

BILL ANALYSIS

H.B. 3336
By: Hopson
Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

The manufacture of orthotics and prosthetics is regulated by the Department of State Health Services (DSHS) 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, Health and Safety Code. Manufacture of any medical device, including an orthotic or prosthetic device, is regulated in accordance with federal law and Chapter 431.

In addition to provisions of Chapter 431, the legislature has also adopted regulations for professionals and facilities involved in providing non-manufacturing-related orthotic and prosthetic services. 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. These nonmanufacturing services are regulated under the Texas Orthotics and Prosthetics Act (TOPA), Chapter 605, Occupations Code. Professionals and facilities licensed under Chapter 605 are overseen by the Texas Board of Orthotics and Prosthetics. For the past twenty years individuals engaged in the practice of orthotics and prosthetics have been required only to obtain a license under Chapter 605. Recently, 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 and Chapter 605.

H.B. 3336 provides that a professional licensed to provide non-manufacturing-related orthotic and prosthetic services is not required to obtain an additional license for a device manufacturer if the professional 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

H.B. 3336 amends the Occupations Code to exempt 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 requirements for a device manufacturer. The bill 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 special patient 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.