BILL ANALYSIS

Senate Research Center
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S.B. 1236
By: Nelson
Health Services
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As Filed

DIGEST

Currently, the Safe Medical Devices Act (SMDA) recognizes that some products are actually a combination of two or more products traditionally regulated separately as either drugs, medical devices, or biologics. In 1990, Congress enacted the SMDA; this act amended the Federal Food, Drug, and Cosmetic Act to allow federal and state governments to make significant improvements in the regulation of medical devices and other related products, including combination products. S.B. 1236 would subject wholesale distributors or manufacturers to either Chapter 431I or Chapter 431L depending upon whether or not the respective primary mode of action of a product is considered a drug or a device.

PURPOSE

As proposed, S.B. 1236 regulates a product that is a combination of a drug and a device.

RULEMAKING AUTHORITY

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

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Chapter 431A, Health and Safety Code, by adding Section 431.006, as follows:

> Sec. 431.006. CERTAIN COMBINATION PRODUCTS. Provides that if the United States Food and Drug Administration determines, with respect to a product that is a combination of a drug and a device, that the primary mode of action of the product is a drug, then a person who engages in wholesale distribution of the product is subject to licensure under Subchapter I; and the primary mode of action of the product is as a device, a distributor or manufacturer of the product is subject to licensure under Subchapter L.

SECTION 2. Emergency clause.
Effective date: upon passage.