BILL ANALYSIS

H.B. 1891
By: Zedler
Public Health
Committee Report (Unamended)

BACKGROUND AND PURPOSE

In 1997, the United States Congress enacted the Food and Drug Administration Modernization Act in which numerous sections of the Federal Food Drug and Cosmetic Act were either deleted or modified. Modifications of the required labeling on certain prescription drugs were made to improve readability of overcrowded labels. One of the requirements of the Food and Drug Administration Modernization Act was to change the phrase "Caution: Federal Law Prohibits Dispensing Without Prescription" to the shorter phrase "RX Only". House Bill 1891 also replaces the phrase " Caution: State Law Prohibits Dispensing Without Prescription" in favor of the "RX Only" phrase.

House Bill 1891 amends several sections of the Health and Safety Code, Chapter 431, Texas Food Drug and Cosmetic Act to achieve uniformity with labeling requirements for prescription drugs as required by the Federal Food Drug and Cosmetic Act. The bill will delete certain defunct labeling requirements for insulin, antibiotics and narcotic drugs; and, will modify a required statement on prescription drug labels to be uniform with the Federal Food Drug and Cosmetic Act. This bill will make prescription drug labels easier to read and understand.

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

Health and Safety Code, Chapter 431, Texas Food Drug and Cosmetic Act (TFDCA) is amended to bring it into uniformity with the Federal Food Drug and Cosmetic Act (Federal Act) as amended by the Food and Drug Administration Modernization Act (Public Law 105-115) of 1997. The bill makes changes to a misbranded drug or device, labeling and updates language to reflect the changes in federal law. Sections are renumbered and references updated to conform with the Federal Act.

EFFECTIVE DATE

September 1, 2003