

SUBJECT: Regulating orthotists and prosthetists

COMMITTEE: Human Services — committee substitute recommended

VOTE: 7 ayes — Hilderbran, Naishtat, Davila, J. Jones, Krusee, Maxey, Wohlgemuth

0 nays

2 absent — Denny, Park

WITNESSES: For — Dennis Christopher Cole, National Association for the Advancement of Orthotics and Prosthetics; Donald F. Hayden, Texas Physical Therapy Association; Mike Allen, Certified Orthotic and Prosthetic Advocates; James McCoy, Texas Chapter of American Academy of Orthotist and Prosthetists; six people representing themselves

Against — Dr. Deborah Kelly and eight people representing the Board for Orthotist Certification; Ken Wells, Kevin King, Lane Kelley Kimbrough, International Association of Orthotics and Prosthetics; Karen Kenney, Texas Pharmacy Association; 18 people representing themselves

DIGEST: CSHB 1193 would create the Orthotics and Prosthetics Act and establish the Texas Board of Orthotics and Prosthetics as part of the Texas Department of Health. A person 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 and 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 is not surgically implanted and is 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.

A person practicing comprehensive prosthetic or orthotic patient management who does not meet the act requirements by October 1, 1996, and is not exempt, would be required to comply with educational and licensing requirements on or before October 1, 2002. A board member would be required to have the appropriate license by February 1, 1997.

The act would not apply to a podiatrist practicing under the laws regulating podiatry, a pedorthist certified by the Board for Certification in Pedorthics or its successor entity or a certified fitter or certified master orthotist who holds a credential issued by the National Association of Retail Druggists and working within the scope of practice as defined by the Texas Rehabilitation Commission.

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.

Board membership and duties

The board would consist of six members appointed by the governor for staggered six-year terms, to 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. The governor would be required to appoint the board by October 1, 1995. Board members would be entitled to compensation and travel expense reimbursement as provided by the general appropriations act.

The board would license applicants and could collect fees, set either by the general appropriations act or in amounts reasonable and necessary for the

administration and implementation of the act. The board would also be required to approve licensing requirements and examinations and could investigate complaints and reprimand or sanction license holders.

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 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 to include 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.

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 had provided comprehensive orthotic, prosthetic or orthotic and prosthetic care for three years preceding the date of application or could successfully pass all written and practical examinations required by the board.

Assistant licenses and technician registration. Applicants for a prosthetist assistant license, 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 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 if the person had practiced for five 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 is 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, 2003.

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 has been licensed by the state in which the person formerly resided that has 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 is working toward fulfilling licensing requirements and holds 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 holds a license in a state that has licensing requirements that are equal to or exceed 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 fails to comply with continuing education requirements that the license holder has 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 violates 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 is conducted. A facility would be required 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.

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 people who do not speak English, open meetings requirements, conflict of

interest prohibitions, funds accountability reports and equal employment opportunity policies.

Effective dates

The act would take effect September 1, 1995, except for provisions which would take effect October 1, 1996, that would prohibit the practice of prosthesis or orthosis without a license and apply civil penalties. The board would be required to adopt rules by October 1, 1996.

SUPPORTERS SAY: CSHB 1193 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, painfree and productive life and one that is disabling, discouraging, painful and unproductive. The potential for fraud and negligence is widespread, but public need for regulation is unquantified because there is no established agency or process to field and investigate complaints.

CSHB 1193 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), will not sufficiently ensure a minimum standard of quality patient care because of their changing and sometimes competing requirements and political interests. CSHB 1193 would set a qualification floor for all practitioners, who could then choose to exceed minimum state licensing standards through other accreditation bodies.

Current marketplace practices cannot ensure quality care. An unknown number of practitioners delivering care 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 (ie., 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.

A good educational and clinical background and continuing education are essential in 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 good 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.

CSHB 1193 would create a regulatory system capable of responding to a growing profession and potential problems. 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 illnesses, such as hepatitis or HIV. It would be shortsighted and ineffective to create a regulatory structure that would establish no minimum qualification standards, enforcement or consumer protections. CSHB 1193 would be creating an effective regulatory system 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.

The grandfather clause is a necessary and beneficial compromise to enact needed regulation. It would allow practitioners to continue their livelihood and would maintain patient access to care from practitioners they trust. Exemptions for certified master orthotists who work in drugstores are necessary because their scope of practice is usually limited to pre-fabricated soft goods sold over the counter and do not fall within the delivery of comprehensive (full body) patient services targeted for regulation. If certified master orthotists do more than their scope of practice as defined in this act, they would fall under licensure requirements.

**OPPONENTS
SAY:**

CSHB 1193 would establish licensing and regulation that is unnecessary and too extreme. There has been no public outcry for regulation. It is an attempt by some practitioners to enhance the status of their profession and to exclude others from practice. Instead of improving patient care it may serve to limit patient access to care by limiting the supply of practitioners.

CSHB 1193 educational requirements are too high and are unnecessary. Getting a bachelor's degree in any field, such as music or journalism, would not necessarily make a person a better practitioner. Most practitioners today do not have a bachelor's degree but they are satisfying patients and physicians. Clinical experience and training is the most important asset a practitioner can hold, not a four-year degree. Written and oral examination is the best way to ensure quality care.

CSHB 1193 would create a multi-tiered regulation scheme that would be spending money to regulate something that is not a problem. Licensing fees will 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 and location of the profession and to respond to consumer complaints. Only two other states, New Jersey and Mississippi, regulate this profession.

The best regulator 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 many physicians now refer to BOC accredited practitioners. Patients can tell when devices fail to fit and when they are receiving good or bad care.

OTHER
OPPONENTS
SAY:

CSHB 1193 does not adequately ensure quality care because the education and training standards are too low and too many people may be exempted from licensure.

The grandfather clause for licensed practitioners is too lenient and would allow people of minimal educational and experience backgrounds to operate legitimately as orthotists and prosthetists. The grandfather provision should require at least five or more years of practice or some additional educational or examination requirements. Certified master orthotists should fall under licensure or registration regulation — the state has a compelling reason to monitor and regulate their practice just as it does other practitioners in this field.

If the state is serious about ensuring quality patient care, ABC certification should be considered the minimum standard (a bachelor's degree, one year

of residency and a stringent clinical and written examination) and board membership should include at least one ABC certified practitioner. ABC is a credentialing standard used by programs in the Texas Department of Health, the Texas Rehabilitation Commission and the Texas Department of Criminal Justice. According to the latest membership directories, about 162 practitioners in Texas are already ABC certified whereas there are only about 48 BOC accredited practitioners, who meet less stringent educational requirements.

NOTES:

Major differences between the committee substitute and the original version include: the committee substitute moved the administrative responsibilities from the Texas Rehabilitation Commission to the Texas Department of Health, it added to and refined the list of defined terms, it added licensure requirements for assistants, registration requirements for technicians and accreditation requirements for facilities, it added grandfather clauses for current practitioners of orthotics and prosthetics, it required board members to have practiced for five years instead of three years to qualify for the board, it added a provision to specifically exempt certain persons from the act, it added a provisional license and removed requirements specifying ABC standards or certification.