

BILL ANALYSIS

Senate Research Center

S.B. 1271
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Health & Human Services
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Enrolled

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

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 legislature took the step of adopting statutory language that mirrors the federal law in the Texas Food, Drug, and Cosmetic Act, Chapter 431, Texas Health and Safety Code. The manufacture of any medical device, including an orthotic or prosthetic device, is regulated in accordance with federal law and Chapter 431.

In addition to Chapter 431, the Texas Legislature also adopted Chapter 605 (Orthotists and Prosthetists), Occupations Code, 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 Chapter 605, Occupation Code. 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 Chapter 431, Health and Safety Code, and Chapter 605, Occupations Code.

S.B. 1271 amends current law relating to the requirement that an orthotist or a prosthetist be licensed as a device manufacturer if fabricating or assembling without an order from certain health care professionals.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter F, Chapter 605, Occupations Code, by adding Section 605.2515, as follows:

Sec. 605.2515. ADDITIONAL LICENSE: DEVICE MANUFACTURER. Exempts 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 from licensing as a device manufacturer under Subchapter L (Device Distributors and Manufacturers), Chapter 431 (Texas Food, Drug, and Cosmetic Act), Health and Safety Code. Requires 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 to be licensed as a device manufacturer under Subchapter L, Chapter 431, Health and Safety Code.

SECTION 2. Effective date: upon passage or September 1, 2009.