

BILL ANALYSIS

S.B. 1271
By: Uresti
Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

The manufacture of orthotics and prosthetics is regulated by the Department of State Health Services in accordance with federal regulations on medical devices. While the federal Food, Drug, and Cosmetic Act, which governs the regulation of medical devices, is preemptive, the Texas Legislature took the step of adopting statutory language similar to that federal law in the Texas Food, Drug, and Cosmetic Act. The manufacture of any medical device, including an orthotic or prosthetic device, is regulated in accordance with those federal and state laws.

In addition, the Texas Legislature adopted law regulating the professionals and facilities involved in providing services relating to orthotics and prosthetics. These services include measuring, custom fitting, custom fabrication, adjusting, aligning, assembling, servicing, and dispensing previously manufactured and customized devices to consumers under an order from certain licensed medical professionals.

For the past 20 years, individuals engaged in the practice of orthotics and prosthetics have been required to obtain a license under state law. Recently, some questions have been raised as to whether certain individuals engaged in orthotic and prosthetic services should be required to obtain dual licenses under both the Texas Food, Drug, and Cosmetic Act and that additional state law.

S.B. 1271 clarifies that a professional licensed to practice orthotics or prosthetics is not required to obtain a device manufacturer license under the Texas Food, Drug, and Cosmetic Act if the individual is acting under an order from a licensed physician, chiropractor, or podiatrist for the treatment of a specific patient.

RULEMAKING AUTHORITY

It is the committee's opinion that this bill does not expressly grant any additional rulemaking authority to a state officer, department, agency, or institution.

ANALYSIS

S.B. 1271 amends the Occupations Code to provide that a person licensed to practice orthotics or prosthetics who measures, designs, fabricates, fits, assembles, adjusts, or services an orthosis or a prosthesis under an order from a licensed physician, chiropractor, or podiatrist for a specific patient is exempt from licensing requirements for a device manufacturer. The bill provides that a person licensed to practice orthotics or prosthetics who fabricates or assembles an orthosis or a prosthesis without an order from a licensed physician, chiropractor, or podiatrist for a specific patient is required to be licensed as a device manufacturer.

EFFECTIVE DATE

On passage, or, if the act does not receive the necessary vote, the act takes effect September 1, 2009.