STORAGE NAME: H0759
DATE: March 20, 1997

HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH CARE STANDARDS & REGULATORY REFORM
BILL RESEARCH & ECONOMIC IMPACT STATEMENT

BILL #: HB 759

RELATING TO: Home Medical Equipment Suppliers

SPONSOR(S): Representative Geller

STATUTE(S) AFFECTED: Creates sections 400.81, 400.815, 400.82, 400.821, 400.822, 400.823, 400.824, 400.825, 400.83, 400.84, 400.843, 400.845, 400.85, 400.86, 400.65, F.S.

COMPANION BILL(S): SB 2232 (s), HB 757 (c), SB 2234 (c)

ORIGINATING COMMITTEE(S)/COMMITTEE(S) OF REFERENCE:
(1) HEALTH CARE STANDARDS & REGULATORY REFORM
(2) GOVERNMENTAL RULES & REGULATIONS
(3) FINANCE & TAXATION
(4) HEALTH & HUMAN SERVICES APPROPRIATIONS
(5)

I. SUMMARY:

The bill requires licensure of home medical equipment (HME) providers and creates standards that HME operators must meet 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 residence. It creates a two year licensure period with licensing exemptions for certain entities already subject to licensure under Florida law. The exemptions include nursing homes, home health agencies, hospices, hospitals, and certain other licensed health care providers.

The Agency for Health Care Administration is identified as 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. The background checks include Florida Department of Law Enforcement (FDLE) criminal history and abuse registry checks for owners and employees. Owners and general managers are also subject to Federal Bureau of Investigation (FBI) checks. Provisional licenses may be issued and general managers may be employed pending FBI results.

The bill establishes minimum training standards for HME personnel who instruct patients on operation of equipment. It requires HME operators to inform patients of operating hours, warranties, and complaint procedures, and to establish emergency service procedures for after normal business hours, warranties, and complaint procedures. It requires HME operators to provide equipment and services in accordance with a patient's plan of care or prescription, to honor warranties, maintain equipment, and keep patient records.

The bill has a fiscal impact on state government, and no fiscal impact on local government or the private sector.

II. SUBSTANTIVE ANALYSIS:

A. PRESENT SITUATION:

Currently, there are no existing statewide regulatory requirements for an individual or entity to start up and operate a medical equipment business in Florida and serve the general public. Those HME providers who deal with oxygen are presently under the jurisdiction of the Department of Health, Board of Pharmacy, and pay an annual inspection fee for the oxygen requirement only.

There are approximately 8,800 Medicare-enrolled Durable Medical Equipment suppliers and approximately 1,560 Medicaid-enrolled Durable Medical Equipment suppliers in Florida.

Studies relating to the Medicaid and Medicare Programs in Florida have identified fraud and quality concerns in the medical equipment industry. The agency has indicated that a number of home HME's have filed claims with Medicare or Medicaid when in fact, no services were provided, resulting in Grand Jury investigations. 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 developed and put in place to prevent enrollment of and payment to fraudulent providers.

Some medical equipment providers have not offered instructions on how to access help if there are questions about operation of the equipment or what to do if the equipment malfunctions.

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 fraud investigation staff is devoted to handling 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 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 1,560. 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 expects to spend $27 million on DME reimbursement in fiscal year 96/97. Even with the agency's and HCFA's efforts,

which have attempted to create barriers to DME fraud, it is not unreasonable to use the national 10% average to estimate that fraud will cost $2.7 million in the Medicaid program alone this year.

B. EFFECT OF PROPOSED CHANGES:

The proposed home medical equipment (HME) licensing legislation would create a regulatory mechanism through the Agency for Health Care Administration for home medical equipment (HME) providers. It creates standards for licensure and regulation of HME providers. These requirements include submission of projected financial statements for the first two years of operation and satisfactory proof of compliance with background screening requirements. HME suppliers must also obtain and maintain professional and commercial liability insurance. A provisional license is permitted for a period of 45 days. Licensure fees are to be established by the agency by rule

It requires an application for licensure to include equipment and services offered, those with whom the provider contracts, demonstration of financial ability to operate, professional and commercial liability insurance, and compliance with chapter 435, F.S., level 2 background screening requirements for any owner, officer, director, agent, managing employee, general manager, affiliated person, or any partner or shareholder having at least 5% interest in the owning corporation, partnership, or other business entity. Level 2 requirements include an abuse registry check and criminal checks through the Florida Department of Law Enforcement and the Federal Bureau of Investigation. Provides for a provisional license for new applicants during which time an inspection demonstrating substantial compliance must occur. Requires an application for renewal of license and change of ownership. Creates authority to collect biennial licensure and inspection fees.

It establishes minimum standards for all providers subject to licensure, including providing at least one category of equipment directly, filling orders from its own inventory, maintaining trained personnel to provide HME services, assure that patients are made aware of service hours and emergency service procedures, honor all warranties express and implied under applicable state law, answer any questions or complaints a consumer has about an item or use of an item that they buy or rent, maintain and repair items rented to consumers, accept returns of substandard or unsuitable items from consumers, disclose consumer information to each consumer who rents or purchases items, including all applicable warranty information, including the provider standards to which it must conform, maintain patient payment and service records and ensure their confidentiality, designate appropriate staff as intake coordinators, assure that order intake personnel are appropriately trained in the types of equipment and products, commonly occurring medical conditions, service procedures, third-party billing, insurance requirements and coverage, train intake coordinators in a basic understanding of the following areas: dealing with patient and care giver needs; other, non-home medical equipment provider services as they relate to home medical equipment services and
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 in the home. This bill provides for licensure for providers of DME products (oxygen tanks, commodes, walkers, electric beds); however, providers offering DME that do not require any of these services are not subject to this licensure, i.e., many retailers that stock shelf items.

It establishes administrative penalties for violations of this bill, and for fines not to exceed $10,000 per day, per violation. Establishes the ability to impose 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.

The agency is directed to implement rules establishing minimum standards relating to qualification and minimum training requirements, (as previously stated) application, renewal and inspection fees, financial ability to operate, and procedures for maintaining patient records.

The bill has a fiscal impact on state government.

The bill takes effect October 1, 1997.

C. APPLICATION OF PRINCIPLES:

1. <u>Less Government:</u>

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 has been incorporated.

(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?

Yes. All applicants must pay a biennial license processing fee. Those not exempt from standard licensure will pay an inspection fee. Those exempt from standard license inspection via accreditation 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, and enforcement of the new standards for operation as an HME provider.

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?

The beneficiaries are the users of medical equipment who will be assured of a minimum standard of practice, 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 could be anticipated to be passed through 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?

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?

The bill provides for the protection of families from fraud, unsafe, or inadequate services.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates part IX of chapter 400, F.S., providing requirements for licensure of home medical equipment providers.

Section 400.81 provides for legislative intent to provide licensure of home medical equipment providers and establishes minimum standards for home medical equipment suppliers.

Section 400.815 defines terms used in the 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. An exemption is provided for prosthetics or customized orthotics. Home medical equipment services are defined as equipment 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 HME products and services, or HME products that require an HME service.

Section 400.82 further 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 400.821 requires an application for licensure to include equipment and services offered, those with whom the provider contracts, demonstration of financial ability to operate, professional and commercial liability insurance, and compliance with chapter 435, F.S., level 2 background screening requirements for any owner, officer, director, agent, managing employee, general manager, affiliated person, or any partner or shareholder having at least 5% interest in the owning corporation, partnership, or other business entity. Level 2 requirements include an abuse registry check and criminal checks through the Florida Department of Law Enforcement and the Federal Bureau of Investigation. Provides for a provisional license for new applicants during which time an inspection demonstrating substantial compliance must occur. Requires an application for renewal of license and change of ownership. Creates authority to collect biennial licensure and inspection fees.

Section 400.822 establishes administrative penalties for violations of this bill, and for fines not to exceed $10,000 per day, per violation. Establishes the ability to impose 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.

Section 400.823 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, in lieu of periodic licensure inspection by the agency.

Section 400.824 establishes minimum standards for all providers subject to licensure, including providing at least one category of equipment directly, filling orders from its own inventory, maintaining trained personnel to provide HME services, assure that patients are made aware of service hours and emergency service procedures, honor all warranties express and implied under applicable state law, answer any questions or complaints a consumer has about an item or use of an item that they buy or rent, maintain and repair items rented to consumers, accept returns of substandard or unsuitable items from consumers, disclose consumer information to each consumer who rents or purchases items, including all applicable warranty information, including the provider standards to which it must conform, maintain patient payment and service records and ensure their confidentiality, designate appropriate staff as intake coordinators, assure that order intake personnel are appropriately trained in the types of equipment and products, commonly occurring with medical conditions, service procedures, third-party billing, insurance requirements and coverage, train intake coordinators in a basic understanding of the following areas: dealing with patient and caregiver needs; other, non-home medical equipment provider services as they relate to home medical equipment services and home care patient crisis management, establish procedures for maintaining a record of the employment history, including background screening of all home medical equipment provider personnel, maintain safe premises, and maintain compliance with all other state and federal laws.

Section 400.825 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 400.83 establishes requirement for maintaining clinical records. House Bill 757, which accompanies this bill, establishes patient records obtained by the agencies through inception of an HME provider as exempt from public records disclosure law, due to the confidentiality of this information.

Section 400.83 requires home medical equipment providers to notify patients of the toll-free telephone number for central abuse registry to patients.

Section 400.843 establishes background screening requirements for home medical equipment provider personnel, as defined in chapter 435, level 1. Level 1 requirements include an abuse registry check and criminal checks through the Florida Department of Law Enforcement, but do not include a federal criminal check through the Federal Bureau of Investigation. Allows for exemptions from disqualification from employment. Requires screening for employees hired on or after October 1, 1997, the effective date of this bill. Prohibits the use of information obtained during screening for any other purpose than to determine good moral character for employment. House Bill 757, which accompanies this bill, establishes screening records obtained for this background screening as exempt from the public records disclosure law, due to the confidentiality of this information.

Section 400.845 establishes procedures for screening of home medical equipment supplier personnel. Within five days of start of employment the employee must submit information necessary to conduct the required screening. The employee must be on probationary status pending the results of the screening and must be terminated for non-compliance.

Section 400.85 creates the authority to institute injunction proceedings.

Section 400.86 prohibits certain referral relationships with other health care professionals.

Section 400.65 prohibits rebates and provides penalties.

Section 2. Provides an effective date of October 1, 1997.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

Amount Year 1 (FY 97-98)	Amount Year 2 (FY 98-99)

1. Non-recurring Effects:

A. Non-recurring Effects:

Expenditures:

Health Care Trust Fund		
Budget Entity: Health Facility Regulation		
Program Component: Health Care Quality Improvement		
Furniture & Equipment for FTEs		
17 Professional Staff - $2,132 @17	36,244	0
3 Support Staff - $1,469 @ 3	4,407	0
Total Expenses (20)	40,651	0
Operating Capital Outlay		
17 Professional Staff - $3,167 @ 17	53,839	0
3 Support Staff - $3,247 @ 3	9,741	0
Total OCCO	63,580	0
Total Non-Recurring Effects	104,231	0

2. Recurring Effects:

Revenues:

Health Care Trust Fund		
Budget Entity: Health Facility Regulation		
Program Component: Health Care Quality Improvement		
Revenue Category: Fees		
Licensure Processing Fees ($300)	900,000	45,000
Inspection Fees ($400)	1,140,000	57,000
Administrative Fines	50,000	50,000
Total Revenues	2,090,000	152,000

Expenditures:

Health Care Trust Fund		
Budget Entity: Health Facility Regulation		
Program Component: Health Care Quality Improvement		
Full Time Equivalent Staff 20 (9 mon) 20		
Salaries and Benefits (10% over min + 39% bene)		
3 Administrative Secretaries (pay grade 19)	55,897	74,530
1 Senior Human Services Program Specialist (pay grade 22)	33,154	44,205
1 Program Administrator (pay grade 25)	40,173	53,564
1 Health Facilities Consultant Supervisor		

(pay grade 26)	42,857	57,143
13 Health Evaluators II (pay grade 21)	405,342	540,456
1 Senior Attorney (pay grade 220)	35,779	47,705
Total Salaries and Benefits (20)	613,202	817,602

Expenses:

General Revenue Fund		
Office Expenses		
Professional Staff (17 x $13,189)	168,160	224,213
Support Staff (3 x $8,221)	18,497	24,663
Total Expenses (20)	186,657	248,876

3. Long Run Effects Other Than Normal Growth:

Unknown.

4. Total Revenues and Expenditures:Revenues:

Health Care Trust Fund		
Budget Entity: Health Facility Regulation		
Program Component: Health Care Quality Improvement		
Total Revenues	2,090,000	152,000

Expenditures:

Health Care Trust Fund		
Budget Entity: Health Facility Regulation		
Program Component: Health Care Quality Improvement		
Total Non-Recurring Effects	104,231	0
Total Salaries and Benefits	613,202	817,602
Total Expenses	186,657	248,876
Total Expenditures	904,090	1,066,478
Carry-over Revenues (for next fiscal year)	1,185,910	
Revenues Carried-over (from prior fiscal year)		1,185,910
Total Balance	0	271,432

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:

   Licensure fees collected will impact those subject to licensure. Each applicant will be required to pay a licensure fee (estimated to be up to $300 for initial licensure and biennial renewal). Each applicant subject to inspection is subject to an inspection fee (estimated to be up to $400 biennially). Providers are also subject to administrative fines for non-compliance.

   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 $21 plus $24 for the Federal Bureau of Investigation, totaling $45.

2. Direct Private Sector Benefits:

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

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

   Background screening will affect the employability of individuals who have been convicted of certain crimes. Individuals with abuse or neglect backgrounds would not be allowed to conduct business in this industry.

D. FISCAL COMMENTS:

Fiscal analysis shows licensure fees from all providers in the first year, but uses these revenues to cover expenses over a two- year period, since the licensure extends for a two year period. The only licensure fees expected in the second fiscal year are for new businesses applying for licensure.

Based on an estimate that 5% of all providers subject to this licensure are accredited, estimated workload includes standard licensure inspections of 2850 (95%) of providers.

Year 2 fees are based on an estimated 5% growth in this industry:
3000 providers x 5% growth = 150 providers x $300 = $45,000 in licensure fees
150 providers x 95% subject to inspection = 143 providers x $400 = $57,200 in inspection fees.

Since this bill has an effective date of October 1, 1997, the fiscal analysis for the first year is based on nine months of expenditures. However, since the proposed amendment requires existing providers to submit an application and licensure fees before January 1, 1998, the revenues for the first year will represent 12 months of revenues. See fiscal analysis following amendments.

Full Time Equivalents were calculated based on annual workload as follows:

Inspection Staff	Annually
Standard Licensure Inspection	
Onsite visit and report writing (5 hours annually x 2850)	14250 hours
Follow up visit and report [3 hour annually x 25%(2850)]	2138 hours
Based on 25 % of all surveys requiring follow up visit	
Supervisory review (1 hour annually x 2850)	2850 hours
Total standard inspection hours	19238 hours
Complaint Investigations	
Based on an annual estimate of complaint investigations for 20% of providers	
Onsite visit and report writing (5 hours annually x 600)	3000 hours
Follow up visit and report [2 hour annually x 25%(600)]	300 hours
Supervisory review (2 hour annually x 600)	1200 hours
Total complaint inspection hours	4500 hours
Total field staff hours	23738 hours
Total Full Time Equivalents (23738/1856 hrs per FTE)	13
Licensure staff	
Licensure processing (2 hours annually x 3000)	6000 hours
Total Full Time Equivalents (6000/1856 hrs per FTE)	3
Support staff	
Full Time Equivalents (ratio of 1 support staff for 5 professionals)	3
Legal staff	
The Agency for Health Care Administration will require an attorney to assess administrative penalties and prosecute cases before the Division of Administrative Hearings.	1
Total Full Time Equivalents	20

Values used to estimate processing times are based on current experience with similar licensing programs, adjusted for responsibilities associated with HME licensure.

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 an 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:

House Bill 757, which accompanies this bill, establishes patient records obtained by the agencies through inception of an HME provider as exempt from public records disclosure law, due to the confidentiality of this information.

Language has been drafted to clarify that the agency would not have unlimited rulemaking authority in setting fees (specific fees are identified).

Section 11.62, F.S., the Sunrise Act, provides for legislative review of proposed regulation of unregulated functions. Section 11.62(2)(a), F.S., provides: “That no profession or occupational be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state be exercised only to the extent necessary for that purpose; Section 11.62(3)(a), (b), (c), and (d), F.S., states:

> (3) In determining whether to regulate a profession or occupation, the Legislature shall consider the following factors:
> (a) Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare and whether the potential for harm is recognizable and not remote;
> (b) Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
> (c) Whether the public is or can be effectively protected by other means ; and
> (d) Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE STANDARDS & REGULATORY REFORM:

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