have revealed the following scenarios: Billings for services not provided, delivering and billing for unnecessary equipment, and overbilling. In order to falsify the billing information, the criminals buy Medicaid identification numbers from recipients or brokers, and may also pay physicians for the use of their signatures on certificates for medical necessity.

We strongly commend the recent enforcement and prevention actions of the Agency as both positive and necessary. The Agency has the authority to revise the provider qualification requirements and to enter into new contracts as the need arises, and it must continue to diligently exercise this authority in order to be an effective regulator.

Following are highlights of actions taken to deter fraud and abuse in the Medicaid Program: complete revamping of the provider agreement, and the inclusion of business partner identifying information; re-enrollment of all provider types; criminal background checks (FDLE and FBI); surety bond requirements for high-risk provider groups; on-site inspections prior to entering provider agreements; and numerous claims processing and payment system edits. As a result of these changes, the number of Medicaid-authorized DME providers has decreased from 4,000 to 1,560. The agency estimated Medicaid savings in the DME area to be \$20 million annually.

The main impetus behind much of the fraudulent conduct is the lax regulatory "infrastructure" of the *Medicare* program coupled with its relatively high levels of reimbursement, minimal restrictions on duration of services, confusing labyrinth of reimbursement guidelines developed by and administered by contracted fiscal agents, and insufficient regulatory oversight. In contrast, the private insurance industry reports that it has fairly stringent guidelines as to the amount, duration, and scope of DME services that insurers will reimburse. Consequently, similar fraudulent abuses are not perceived to take place as frequently in the private insurance industry.

III. Effect of Proposed Changes:

Section 1. Creates part X of chapter 400, F.S., containing the following summarized provisions:

Section 400.92 Legislative intent. Declares the intent of the Legislature to provide for the licensure of HME providers and to provide for the development, establishment, and

enforcement of basic standards to ensure quality home medical equipment, products, and services.

Section 400.925 Definitions. The following terms are defined for use in part IX of chapter 400, F.S.: “accrediting organizations,” “affiliated person,” “agency,” “applicant,” “consumer,” “department,” “general manager,” “home medical equipment,” “home medical equipment provider,” “home medical equipment provider personnel,” “home medical equipment services,” “licensee,” “moratorium,” “person,” “premises,” and “residence.”

Section 400.93 Home medical equipment providers to be licensed; expiration of license; exemptions; unlawful acts; penalties. Requires licensure under part IX, chapter 400, F.S., of *any person or entity that holds itself out to the public as providing home medical equipment and services or accepts physician orders for home medical equipment and services or providing home medical equipment that typically requires home medical equipment services.* Home medical equipment providers are required to be licensed by AHCA to operate in Florida or to provide HME and HME services to consumers in Florida. A license is valid for two years from its effective date. A license is required for all HME providers operating on separate premises, even if operated under the same management.

Subsection (5) of this section exempts from the licensure requirements under part IX of chapter 400, F.S., several entities, *unless* such an otherwise exempted entity has a *separate* company, corporation, or division that *is in the business of providing home medical equipment and services for sale or rent to consumers at their regular or temporary place of residence.* The following entities are exempted from licensure as HME providers:

1) providers operated by the federal government; 2) state licensed nursing homes; 3) state licensed home health agencies; 4) state licensed hospices; 5) state licensed intermediate care facilities; 6) homes for special services; 7) transitional living facilities; 8) state licensed hospitals and ambulatory surgical centers; 9) manufacturers and wholesale distributors when not selling directly to consumers; (10) licensed health care practitioners who utilize HME in the course of their practice, but who do not sell or rent HME to their patients; and (11) state licensed pharmacies.

Under this section, it is unlawful for any person to advertise or offer HME and HME services to the public, unless the person has a valid license or is exempted from licensure under subsection (5) of this section, and it is unlawful for a licensee to advertise or indicate to the public that it holds an HME provider license other than the one it has been issued. To do so subjects the person or licensee to injunction proceedings that AHCA is authorized to initiate and such conduct is designated a violation of the Florida Deceptive and Unfair Trade Practices Act. Additionally, a first occurrence of such conduct is designated as a second degree misdemeanor, a second and any subsequent violation is designated a first degree misdemeanor.

Operation of an unlicensed HME provider is sanctionable as follows: 1) a third degree felony; 2) AHCA fraud referral to the appropriate government reimbursement program that has paid for services; and 3) if concurrently operating licensed and unlicensed premises, an AHCA-imposed moratorium on accepting new patients or revocation of existing licenses until the

unlicensed premises are licensed. A provider that is found to be operating without a license may apply for licensure, but must cease operations until a license *is awarded by AHCA*.

Section 400.931 Application for license; fee; provisional license; temporary permit.

Application for an HME provider license must be made under oath on a form furnished by AHCA. The applicant must provide satisfactory proof (for example, among other requirements, submitting reports, by category, of the equipment and services to be provided) of compliance with part IX of chapter 400, F.S., and applicable administrative rules. The application must be accompanied by a nonrefundable license fee of up to \$300 for license processing *and* a fee up to \$400 for inspection. State, county, and municipal governments applying for an HME license are exempted from payment of these fees.

Initial licensure applicants must demonstrate financial ability to operate, which may be accomplished by submission of a \$50,000 surety bond to AHCA. Applicants for licensure renewal that have demonstrated financial *inability* to operate must, also, demonstrate financial ability to operate. Also, an HME provider must obtain and maintain professional and commercial liability insurance of a minimum of \$250,000 per claim, and must submit proof of such coverage with the licensure application. The coverage is required for contracted services as well.

Each licensure applicant must submit to level 2 background screening, as provided under chapter 435, F.S., of its general manager and financial officer. Additionally, AHCA is authorized to require background screening for a member of an applicant's or licensee's board of directors or an officer or an individual owning 5 percent or more of the licensee *if AHCA has probable cause to believe that such individual has been convicted of an offense prohibited under level 2 standards for screening* under chapter 435, F.S. However, an applicant or licensee is exempted from the screening requirement upon submitting proof of compliance with level 2 background screening requirements under any other state health care licensure requirements within the previous 5 years. If an applicant has been excluded, permanently suspended, or terminated from the Medicare or Medicaid program, the applicant must submit a description and explanation of such actions along with its application, except that submission of proof of compliance with ownership disclosure and control interest requirements of the Medicare or Medicaid program exempts an applicant from the need to submit such documentation. A similar requirement is made relating to the conviction of an offense prohibited under level 2 standards of chapter 435, F.S., by a member of the applicant's board of directors, its officers, or any individual owning 5 percent or more of the applicant, except for certain persons associated with not-for-profit organizations. An applicant for licensure renewal is required to submit to AHCA, under penalty of perjury, an affidavit of compliance with background screening requirements.

The agency may not grant a license to an applicant who fails to meet the level 2 screening standards, unless an exemption from disqualification has been granted by the agency under chapter 435, F.S. The Agency for Health Care Administration is also authorized to deny a license to, or revoke the license of, any potential licensee if the applicant has falsely represented a material fact or has omitted a material fact from its application or has previously been excluded, permanently suspended, or terminated from the Medicaid or Medicare program.

An approved licensure applicant must be issued a provisional license by AHCA that remains in effect for 90 days pending receipt of the FBI's background screening and during which period AHCA must conduct an inspection survey to further determine that the applicant is in substantial compliance with licensure requirements. If substantial compliance is demonstrated, AHCA is required to issue a standard license that expires 2 years after the effective date of the provisional license. This section also provides other requirements and standards pertaining to licensure renewal, change of ownership, and change of general managers. A provisional license may be issued to an HME provider against whom a proceeding for revocation or suspension, or for denial of a renewal application is pending at the time of licensure renewal. Such a provisional license is to remain in effect until final disposition of such proceedings by AHCA. If judicial relief from AHCA's final disposition is sought, the court may issue a temporary permit for the duration of the judicial proceeding.

Section 400.932 Administrative penalties; injunctions; emergency orders; moratoriums.

For certain specified violations of part IX of chapter 400, F.S., or applicable administrative rules, an HME provider is subject to penalties and sanctions imposed by AHCA. Such providers may be denied a license, have their license revoked or suspended, have their operations enjoined, or be fined up to \$5,000 per violation, per day. Additionally, AHCA may issue an emergency order immediately suspending or revoking an HME provider license or impose an immediate moratorium when it determines that *any condition within the responsibility of the home medical equipment provider presents a clear and present danger to public health and safety.*

Section 400.933 Licensure inspections and investigations. The Agency for Health Care Administration is required to make or cause to be made, as it considers necessary, licensure inspections, inspections directed by the federal Health Care Financing Administration, and licensure complaint investigations. In lieu of its own periodic inspections for licensure, AHCA is required to accept the survey or inspection of an accrediting organization if the accreditation is not provisional and the HME provider authorizes release of, and AHCA receives the report of, the accrediting organization or a copy of a valid medical oxygen retail establishment permit issued by the Department of Health under chapter 499, F.S.

Section 400.934 Minimum standards. This section lists the minimum requirements that an HME provider must meet to obtain and maintain a license. The standards are generally typical of all state regulatory requirements for health care providers, except that they are tailored to HME providers. However, some distinctive requirements are that an HME provider must: provide at least one category of equipment directly, filling orders from its own inventory; maintain and repair directly, or through a service contract with another company, items rented to consumers; at the time of the initial delivery, set up an appropriate follow-up HME service schedule as needed for such times as, but not limited to, periodic maintenance, supply delivery, and other related activities; accept returns of substandard or unsuitable items from consumers; and upon request by the consumer or as otherwise required by state or federal laws, rules, and regulations, assist consumers with meeting the necessary filing requirements to obtain third-party payment to which a consumer may be entitled.

Section 400.935 Rules establishing minimum standards. The Agency for Health Care Administration is delegated authority to adopt, publish, and enforce rules to implement part

IX of chapter 400, F.S., which must provide reasonable and fair minimum standards relating to ten enumerated areas. The ten areas of specific rulemaking authority provided under the bill are: 1) qualifications and minimum training requirements of all HME provider personnel, 2) license application and renewal, 3) license and inspection fees, 4) financial ability to operate, 5) administration of HME providers, 6) procedures for maintaining patient records, 7) ensuring that HME and HME services provided by an HME provider are in accordance with the plan of treatment established for each patient, when provided as a part of a plan of treatment, 8) contractual arrangements for the provision of HME and HME services by providers not employed by the HME provider providing for the consumer's needs, 9) physical location and zoning requirements, and 10) HME requiring HME services.

Section 400.94 Patient records. Home medical equipment providers are required to maintain, for each patient, a patient record that includes HME and HME services the HME provider has provided. Specifically, the records must contain: any physician's order or certificate of medical necessity, if the equipment was ordered by a physician; signed and dated delivery slips verifying delivery; notes reflecting all services and maintenance performed, and any equipment exchanges; the date on which rental equipment was retrieved; and such other information as is appropriate to specific patients in light of the particular equipment provided to them. Home medical equipment providers are required to retain and maintain patient records for 5 years following termination of services. If a patient transfers to another HME provider, a copy of his or her record must be provided to the other HME provider, upon request.

Section 400.95 Notice of toll-free telephone number for central abuse registry. A consumer and the consumer's immediate family, if appropriate, must be informed of the right to report abusive, neglectful, or exploitative practices on or before the first day HME is delivered by a state licensed HME provider. Home medical equipment providers are required to establish appropriate policies and procedures for notifying consumers of this right. Additionally, consumers must be provided, in a clearly legible manner, the statewide toll-free telephone number for the central abuse registry with language that states: "*To report abuse, neglect, or exploitation, please call toll-free 1-800-962-2873.*"

Section 400.953 Background screening of home medical equipment provider personnel. Requires all HME provider personnel to undergo level 1 employment screening in accordance with chapter 435, F.S. An exemption from employment disqualification may be granted by AHCA. The general manager of each HME provider must annually sign an affidavit, under penalty of perjury, attesting that all personnel hired on or after July 1, 1999, who enter the home of a patient in the capacity of their employment have been screened and all other personnel have worked for the HME provider continuously since before July 1, 1999. However, AHCA is required to accept proof of compliance with the screening requirements relating to state employment, licensure as a nurse, or employment in certain specified health care or social services facilities or for the provision of certain specified services in lieu of employment screening under this section, if the person has been continuously employed in the same type of occupation for which he or she is seeking employment without a breach in service of no more than 180 days, the proof of compliance is not more than 2 years old, and the person has been screened by FDLE and through the central abuse registry and tracking system maintained by the Department of Children and Family Services. Employers and

contractors are required to *directly* provide proof of compliance with screening requirements to other employers and contractors. A potential employer or contractor may not accept proof of compliance from the person who is subject to screening. A licensed HME provider who terminates an employee's employment due to receipt of notice of a confirmed report of adult abuse, neglect, or exploitation is immunized from liability. The cost of screening is the responsibility of the HME provider or the screened person, at the provider's discretion. Certain misuse of information obtained through the screening process or operating or attempting to operate a licensed HME provider with personnel who do not meet the minimum standards for good moral character, as required under this section, are designated a first degree misdemeanor and misuse of information obtained from juvenile records is designated a third degree felony.

Section 400.955 Procedures for screening of home medical equipment provider personnel. Requires a person employed by an HME provider to submit, within 5 working days after starting to work, information necessary for employment screening and screening through the central abuse registry and tracking system maintained by the Department of Children and Family Services. Additionally, the employee must sign an affidavit stating whether the person meets the minimum standards for good moral character. The employee is made responsible for submitting, within 30 days, all missing information necessary for screening subject to automatic disqualification from employment for failure to produce such information or failure to show reasonable efforts to obtain the information. Home medical equipment personnel hired subsequent to July 1, 1999, must be placed on probationary status pending determination of compliance with minimum standards for good moral character. The general manager of each HME provider must annually sign an affidavit, under penalty of perjury, warranting that all personnel hired on or after July 1, 1999, have been screened and that its remaining personnel have worked for the provider continuously since before July 1, 1999. Home medical equipment providers must automatically terminate the employment of personnel found in noncompliance with the minimum standards for good moral character, unless such employees have been exempted from disqualification, as provided in the bill.

Section 400.96 Injunction proceedings. Authorizes AHCA to institute injunction proceedings when it determines that an HME provider has violated a provision under part IX of chapter 400, F.S., as created in this bill, or applicable administrative rules. The violation must constitute an emergency affecting the immediate health and safety of a patient or consumer.

Section 400.965 Prohibited acts. Requires applicants, as a condition of licensure, to comply with state and federal laws relating to prohibited patient referrals and rebates.

Section 2. Provides for licensure of HME providers in existence on the effective date of the bill. Such provider, assuming the bill becomes law in 1999, must submit an application and fees as specified in the bill for licensure by December 31, 1999. The Agency for Health Care Administration, until it acts to deny or grant the initial licensure application, must deem as meeting licensure requirements an existing provider that submits an application and the appropriate fees prior to December 31, 1999. However, an existing provider that submits an application for licensure *after* December 31, 1999, may not continue to operate its business until AHCA approves its application and the applicant obtains its license.

Section 3. Provides an appropriation from the Health Care Trust Fund of \$701,370 and allocates 13 full-time-equivalent staff positions to AHCA to implement the provisions of the bill.

Section 4. Provides for the bill to take effect July 1, 1999.

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:

Section 400.94, F.S., as created in this bill, declares patient records of HME providers to be patient records within the meaning of s. 455.667, F.S. Subsections 455.667(7) and (8), F.S., exempt patient records in the possession of the Department of Health or a regulatory board from the Public Records Law. Additionally, under the bill, AHCA may come into possession of such records through its regulatory jurisdiction and oversight. Senate Bill 674 is the companion bill filed for consideration of the Public Records Law exemption issues raised in this bill.

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 establishes the following biennial fees: license processing fee not to exceed \$300 and an inspection fee not to exceed \$400. The Agency for Health Care Administration expects to charge up to the cap for both licensure and inspection fees. As a result, biennial licensure, inspection fees, and projected administrative fine revenues are estimated to be \$1,826,700 over the first two years of regulation. The total two-year fiscal projection of \$1,826,700 from the agency includes an estimate of 10% growth in first-time licensure applicants during the second year of the biennial licensure period resulting in estimated revenues of \$98,100 from licensure fees and \$58,800 from inspection fees during the second year. The agency's fiscal analysis reflects expenditures only from paid-in licensure fees and other regulatory fees and does not include any allocations from the General Revenue Fund.

B. Private Sector Impact:

Home medical equipment providers will be subject to licensure costs of up to \$700 every two years that they are not currently required to incur. Initial applicants for HME licensure must submit a \$50,000 surety bond. Providers are required to obtain and maintain professional and

commercial liability insurance coverage of a minimum of \$250,000 per claim. Subcontractors of an HME provider are required to have a minimum of \$250,000 per claim liability insurance coverage as well. Additionally, HME providers are made subject to administrative fines of up to \$5,000 per violation, per day for violating licensure requirements.

C. Government Sector Impact:

Section 3 of the bill provides an appropriation of \$701,370 from the Health Care Trust Fund, and 13 full-time-equivalent staff positions.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

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