

## **BILL ANALYSIS**

Senate Research Center

H.B. 492  
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Health & Human Services  
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Engrossed

### **DIGEST**

Currently, the Texas Department of Health (TDH) regulates the wholesale distribution of drugs and medical devices. In recent years, the agency's authority in this area has been challenged administratively and in the courts due to ambiguities in provisions of the Texas Food, Drug & Cosmetic Act. Concern has been raised that clarifications are also needed to address new trends in the wholesale drug distribution business by which pharmacists are contracting with wholesalers and "repackagers" on a consignment basis. Although pharmacy practice is regulated by the Texas Board of Pharmacy, such wholesale drug and medical device transactions may be falling into a jurisdictional gray area without oversight by either the Board of Pharmacy or TDH. H.B. 492 redefines "manufacture" to include the repacking or labeling of food; the process of preparing a drug or drug product, with certain exceptions; the process of preparing a device; and the making of any cosmetic product by certain procedures. This legislation also redefines "food wholesaler," to include an establishment engaged solely in the distribution of alcoholic beverages in sealed containers; and exempts alcohol distributors licensed under certain chapters of the Alcoholic Beverage Code from the application of Chapter 431J, Health and Safety Code, regarding food manufacturers and wholesalers. In addition, this bill requires a hearing on an emergency order to be held under the contested case provisions of Chapter 2001, Government Code, and the Texas Board of Health's formal hearing rules.

### **PURPOSE**

As proposed, H.B. 492 sets forth activities covered by the Texas Food, Drug, and Cosmetic Act.

### **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 Section 431.002(23), Health and Safety Code, to redefine "manufacture" to include repackaging or labeling of any food; the process of preparing, propagating, compounding, processing, packaging, holding, repackaging, labeling, testing, or quality control of a drug or drug product, with certain exceptions; the process of preparing, fabricating, assembling, processing, packing, repacking, labeling, or relabeling a device; or the making of any cosmetic product by certain procedures, including manipulation, sampling, or testing applied to the product.

SECTION 2. Amends Sections 431.221(3) and (4), Health and Safety Code, to redefine "food wholesaler" to provide that the term includes an establishment engaged solely in the distribution of alcoholic beverages. Deletes the definition of "manufacture."

SECTION 3. Amends Section 431.2211, Health and Safety Code, to provide that this subchapter does not apply to a person engaged solely in the distribution of alcoholic beverages in sealed containers by holders of licenses or permits issued under Chapter 19-21, 64, or 65, Alcoholic Beverage Code.

SECTION 4. Amends Section 431.045(c), Health and Safety Code, to require a hearing for an emergency order to be held under the contested case provisions of Chapter 2001, Government Code, and the Texas Board of Health's formal hearing rules. Deletes existing text requiring the hearing to

be held under Texas Department of Health rules.

SECTION 5. Effective date: September 1, 1997.

SECTION 6. Emergency clause.