

STORAGE NAME: h1353.hcr

DATE: April 16, 1997

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

BILL #: HB 1353

RELATING TO: Regulation of Orthotists and Prosthetists

SPONSOR(S): Representative Dawson-White

STATUTE(S) AFFECTED: Creates a new section

COMPANION BILL(S): CS/CS/SB 496(s)

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

- (1) HEALTH CARE STANDARDS & REGULATORY REFORM
- (2) HEALTH & HUMAN SERVICES APPROPRIATIONS
- (3)
- (4)
- (5)

I. SUMMARY:

The bill provides for the regulation of the practice of orthotics and the practice of prosthetics. It creates licensure requirements, including fees, for orthotists, orthotic assistants, prosthetists, prosthetic assistants, fitters, fitter assistants, and pedorthotists. It provides definitions of practice, creates the Board of Orthotists and Prosthetists and establishes grounds for which an orthotic or prosthetic practitioner may be disciplined.

Individuals who have practiced orthotics or prosthetics full-time continuously since July 1, 1992, may become licensed without having to take an examination or meet the education requirements for the appropriate licensure category. Exemptions to licensure requirements are provided for orthotics and prosthetics and the use of protected professional titles is prohibited.

The Department of Health and the Agency for Health Care Administration indicate that the bill will have a fiscal impact. All costs will be borne by the licensees, through collection of fees and fines. There is no fiscal impact on local government or the private sector.

II. SUBSTANTIVE RESEARCH:

A. PRESENT SITUATION:

The practice of prosthetics and the practice of orthotics are not currently regulated in Florida. Prosthetists write specifications for, make, fit, and repair braces, artificial limbs and prosthetic devices (protheses) following a prescription by a physician for patients with a total or partial absence of a limb. Orthotists provide care to patients with disabling conditions of the limbs and spine by fitting and preparing supportive devices (orthoses) under the direction of a physician.

To practice orthotics or prosthetics, individuals must obtain a baccalaureate degree, a certificate, or receive on-the-job training in an apprenticeship. Orthotists and prosthetists have traditionally been taught in apprenticeships, and over the past couple of decades college-level education and training has become available. Certifying agencies have not reached a consensus on the minimum level of training and education needed to practice prosthetics and orthotics. One agency emphasizes on-the-job practical experience and the passage of an examination to test a practitioner's skills, while another agency focuses on a combination of college-level education and training in addition to passage of an examination. There are three universities (California State University, Dominguez Hills; University of Texas, Dallas; and University of Washington, Seattle) in the United States that have programs granting baccalaureate degrees in orthotics or prosthetics. There was a prosthetics and orthotics degree program at Florida International University which closed down in August, 1995, after the university sustained several budget cuts. Florida currently does not have any institutions offering accredited training programs or college-level degree programs in prosthetics or orthotics. Five institutions in the United States (2 in California, 1 in Minnesota, 1 in Connecticut, and 1 in Illinois) offer a nationally accredited 10-12 month certification training program in orthotics and/or prosthetics.

Prosthetic and orthotic practitioners may be certified by three different certifying agencies: the American Board for Certification in Orthotics and Prosthetics (ABC), the Board for Orthotists Certification (BOC), and the National Association for Retail Druggists (NARD). The requirements for ABC include college-level education and training in orthotics and prosthetics and successful passage of a comprehensive written and practical examination. The American Board for Certification gives applicants three ways to sit for its certification examination. An applicant must have: 1) a bachelor's or higher degree in orthotics and/or prosthetics; 2) a bachelor's or higher degree in any major and completion of an approved 10-12 month orthotics and/or prosthetics certification training program and 1 year of clinical experience; or 3) an associate degree and completion of an approved 10-12 month orthotics and/or prosthetics certification training program and 4 years of experience.

The Board for Orthotists Certification only certifies orthotists and its requirements include completion of 2 years of practical experience and 40 hours of education in orthotics and passage of a written and practical examination. The National Association for Retail Druggist's certification program is designed for pharmacy professionals who may fit and sell orthotic devices. The orthotic devices pharmacists commonly fit and sell include orthopedic wraps and supports, but are not limited to supportive devices for patients with disabling conditions of the limbs and spine. The duration of NARD certification training ranges from one semester in a school of pharmacy program to five

days in a manufacturing setting. The certification programs affiliated with NARD are accredited by the National Commission for Certifying Agencies.

Two states, New Jersey and Mississippi, regulate the practice of orthotics and the practice of prosthetics. The New Jersey law requires a minimum of a bachelor's degree to practice prosthetics or orthotics and authorizes a board to establish examination requirements and practice standards. The New Jersey law, enacted in 1991, provides a "grandfather" clause to allow existing practitioners of orthotics and prosthetics to practice and be licensed without an examination. According to officials with ABC, the New Jersey law has not yet been fully implemented to license any practitioners of orthotics and prosthetics. Mississippi requires prosthetists and orthotists to be certified by the American Board for Certification in Orthotics and Prosthetics.

The Sunrise Act, codified in section 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The act requires that all legislation proposing regulation of a previously unregulated profession or occupation be reviewed by the Legislature based on a showing of the following: (1) that substantial risk of harm to the public is a risk of no regulation; (2) that the skills the profession requires are specialized and readily measurable; (3) that other forms of regulation do not or cannot adequately protect the public; and (4) that the overall cost-effectiveness and economic impact of the proposed regulation is favorable. The act requires proponents of regulation of a previously unregulated profession to provide the agency that is proposed to have jurisdiction over the regulation and the legislative committees of reference information concerning the effect of proposed legislation to initially regulate a previously unregulated profession on the department's resources to implement and enforce the regulation.

In response to a sunrise questionnaire, the proponents of the regulation of prosthetists and orthotists relied heavily on a 1996 Washington State Sunrise report which recommended that the practice be regulated to protect the public from potential financial, physical, and psychological harm arising from the activities of these practitioners. Proponents of the regulation indicated that consumers may potentially suffer physical harm due to orthoses and prostheses that are improperly fitted or designed which may cause ulcerations or nonhealing sores or create deformities, leading to further medical intervention, such as surgery. Proponents of the regulation note that an example of fraud in Florida was found by the prosecution of an individual who claimed to be an orthotist who entered nursing homes, fitted elderly residents with orthoses, and then fraudulently billed Medicaid and Medicare for his services. Proponents of the regulation indicate that licensure may provide accountability and potentially prevent fraudulent activities in the practice of prosthetics and the practice of orthotics.

Chapter 455, F.S., sets forth the general regulatory powers and duties of the Department of Business and Professional Regulation and the Agency for Health Care Administration to implement and enforce professional regulation. Effective July 1, 1997, the regulation of health professions will transfer to the newly created Department of Health.

B. EFFECT OF PROPOSED CHANGES:

The bill creates a Board of Orthotists and Prosthetists within the Department of Health. The board shall consist of seven members appointed by the governor and confirmed by the Senate for four-year terms, and terms of original board members are staggered. The board shall be responsible for adopting rules relating to administration of this act and standards of practice for orthotists and prosthetists, and issuing biennial licenses to practice orthotics and prosthetics. Two members of the board must be prosthetists, one prosthetist member must hold a Bachelors of Science in Prosthetics and Orthotics, and one prosthetist must be a practicing prosthetist with at least six years of experience after receiving certification from a national certifying body. Two members must be prosthetic or orthotic users who have never been an orthotist or prosthetist or a practitioner in any closely related profession. One member of the board must be a physician licensed to practice medicine, osteopathic medicine, chiropractic medicine, or podiatry in Florida. The board's official headquarters shall be in Tallahassee and the provisions of chapter 455, F.S., apply to the activities of the board. The board is authorized to adopt rules to administer regulations relating to the practice of orthotics and the practice of prosthetics.

The bill creates definitions of practice for each category of orthotics and prosthetics practitioner to defined activities which are performed pursuant to a licensed physician's written prescription. It requires a prosthetist whose patients are under the care of a licensed occupational therapist or physical therapist to consult with the therapist if the therapist has notified the prosthetist of specific recommendations regarding the fitting, design, or fabrication of a prosthesis or treatment with a prosthesis for the patient.

For each licensure category, applicants must pay an application fee no greater than \$500 and an examination fee no greater than \$500 and take the appropriate licensure examination, including a practical examination demonstrating clinical patient management, when appropriate, and written examinations, to demonstrate orthotic or prosthetic problem-solving skills.

An exemption from examination is provided for those who have practiced orthotics continually since July 1, 1992 and apply for licensure prior to January 1, 1998.

The bill allows persons seeking licensure without examination as a prosthetist, orthotist, prosthetist-orthotist who have not practiced for five years, to become provisionally licensed to practice under the supervision of a fully licensed practitioner to meet the five-year experience requirement. It authorizes the board to issue a provisional license to any person who submits proof of having received certification as an orthotist, a prosthetist, or a prosthetist-orthotist from a national certifying body and who has practiced orthotics or prosthetics for less than five years and who pays the application fee and the provisional license fee.

The bill provides for the delegation of duties to nonlicensed supportive personnel, if under direct supervision. It exempts persons licensed to practice medicine or podiatry in Florida, persons performing services for the federal government, and persons working under supervision while working toward internship or education requirements. It exempts any licensed pharmacist or any person acting under the supervision of a licensed pharmacist from the requirements of the bill relating to orthotics, if the pharmacist or the person under the pharmacist's supervision has received a certificate

demonstrating satisfactory completion of a minimum of 40 hours of training in orthotics from a national pharmacy organization or a certificate demonstrating completion of training from a manufacturer of orthotic devices. The bill provides that the practice of orthotics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist must be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in the pharmacy practice act and must be subject to the regulation in the same manner as any other pharmacy practice.

The bill specifies grounds for which licensed prosthetic and orthotic practitioners may be disciplined by the board for acts of misconduct and prohibits the use of specified professional titles by persons other than those licensed under the bill.

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 bill creates a licensing board with rulemaking authority.

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

Persons offering orthotic/prosthetic services must obtain licensure. The Agency for Health Care Administration will be responsible for investigation of complaints associated with this regulation.

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

Those applying for licensure under this act will be dependent upon the board to process this licensure. The public will depend upon the agency to investigate complaints.

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. The bill establishes fees not to exceed \$500 for licensure application and biennial renewal, and \$500 for examination. The board has authority to establish fees for approval of continuing education courses required for licensure renewal.

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?

The department indicates that occupational licensure fees may be required by counties or municipalities for licensees to practice.

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?

Yes, those individuals who will become licensed will pay fees.

4. Individual Freedom:

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

No. Individuals subject to this regulation have not been regulated in the past.

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

Yes. This bill prohibits the practice of orthotics and prosthetics without proper licensure.

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?

N/A

D. SECTION-BY-SECTION RESEARCH:

Section 1. Provides definitions of relevant terms, including the professions of orthotists, prosthetists, prosthetic assistant, orthotic assistant, pedorthotist, fitter, and fitter assistant.

Section 2. Establishes the Board of Orthotists and Prosthetists within the Department of Health. Establishes the parameters for board composition and membership.

Section 3. Establishes the authority for the board to adopt rules.

Section 4. Establishes licensure requirements, including minimum educational and experience requirements. All applicants for licensure under this section must complete an application and pay a fee, a licensure examination and a fee, be of good moral character, be 18 years of age or older, have completed appropriate education, practical training, and clinical internship.

An orthotist must have a Bachelor of Science degree in Orthotics and Prosthetics and an appropriate one-year internship or residency program.

An orthotic assistant must have an associate degree in a related field and an appropriate three-year internship. An applicant may qualify for a waiver of two years of the required internship.

A prosthetist must have a Bachelor of Science degree in orthotics and prosthetics and an appropriate one-year internship or residency program.

A prosthetist assistant must have an associate degree in a related field and an appropriate three-year internship. An applicant may qualify for a waiver of two years of the required internship.

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A fitter must have a high school diploma or its equivalent, a minimum of 40 hours of training in orthotics education, approved by the board, and two years of experience in orthotics education, approved by the board.

A pedorthotist must have a high school diploma or its equivalent and a minimum of 10 hours of training, approved by the board.

Section 5. Exempts an applicant for licensure from examination for persons who have practiced orthotics or prosthetics full-time, continuously, since July 1, 1992, in an established prosthetic or orthotic facility.

Section 6. Creates biennial renewal of license. Establishes a renewal fee not to exceed \$500. Provides for adoption of rules establishing a procedure for license renewal and continuing education requirements, not to exceed 30 hours biennially.

Section 7. Provides for establishment of a temporary license not to exceed one year, for an applicant who has recently moved to the state and is licensed in another state, and an applicant who has engaged the in full-time practice of orthotics and prosthetics for five years between July 1, 1992 and July 1, 1997. Such a license may be renewed for up to one year if the licensee is certified by the American Board of Certification of Orthotists and Prosthetists.

Section 8. Provides for delegation of duties to nonlicensed supportive personnel, if under direct supervision.

Section 9. Prohibits false statements to the board and the practice of orthotics and prosthetics without a license. Provides that violators are guilty of a second degree misdemeanor.

Section 10. Provides for disciplinary action for violations that include attempting to procure a license by fraudulent misrepresentation; adverse action against a license to practice orthotics and prosthetics in another jurisdiction; violating laws in any jurisdiction relating orthotics and prosthetics; fraudulent, deceptive or misleading advertising; violation of an order of the board, the agency, or the department; violation of chapter 455, F.S.; practicing with a revoked, suspended or inactive license; and malpractice failure to maintain the level of care and skill recognized as acceptable by a reasonably prudent licensed practitioner.

Adopts penalties in s. 455.227(2), F.S.

Section 11. Provides for exemptions from licensure.

Section 12. Prohibits the use of titles without proper licensure, including "orthotist", "prosthetist", and "fitter".

Section 13. Provides an effective date of July 1, 1997.

III. FISCAL RESEARCH & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE AGENCIES/STATE FUNDS:

1. Non-recurring Effects:

The Department of Health estimates the following fiscal impact to administer and enforce the proposed regulation for prosthetists and orthotists:

Non-recurring Costs:	<u>1997-98</u>	<u>1998-99</u>
a. Exam Development and Administration		
Exam Development		
(5 exams @ \$186,000 each)	\$620,000	\$310,000
(18 months to develop exams)		
Office set-up - 2 F.T.E. Staff		
(\$2,132 Expenses per person)	4,264	
2 F.T.E. Staff (\$4,788 OCO per person)	9,576	
b. Board Office		
Office Set-up - 3 F.T.E. Staff		
(\$2,132 Expenses per person)	6,396	
3 F.T.E. Staff (\$4,788 OCO per person)	14,364	
 Total Non-recurring Costs	 \$654,600	 \$310,000

2. Recurring Effects:

	<u>1997-78</u>	<u>1998-99</u>
a. Exam Development and Administration		
Exam Administration		
(50 applicants per year at \$69,000)		\$69,000
Exam Development 1.0 F.T.E.	29,143	36,857
Exam Development/Administration		
1.0 F.T.E.	19,004	25,339
Expenses 2.0 F.T.E.	16,586	22,114
b. Board Operations		
Cost of stipends, meetings, lodging,		
airfare, court reporters, legal advertising		
and communications for board members	34,604	46,138
c. Board Office Operations		
1 Program Administrator	30,880	41,173
1 Regulation Specialist II	26,040	34,720
1 Regulation Specialist I	20,969	27,959
Expenses 3.0 F.T.E.	24,878	33,171

Total Recurring Costs \$202,104 \$336,471

The department estimates that the expenditures for the biennial period 1997-99, total \$1,503,175.

The department estimates that it will collect an application fee of \$500 and an initial licensure fee of \$250; fiscal year 1997-98, 440 applicants paying an application fee of \$500 and an initial licensure fee of \$250 totaling \$330,000; for FY 1998-99, 100 applicants. **Recurring Costs:** paying an application and temporary license fee, \$500, initial license fee, \$250, and examination fee, \$500 totaling \$125,000. Total revenue is estimated at \$455,000 for the biennial period 1998-99.

3. Long Run Effects Other Than Normal Growth:

None.

4. Total Revenues and Expenditures:

According to the Department of Health:

Revenues: non-recurring revenue would be \$255,000 for 340 applicants in FY 1997-98 (application fee of \$500; initial license fee of \$250). Recurring revenue would be \$75,000 for 100 applicants in FY 1997-98 and \$125,000 for 150 applicants in FY 1998-99 (application fee for temporary and new license of \$500; initial license fee for temporary and new license of \$250; exam fee of \$500).

Biennial total revenue would be \$455,000.

Expenditures: Total expenditures for FY 1997-98 would be \$856,704 and for FY 1998-99 they would be \$646,471. Biennial total expenditures would be \$1,503,175.

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:

Indeterminate.

2. Direct Private Sector Benefits:

Assurance that those professionals subject to this licensure will meet a minimum level of education, competence, and character standards.

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

None.

D. FISCAL COMMENTS:

The Agency for Health Care Administration indicates that the Bureau of Consumer and Investigative Services of the processes complaints regarding licensed health care professionals. In fiscal year 95/96, 12,400 complaints were received; however, between July 1, 1996 and December 31, 1996, 8,910 complaints have been received. These figures represent an annualized 44% increase since last fiscal year. The number of complaints received regarding physicians last year represented an average of 8% of those licensed to practice medicine. Based upon the increase in complaints since July 1, 1996, the ratio of 8% is used to estimate the number of complaints regarding orthotists and prosthetists that will require investigation. A newly created licensure program should result in a significant number of complaints initially, due to reporting of unlicensed individuals, increasing the ratio by half, to 12% of those subject to licensure. Based on the estimated 1,000 professionals subject to licensure, 120 complaints are expected in the first year. Anticipated growth in the industry is expected to increase the number of individuals subject to this licensure, and maintain this volume of complaints annually.

To process 120 complaints, the agency will require three full-time equivalents (FTE's). Based on experience, two investigation specialists will be necessary to investigate, process documentation, and initiate enforcement for 120 complaints. The Bureau of Consumer and Investigative Services will need one position in consumer services, handling issues related to advertising and non-compliance in other states, and one in the field, performing on-site inspections. Approximately 40% of complaints handled require action by agency attorneys; therefore, the agency will also require an attorney to prosecute cases before the board and Division of Administrative Hearings.

This bill creates the Board of Orthotists and Prosthetists within the Department of Health. In terms of fiscal impact of state agencies, this analysis only forecasts the impact on the Agency for Health Care Administration, responsible for investigation of complaints. The revenue to support the necessary agency staff will come from licensure fees through a budget transfer from the Department of Health to the Agency for Health Care Administration.

The Department of Health indicates that it appears there may be a suitable national examination for orthotists and prosthetists (the certification examination developed by the American Board of Certification for Orthotics and Prosthetics). However, it is unclear whether there are appropriate examinations for the other five levels of licensure. Therefore, fiscal impact for the development of these examinations is included. The Bureau of Testing within the Department of Business and Professional Regulation estimates that the range of cost is \$186,000 to \$326,000, depending on complexity, to develop an examination with a practical and with clinical skill problems. Practical exams usually generate more challenges from the applicants who fail, and would result in higher litigation costs, which are borne by the profession.

Recurring costs of administering an examination are based on experience with the state-developed and administered chiropractic licensing examination, which costs approximately \$200,000 annually for about 150 candidates.

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:

Section 24 of Article I of the State Constitution governs the creation and expansion of exemptions relating to public records and meetings to provide in effect, that any legislation which creates a new exemption or that substantially amends an existing exemption must also contain a statement of the public necessity that justifies the exemption. Article I, s. 24, Fla. Const. provides that any bill which contains an exemption may not contain other substantive provisions, although it may contain multiple exemptions.

The bill creates by implication, public records and meetings law exemptions to the extent the existing exemptions for disciplinary actions applicable to professions in chapter 455, F.S., apply to the newly created regulation for persons engaging in the practice of orthotics and the practice of prosthetics. Proponents of the bill indicate that they intend to seek sponsorship of such a bill prior to the next legislative session.

The Florida Association of Orthotists and Prosthetists indicates that they support this bill.

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VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH CARE STANDARDS & REGULATORY REFORM:
Prepared by: _____ Legislative Research Director:

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