

SUBJECT: Regulating orthotists and prosthetists

COMMITTEE: Public Health — committee substitute recommended

VOTE: 6 ayes — Berlanga, Hirschi, Coleman, Davila, Glaze, Maxey
0 nays
3 absent — Delisi, Janek, Rodriguez

SENATE VOTE: On final passage, March 4 — voice vote

WITNESSES: For — Mike Allen; Kim Doolan; Debbie Gauthier; Karen Kinney Reagan, Texas Pharmacy Association
Against — None
On — Jim Zukowski, Texas Department of Health

DIGEST: CSSB 291, the proposed Orthotics and Prosthetics Act, would establish a Texas Board of Orthotics and Prosthetics as part of the Texas Department of Health. Persons without a license under the act could not practice or pose as practicing prosthetics or orthotics or act as an assistant to a person who practices prosthetics or orthotics.

"Orthosis" would be defined as a custom-fabricated or fitted medical device designed to provide for the support, alignment, prevention or correction of neuromuscular or musculoskeletal disease, injury or deformity. Devices would not include elastic supports, plastic splints, trusses, dental appliances or other similar devices sold by drugstores, department stores, or corset stores.

"Orthotics" would be defined as the science and practice of measuring, designing, fabricating, fitting, adjusting or servicing an orthosis under an order from a physician, chiropractor or podiatrist.

"Prosthesis" would be defined as a custom-fabricated or fitted medical device that was not surgically implanted and was used to replace a missing

body part, but would not include an artificial eye, ear, finger, toe, a dental appliance, artificial breasts, eyelashes, wigs or other cosmetic devices. "Prosthetics" would refer to the science and practice of measuring, designing, fabricating, fitting, adjusting or servicing a prosthesis under an order from a licensed physician, chiropractor or podiatrist.

The act would not apply to a podiatrist practicing under the laws regulating podiatry; a chiropractor practicing under laws that regulate chiropractic; an occupational therapist practicing under laws regulating occupational therapy; a physical therapist operating under laws regulating physical therapy; a pedorthist certified by the Board for Certification in Pedorthics; or a certified fitter or certified master orthotist who holds a credential issued by the National Community Pharmacists Association and working within the scope of practice as defined by the board or who provides specified and listed services.

The act would also not apply to persons licensed by another state agency who practice within their applicable licensure laws and rules and do not represent to others to practice the profession of orthotics or prosthetics.

The bill would take effect September 1, 1997, and application of prohibited acts and civil penalties would take effect October 1, 1998.

Board membership and duties

The governor would be required to appoint the board by October 1, 1997. The board would be subject to sunset review and would be abolished by September 1, 2009, unless continued in existence by the Legislature.

Membership. The board would consist of six members, appointed by the governor for staggered six-year terms and include one licensed orthotist, one licensed prosthetist, and one licensed prosthetist orthotist. The board would also include one public member who uses an orthosis, one public member who uses a prosthesis, and one public member who does not use an orthosis or prosthesis. Board members would be entitled to compensation and travel expense reimbursement as provided by the general appropriations act.

Duties. The board would license applicants and could collect fees, either set by the general appropriations act or set in amounts reasonable and necessary for the administration and implementation of the act. The board also would have to adopt rules to carry out its duties by October 1, 1998, submit proposed rules to the attorney general for review, and approve examinations. It could investigate complaints and reprimand or sanction license holders.

Miscellaneous. The board would also be required to comply with provisions standard to most licensing agencies concerning public information activities, complaint information files, public participation in board meetings, accessibility for persons who do not speak English, open meetings requirements, conflict of interest restrictions, state audit requirements, and equal employment opportunity policies.

Licensing requirements

All applicants for licensing or registration would be required to file a written application with the board and pay a nonrefundable application fee. A license would be valid for two years and could be renewed.

To become a licensed orthotist, a licensed prosthetist, or a licensed prosthetist orthotist, an individual would have to be a state resident and have completed formal classroom education and clinical practice training as prescribed by board rule, completed a clinical residency, and passed all written and practical examinations approved and required by the board.

The board would be required to establish educational requirements for licensure, including a bachelor's degree in orthotics and prosthetics or a bachelor's degree and a prosthetic or orthotic certificate from a recognized practitioner educational program and not less than 1,900 hours of clinical residency. The board also would have to establish alternative educational requirements allowing for an associate's degree and not less than 4,500 hours of postgraduate clinical experience. The alternative educational requirement would expire January 1, 2005.

A Texas resident could be exempt from license registration or requirements if the person applied for an exemption within 181 days after board rules

were adopted and published and if the person provided comprehensive orthotic, prosthetic, or orthotic and prosthetic care for three to six years preceding the date of application or presented satisfactory evidence that the person possessed unique qualifications. Persons could receive a license if they practiced orthotics or prosthetics for less than three years by passing all written and practical examinations if examination application were made by 181 days after the date the board's rules were finally adopted.

Pharmacists. The board would have to issue a license to a person who applied and was licensed or regulated by the State Board of Pharmacy and certified by the National Community Pharmacists Association as a certified fitter or master orthotist. The licensing fee could be no more than \$50.

Assistant licenses and technician registration. Applicants for a prosthetist assistant license or orthotist assistant license or for registration as a registered prosthetic technician or registered orthotic technician would be required to present evidence of completing educational and clinical or laboratory programs as prescribed and adopted by the board. An assistant could provide only ancillary patient care services as defined by the board.

A Texas resident could apply for an exemption from the license requirements if the person applied within 181 days of final adoption of board rules and had practiced for three consecutive years in Texas within the scope of assistant practice for an assistant's license or as a technician for technician registration.

Provisional or temporary licenses. A provisional license could be issued to an individual who was actively engaged in complying with educational and clinical licensing requirements and could be revoked if the board determined that the license holder is not in compliance with the act. A provisional license would be valid for two years. The section governing provisional licensure would expire January 1, 2005.

A temporary license could be issued to a person who recently became a Texas resident, applied for licensing as an orthotist, prosthetist or both; and had been practicing the profession of orthotics since January 1, 1996, or licensed by the state in which the person formerly resided that had licensing

requirements equal to or exceeding Texas requirements. A temporary license would be valid for one year and could be renewed once.

Student registration. The board could issue a student registration certificate to an individual who was working toward fulfilling licensing requirements and held a bachelor's degree in orthotics and prosthetics or a bachelor's degree and a orthotic or prosthetic certificate from a recognized educational program. A student registrant could work only under the supervision of a licensed orthotist, a licensed prosthetist, or a licensed prosthetist orthotist. A student registration certificate would be valid for two years and could be renewed once.

Examination exemption. An applicant who held a license in a state that had licensing requirements that were equal to or exceeded Texas requirements could be exempted from licensing examination requirements.

Continuing education

An applicant for license renewal would be required to submit evidence of satisfactory completion of board-required continuing education requirements. The board would be required to notify each license holder who failed to comply with continuing education requirements that the license holder had three months to take the required continuing education courses or be subject to license suspension or revocation.

Disciplinary and penalty provisions

A person licensed under the bill would commit a violation by offering to pay or accept remuneration as prohibited under sec. 161.091 of the Health and Safety Code.

After notice and opportunity for a hearing, the board could revoke, suspend or refuse to renew a license if the license was obtained by fraud or misrepresentation, if the person violated the act or rules, or if the person engaged in fraud, deceit, unprofessional or unethical conduct, gross negligence or malpractice in providing services. A revoked license could be reinstated on terms the board considers necessary after one year.

A person who violated the act would be subject to a civil penalty of \$200 for the first violation and \$500 for each subsequent violation. Each day of violating prohibitions against practicing without a license would be considered a separate violation.

Facility accreditation

The board would be required to adopt requirements for the accreditation of an orthotic or prosthetic facility in which the profession and practice of orthotics or prosthetics was conducted. A facility would have to be under the on-site direction of a licensed orthotist or prosthetist for which the accreditation is sought.

The board could require only one application for the accreditation of all facilities owned by one person. Each facility would be required to meet board requirements. Board rules could not prohibit a licensed individual from practicing in an orthotic or prosthetic facility within the scope of the individual's license.

SUPPORTERS SAY:

CSSB 291 would regulate at no cost to the state an important patient care profession that is now completely unregulated. Appropriate fitting and servicing of an orthosis or a prosthesis can make the difference between a satisfying, pain free and productive life and one that is disabling, discouraging, painful and unproductive. The potential for fraud and negligence is widespread, but the public need for regulation is unquantified because there is no established agency or process to field and investigate complaints.

Licensing is needed because the field of orthotics and prosthetics is relatively new and rapidly changing with new technologies. A good educational and clinical background and continuing education are essential to providing quality patient care. The practice of orthotics and prosthetics has changed significantly in recent years and will continue to become more complex and sophisticated. Practitioners today need a sound background in anatomy, physics and biomechanical engineering to properly fit, fabricate and adjust today's devices, such as electronic hands, wrists and elbows. In the past 10 years over 30 types of feet alone have been developed.

Practitioners need to stay on top of their field to serve and protect their patients.

CSSB 291 would create a regulatory system capable of responding to a growing profession and potential problems — registration would not be enough to protect patients. Regulating technicians and assistants is important to ensure correct application of a device for maximum patient benefits. Regulating facilities is important to prevent the spread of infection between patients from open or healing wounds or such illnesses as hepatitis or HIV. It would be shortsighted and ineffective to create regulation that would establish no minimum qualification standards, enforcement or consumer protections.

CSSB 291 also would enact regulation at no cost to the state, and by administratively attaching to TDH, would be effectively coordinating with and using existing state public health resources and personnel. Texas would rank among other states, such as Florida, Washington, Mississippi and New Jersey, in regulating the growing practice of orthotics and prosthetics.

Current marketplace practices cannot ensure quality care. CSSB 291 would have the state — not private interests — set independently established minimum standards for quality care. Accreditation by private organizations, such as the American Board of Certification (ABC) or the Board for Orthotist Certification (BOC), would not sufficiently ensure a minimum standard of quality patient care, and many practitioners are not certified by either the BOC or the ABC. Many patients are referred to prosthetists or orthotists on the basis of traditional or historical business practices (i.e., the only practitioner in a certain part of town) or through personal relationships. Patients are often unfamiliar with what constitutes an acceptably comfortable fit or delivery of care. Without regulation, as devices become more sophisticated and expensive the incentives and opportunities for fraud or negligent practices expand.

Grandfather clauses allowing for licensing exemptions would allow practitioners to continue their livelihood and to maintain patient access to care from practitioners they trust.

OPPONENTS
SAY:

CSSB 291 would establish a multi-tiered licensing and regulation system that is probably unnecessary to oversee the activities of less than 300 practitioners. There has been no great public outcry for regulation; this is an attempt by some practitioners to enhance the status of their profession. Instead of improving patient care, it could limit patient access to care by limiting the supply of practitioners.

Pharmacists would be inappropriately regulated under this bill, and should receive complete exemption from licensure requirements, as would other health care professionals operating under statutory practice acts. Pharmacists do not perform the type of extensive prosthetic fitting and production that requires regulation, and their overall pharmacy practice and performance is already regulated under a separate licensing act.

The best regulators of orthotics and prosthetics is the marketplace — the referring doctors and the patients. Doctors are not going to jeopardize their practices by referring patients to unqualified practitioners, and patients can tell when devices fail to fit and when they are receiving good or bad care. Only two other states, New Jersey and Mississippi, now regulate this profession.

OTHER
OPPONENTS
SAY:

CSSB 291's regulation and fee structures would add to the cost of health care. A more conservative first step to regulating this profession could be to simply register practitioners so that the state would have a method to identify the size of the profession and the location of the practitioners to respond to consumer complaints.

NOTES:

The committee substitute changed the Senate-passed version of the bill by specifically exempting physical therapists and occupational therapists from licensing requirements, and by lowering from five to three years the length of time an assistant or technician would have to had practiced in this state prior to board adoption of rules to receive an exemption from licensure.

During the 74th regular session in 1995, HB 1193 by Berlanga, which is substantially similar to CSSB 291, passed the House and the Senate, but the House voted to table the conference report on the bill.